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Counsel for Plaintiff Intra-Cellular Therapies, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Intra-Cellular Therapies, Inc., *Plaintiff*, v. Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Ltd., *Defendants*.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Intra-Cellular Therapies, Inc. ("Intra-Cellular Therapies," "ITCI," or "Plaintiff"), by its attorneys, files this Complaint for patent infringement against Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Ltd. (collectively, "Zydus") and hereby alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, that arises out of Zydus's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of CAPLYTA® (lumateperone) capsules, 10.5 mg, 21 mg, and 42 mg, prior to the expiration of U.S. Patent Nos. 9,956,227 (the "'227 Patent"), 10,960,009 (the "'009 patent"), 11,026,951 (the "'951 patent"), and RE48,839 (the "RE '839 patent") (collectively, the "Patents-in-Suit").

2. Zydus notified Plaintiff by letter dated February 12, 2024 ("Zydus's First Notice Letter") that it had submitted to the FDA ANDA No. 218652 ("Zydus's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic lumateperone capsules, 10.5 mg, 21 mg, and 42 mg, ("Zydus's ANDA Product") prior to the expiration of U.S. Patent Nos. 10,695,345 ("the '345 patent"), 11,052,084 ("the '084 patent"), 11,690,842 ("the '842 patent"), 11,753,419 ("the '419 patent"), and 11,806,348 ("the '348 patent").

3. On March 28, 2024, Plaintiff sued Zydus in this district for infringement of the patents identified in Zydus' First Notice Letter. *See* Civil Action No. 3:24-cv-04330-MAS-JBD, ECF No. 1. That case is currently pending and has been consolidated with Civil Action No. 3:24-cv-04264. ECF No. 22.

4. On August 29, 2024, Plaintiff sued Zydus in this district for infringement of U.S. Patent Nos. 11,980,617 ("the '617 patent") and 12,070,459 ("the '459 patent"). *See* Civil Action No. 3:24-cv-08856-MAS-JBD, ECF No. 1. That case is currently pending and the has been consolidated with Civil Action No. 3:24-cv-04264. ECF No. 65.

5. On November 1, 2024, Plaintiff sued Zydus in this district for infringement of U.S. Patent Nos. 12,090,155 (the "'155 patent"), 12,122,792 (the "'792 patent"), and 12,128,043 (the "'043 patent"). *See* Civil Action No. 3:24-cv-10240, ECF No. 1. That case is currently pending and has been consolidated with Civil Action No. 3:24-cv-04264. ECF No. 106.

6. Zydus further notified Plaintiff by letter dated December 18, 2024 ("Zydus's Second Notice Letter") that it had submitted to the FDA Zydus's ANDA, seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product prior to the expiration of the '227 Patent, '009 patent, and RE '839 patent, as well as the '459 patent, '043 patent, and '792 patent.

The Parties

7. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

8. Plaintiff Intra-Cellular Therapies ("ITCI") is a corporation organized and existing under the laws of Delaware and having a place of business at 135 Route 202/206, Suite 6, Bedminster, NJ 07921. ITCI is the holder of New Drug Application ("NDA") No. 209500 for the manufacture and sale of lumateperone capsules, 10.5 mg, 21 mg, and 42 mg, which have been approved by the FDA.

9. Upon information and belief, Defendant Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of New Jersey and having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

10. Upon information and belief, Defendant Zydus Lifesciences Ltd. is a corporation organized and existing under the laws of the Republic of India and having a principal place of business at Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, Ahmedabad, Gujarat, India, 382481.

11. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. is the U.S. Regulatory Agent for Zydus Lifesciences Ltd.

12. Upon information and belief, Zydus Lifesciences Ltd. and Zydus Pharmaceuticals (USA) Inc. acted in concert to prepare and submit Zydus's ANDA to the FDA. Upon information and belief, Zydus Lifesciences Ltd. and Zydus Pharmaceuticals (USA) Inc. know and intend that upon approval of Zydus's ANDA, Zydus Lifesciences Ltd. will manufacture Zydus's ANDA Product, and Zydus Pharmaceuticals (USA) Inc. will directly or indirectly market, sell, and distribute Zydus's ANDA Product throughout the United States, including in New Jersey.

13. Upon information and belief, Zydus Lifesciences Ltd. and Zydus Pharmaceuticals (USA) Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Zydus's ANDA Product, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. participated in, assisted, and cooperated with Zydus Lifesciences Ltd. in the acts complained of herein.

14. Upon information and belief, following any FDA approval of Zydus's ANDA, Zydus Lifesciences Ltd. and Zydus Pharmaceuticals (USA) Inc. will act in concert to distribute and sell Zydus's ANDA Product throughout the United States, including within New Jersey.

Jurisdiction

15. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

16. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

17. This Court has personal jurisdiction over each of Zydus Lifesciences Ltd. and Zydus Pharmaceuticals (USA) Inc.

18. Zydus Lifesciences Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Zydus Lifesciences Ltd., itself and through its subsidiary Zydus Pharmaceuticals (USA) Inc., has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Zydus Lifesciences Ltd., itself and through its subsidiary Zydus Pharmaceuticals (USA) Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey and therefore transacts business within the State of New Jersey, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. In addition, Zydus Lifesciences Ltd. is subject to personal jurisdiction in New Jersey because, upon information and belief, it controls Zydus Pharmaceuticals (USA) Inc. and therefore the activities of Zydus Pharmaceuticals (USA) Inc. in this jurisdiction are attributed to Zydus Lifesciences Ltd.

19. Zydus Pharmaceuticals (USA) Inc. is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey, has a principal place of business in the State of New Jersey, is qualified to do business in New Jersey, and has appointed a registered agent for service of process in New Jersey. It therefore has consented to general jurisdiction in New Jersey. In addition, upon information and belief, Zydus Pharmaceuticals (USA) Inc. develops, manufactures, imports, markets, offers to sell,

and/or sells generic drugs throughout the United States, including in the State of New Jersey and therefore transacts business within the State of New Jersey related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

20. Zydus has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certifications"), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

21. Upon information and belief, Zydus, with knowledge of the Hatch-Waxman Act process, directed Zydus's First Notice Letter and Zydus's Second Notice Letter to Plaintiff. Zydus has been a litigant in connection with other infringement actions under the Hatch-Waxman Act. It was reasonably foreseeable that Zydus would be sued in New Jersey, where Zydus Pharmaceuticals (USA) Inc. is located and incorporated.

22. Upon information and belief, if Zydus's ANDA is approved, Zydus will directly or indirectly manufacture, market, sell, and/or distribute Zydus's ANDA Product within the United States, including in New Jersey, consistent with Zydus's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Zydus regularly does business in New Jersey, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in New Jersey. Upon information and belief, Zydus's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. Upon information and belief, Zydus's ANDA Product will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Each of these activities would have a substantial effect within

New Jersey and would constitute infringement of the Patents-in-Suit in the event that Zydus's ANDA Product is approved before the Patents-in-Suit expire.

23. Upon information and belief, Zydus derives substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and which are manufactured by Zydus and/or Zydus Pharmaceuticals (USA) Inc. or Zydus Lifesciences Ltd. Upon information and belief, various products for which Zydus Lifesciences Ltd. or Zydus Pharmaceuticals (USA) Inc. is the named applicant on approved ANDAs are available at retail pharmacies in New Jersey.

Venue

24. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

25. Venue is proper in this district as to Zydus Pharmaceuticals (USA) Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey, has a principal place of business in the State of New Jersey, and is subject to personal jurisdiction in this judicial district.

26. Venue is proper in this district as to Zydus Lifesciences Ltd. pursuant to 28 U.S.C. §§ 1391 and/or 1400(b) because, *inter alia*, Zydus Lifesciences Ltd. is a company organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

Factual Background

27. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

28. CAPLYTA®, which contains lumateperone, is approved for the treatment of schizophrenia in adults, as well as depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate.

29. In Zydus's First Notice Letter and Zydus's Second Notice Letter, Zydus stated that the subject of Zydus's ANDA is lumateperone capsules, 10.5 mg, 21 mg, and 42 mg. In Zydus's First Notice Letter and Zydus's Second Notice Letter, Zydus stated that Zydus's ANDA was submitted under 21 U.S.C. §§ 355(j), (j)(2)(A) and contended that Zydus's ANDA contains bioavailability and/or bioequivalence studies for Zydus's ANDA Product. Upon information and belief, Zydus's ANDA Product is a generic version of CAPLYTA®.

30. In Zydus's First Notice Letter, Zydus stated that it had submitted Paragraph IV certifications to the FDA alleging that the '345 patent, '084 patent, '842 patent, '419 patent, and '348 patent are invalid, unenforceable, and/or not infringed, and that Zydus is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Zydus's ANDA Product prior to the expiration of those patents.

31. In Zydus's Second Notice Letter, Zydus stated that it had submitted Paragraph IV certifications to the FDA alleging that the '227 patent, '009 patent, '459 patent, '043 patent, '792 patent, and RE '839 patent are invalid, unenforceable, and/or not infringed, and that Zydus is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Zydus's ANDA Product prior to the expiration of those patents.

32. The purpose of Zydus's submission of Zydus's ANDA was to obtain, *inter alia*, approval under the Federal Food, Drug, and Cosmetic Act (the "FDCA") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product prior to the expiration of the '227 patent, '009 patent, '459 patent, '043 patent, '792 patent, and RE '839 patent. On information and belief, Zydus intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Zydus' ANDA Product prior to the expiration of the Patents-in-Suit.

COUNT I—INFRINGEMENT OF THE RE '839 PATENT

33. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

34. The RE '839 patent, entitled "Methods and Compositions for Sleep Disorders and Other Disorders" (attached as Exhibit A), was duly and legally issued on December 7, 2021.

35. The inventors named on the RE '839 patent are Sharon Mates, Allen Fienberg, and Lawrence Wennogle.

36. Plaintiff is the owner and assignee of the RE '839 patent.

37. CAPLYTA® is covered by one or more claims of the RE '839 patent, which has been listed in connection with CAPLYTA® in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the Orange Book").

38. In Zydus's Second Notice Letter, Zydus notified Plaintiff of the submission of Zydus's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product prior to the expiration of the Patents-in-Suit, including the RE '839 patent.

39. In Zydus's Second Notice Letter, Zydus also notified Plaintiff that, as part of its ANDA, Zydus had filed Paragraph IV certifications with respect to the RE '839 patent. Upon information and belief, Zydus submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the RE '839 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product.

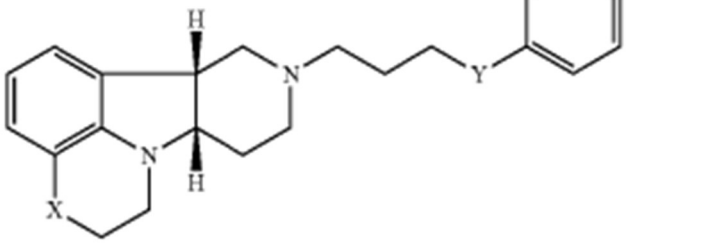
40. According to Zydus's First Notice Letter and Zydus's Second Notice Letter, Zydus's ANDA Product contains lumateperone.

41. Upon information and belief, the use of Zydus's ANDA Product in accordance with and as directed by Zydus's proposed labeling for that product would infringe one or more claims of the RE '839 patent.

42. As an example, claim 1 of the RE '839 patent recites:

> A method for the treatment of one or more 5-HT_{2A}-related disorders, comprising administering to a patient in need thereof a Compound of Formula I:

Formula I



> wherein X is O, —NH or —N(CH_3); and Y is —O— or —C(O) —, in free or pharmaceutically acceptable salt form, in a dose which selectively blocks the 5-HT_{2A} receptor.

43. Upon information and belief, the use of Zydus's ANDA Product in accordance with and as directed by Zydus's proposed label would involve treating one or more 5-HT_{2A}-related disorders, including by administering to the patient in need thereof a free or pharmaceutically acceptable salt form of a Formula I compound (which includes lumateperone) in a dose which selectively blocks the 5-HT_{2A} receptor, as recited in claim 1.

44. Upon information and belief, the use of Zydus's ANDA Product in accordance with and as directed by Zydus's proposed product labeling would infringe one or more claims of the RE '839 patent, literally or under the doctrine of equivalents.

45. Zydus's submission of Zydus's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product before the expiration of the RE '839 patent was an act of infringement of the RE '839 patent under 35 U.S.C. § 271(e)(2)(A).

46. Upon information and belief, Zydus will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product immediately and imminently upon approval of its ANDA.

47. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the RE '839 patent.

48. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the RE '839 patent.

49. Upon information and belief, Zydus plans and intends to, and will, actively induce infringement of the RE '839 patent when Zydus's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Zydus's activities will be done with knowledge of the RE '839 patent and specific intent to infringe that patent.

50. Upon information and belief, Zydus knows that Zydus's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the RE '839 patent, that Zydus's ANDA Product is not a staple article or commodity of commerce, and that Zydus's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Zydus plans and intends to, and will, contribute to infringement of the RE '839 patent immediately and imminently upon approval of Zydus's ANDA.

51. Notwithstanding Zydus's knowledge of the claims of the RE '839 patent, Zydus has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Zydus's ANDA Product with its product labeling following FDA approval of Zydus's ANDA prior to the expiration of the RE '839 patent.

52. The foregoing actions by Zydus constitute and/or will constitute infringement of the RE '839 patent; active inducement of infringement of the RE '839 patent; and/or contribution to the infringement by others of the RE '839 patent.

53. Upon information and belief, Zydus has acted with full knowledge of the RE '839 patent and without a reasonable basis for believing that it would not be liable for infringement of the RE '839 patent; active inducement of infringement of the RE '839 patent; and/or contribution to the infringement by others of the RE '839 patent.

54. Plaintiff will be substantially and irreparably damaged by infringement of the RE '839 patent.

55. Unless Zydus is enjoined from infringing the RE '839 patent, actively inducing infringement of the RE '839 patent, and contributing to the infringement by others of the RE '839 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

COUNT II—DECLARATORY JUDGMENT OF INFRINGEMENT OF THE RE '839 PATENT

56. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

57. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Zydus on the other regarding Zydus's infringement, active inducement of infringement, contribution to the infringement by others of the RE '839 patent, and/or the validity of the RE '839 patent.

58. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Zydus's ANDA Product with its proposed labeling, or any other Zydus drug product that is covered by or whose use is covered by the RE '839 patent, will infringe, induce infringement of, and contribute to the infringement by others of the RE '839 patent, and that the claims of the RE '839 patent are not invalid.

COUNT III—INFRINGEMENT OF THE '227 PATENT

59. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

60. The '227 patent, entitled "Method for the Treatment of Residual Symptoms of Schizophrenia" (attached as Exhibit B), was duly and legally issued on May 1, 2018.

61. The inventors named on the '227 patent are Kimberly Vanover, Peng Li, Sharon Mates, Robert Davis, and Lawrence P. Wennogle.

62. Plaintiff is the owner and assignee of the '227 patent.

63. CAPLYTA® is covered by one or more claims of the '227 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

64. In Zydus's Second Notice Letter, Zydus notified Plaintiff of the submission of Zydus's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product prior to the expiration of the Patents-in-Suit, including the '227 patent.

65. In Zydus's Second Notice Letter, Zydus also notified Plaintiff that, as part of its ANDA, Zydus had filed Paragraph IV certifications with respect to the '227 patent. Upon information and belief, Zydus submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '227 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product.

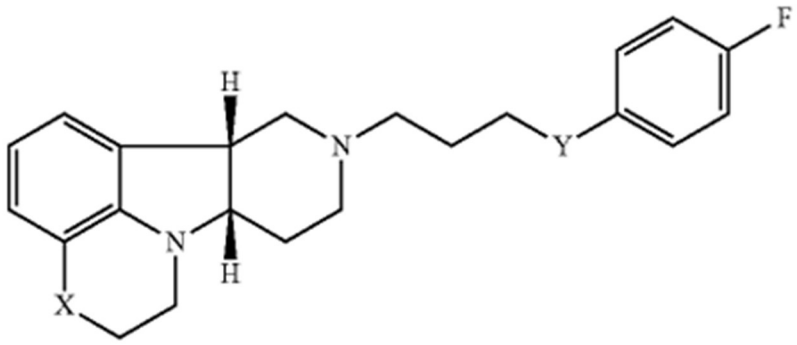
66. According to Zydus's First Notice Letter and Zydus's Second Notice Letter, Zydus's ANDA Product contains lumateperone.

67. Upon information and belief, the use of Zydus's ANDA Product in accordance with and as directed by Zydus's proposed labeling for that product would infringe one or more claims of the '227 patent.

68. As an example, claim 1 of the '227 patent recites:

> A method for the treatment of residual symptoms of schizophrenia as defined in the Positive and Negative Syndrome Scale (PANSS) for Schizophrenia, comprising administering to a patient in need thereof, after treatment of acute symptoms of schizophrenia with an antipsychotic agent, an effective amount of a compound of Formula I:

Formula I



> wherein:
>
> X is —O—, —NH— or —N(CH_3)—;
>
> Y is —O—, —C(R_2)(OH)—, —C(R_3)(OR_1) or —C(O)—; and
>
> R_1 is —C_{1-6} alkyl or —C(O)—C_{1-21} alkyl, optionally saturated or unsaturated and optionally substituted with one or more hydroxyl or

C_{1-22} alkoxy groups wherein such compound hydrolyzes to form the residue of a natural or unnatural, saturated or unsaturated fatty acid;

R_2 is H or —C_{1-6} alkyl; and

R_3 is H or —C_{1-6} alkyl;

in free or pharmaceutically acceptable salt form;

wherein the patient significantly improves on the Prosocial PANSS Factor change from baseline.

69. Upon information and belief, the use of Zydus's ANDA Product in accordance with and as directed by Zydus's proposed label would involve treating residual symptoms of schizophrenia after treatment of acute symptoms of schizophrenia with an antipsychotic agent, including by administering to the patient in need thereof an effective amount of the compound recited in claim 1.

70. Upon information and belief, Zydus's ANDA Product infringes one or more claims of the '227 patent, literally or under the doctrine of equivalents.

71. Zydus's submission of Zydus's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product before the expiration of the '227 patent was an act of infringement of the '227 patent under 35 U.S.C. § 271(e)(2)(A).

72. Upon information and belief, Zydus will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product immediately and imminently upon approval of its ANDA.

73. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '227 patent.

74. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '227 patent.

75. Upon information and belief, Zydus plans and intends to, and will, actively induce infringement of the '227 patent when Zydus's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Zydus's activities will be done with knowledge of the '227 patent and specific intent to infringe that patent.

76. Upon information and belief, Zydus knows that Zydus's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '227 patent, that Zydus's ANDA Product is not a staple article or commodity of commerce, and that Zydus's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Zydus plans and intends to, and will, contribute to infringement of the '227 patent immediately and imminently upon approval of Zydus's ANDA.

77. Notwithstanding Zydus's knowledge of the claims of the '227 patent, Zydus has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Zydus's ANDA Product with its product labeling following FDA approval of Zydus's ANDA prior to the expiration of the '227 patent.

78. The foregoing actions by Zydus constitute and/or will constitute infringement of the '227 patent; active inducement of infringement of the '227 patent; and/or contribution to the infringement by others of the '227 patent.

79. Upon information and belief, Zydus has acted with full knowledge of the '227 patent and without a reasonable basis for believing that it would not be liable for infringement of the '227 patent; active inducement of infringement of the '227 patent; and/or contribution to the infringement by others of the '227 patent.

80. Plaintiff will be substantially and irreparably damaged by infringement of the '227 patent.

81. Unless Zydus is enjoined from infringing the '227 patent, actively inducing infringement of the '227 patent, and contributing to the infringement by others of the '227 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

COUNT IV—DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '227 PATENT

82. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

83. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Zydus on the other regarding Zydus's infringement, active inducement of infringement, contribution to the infringement by others of the '227 patent, and/or the validity of the '227 patent.

84. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Zydus's ANDA Product with its proposed labeling, or any other Zydus drug product that is covered by or whose use is covered by the '227 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '227 patent, and that the claims of the '227 patent are not invalid.

COUNT V—INFRINGEMENT OF THE '009 PATENT

85. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

86. The '009 patent, entitled "Methods of Treating Schizophrenia and Depression" (attached as Exhibit C), was duly and legally issued on March 30, 2021.

87. The inventors named on the '009 patent are Kimberly Vanover, Peng Li, Sharon Mates, Robert Davis, and Lawrence P. Wennogle.

88. Plaintiff is the owner and assignee of the '009 patent.

89. CAPLYTA® is covered by one or more claims of the '009 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

90. In Zydus's Second Notice Letter, Zydus notified Plaintiff of the submission of Zydus's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product prior to the expiration of the Patents-in-Suit, including the '009 patent.

91. In Zydus's Second Notice Letter, Zydus also notified Plaintiff that, as part of its ANDA, Zydus had filed Paragraph IV certifications with respect to the '009 patent. Upon information and belief, Zydus submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '009 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product.

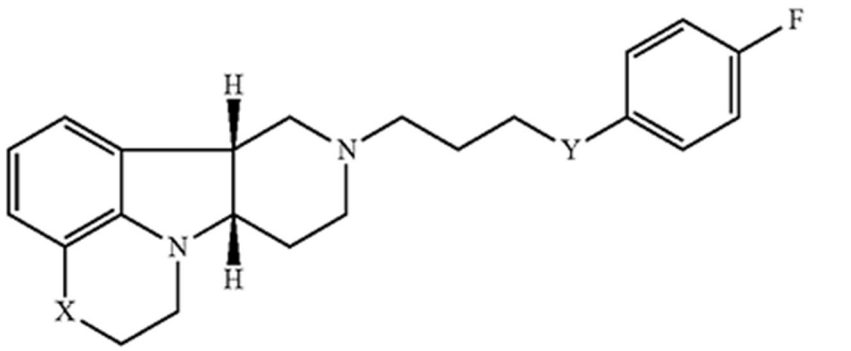
92. According to Zydus's First Notice Letter and Zydus's Second Notice Letter, Zydus's ANDA Product contains lumateperone.

93. Upon information and belief, the use of Zydus's ANDA Product in accordance with and as directed by Zydus's proposed labeling for that product would infringe one or more claims of the '009 patent.

94. As an example, claim 1 of the '009 patent recites:

> A method for the treatment of the negative symptoms of schizophrenia comprising administering to a schizophrenic patient in need thereof an effective amount of a Compound of Formula I:

Formula I



wherein:

X is —N(CH_3)— and Y is —C(O)—;

in free or pharmaceutically acceptable salt form,

wherein the effective amount of the Compound of Formula I is 40 mg to 60 mg per day, measured as the weight of the corresponding free base form of the Compound.

95. Upon information and belief, the use of Zydus's ANDA Product in accordance with and as directed by Zydus's proposed label would involve treating negative symptoms of schizophrenia, including by administering to the patient in need thereof 40 mg to 60 mg (measured as the free base) per day of a Formula I compound in free or pharmaceutically acceptable salt form, as recited in claim 1.

96. Upon information and belief, Zydus's ANDA Product infringes one or more claims of the '009 patent, literally or under the doctrine of equivalents.

97. Zydus's submission of Zydus's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product before the expiration of the '009 patent was an act of infringement of the '009 patent under 35 U.S.C. § 271(e)(2)(A).

98. Upon information and belief, Zydus will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product immediately and imminently upon approval of its ANDA.

99. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '009 patent.

100. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '009 patent.

101. Upon information and belief, Zydus plans and intends to, and will, actively induce infringement of the '009 patent when Zydus's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Zydus's activities will be done with knowledge of the '009 patent and specific intent to infringe that patent.

102. Upon information and belief, Zydus knows that Zydus's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '009 patent, that Zydus's ANDA Product is not a staple article or commodity of commerce, and that Zydus's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Zydus plans and intends to, and will, contribute to infringement of the '009 patent immediately and imminently upon approval of Zydus's ANDA.

103. Notwithstanding Zydus's knowledge of the claims of the '009 patent, Zydus has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Zydus's ANDA Product with its product labeling following FDA approval of Zydus's ANDA prior to the expiration of the '009 patent.

104. The foregoing actions by Zydus constitute and/or will constitute infringement of the '009 patent; active inducement of infringement of the '009 patent; and/or contribution to the infringement by others of the '009 patent.

105. Upon information and belief, Zydus has acted with full knowledge of the '009 patent and without a reasonable basis for believing that it would not be liable for infringement of the '009 patent; active inducement of infringement of the '009 patent; and/or contribution to the infringement by others of the '009 patent.

106. Plaintiff will be substantially and irreparably damaged by infringement of the '009 patent.

107. Unless Zydus is enjoined from infringing the '009 patent, actively inducing infringement of the '009 patent, and contributing to the infringement by others of the '009 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

COUNT VI—DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '009 PATENT

108. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

109. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Zydus on the other regarding Zydus's infringement, active inducement of infringement, contribution to the infringement by others of the '009 patent, and/or the validity of the '009 patent.

110. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Zydus's ANDA Product with its proposed labeling, or any other Zydus drug product that is covered by or whose use is covered by the '009 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '009 patent, and that the claims of the '009 patent are not invalid.

COUNT VII—INFRINGEMENT OF THE '951 PATENT

111. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

112. The '951 patent, entitled "Methods of Treating Bipolar Disorder" (attached as Exhibit D), was duly and legally issued on June 8, 2021.

113. The inventors named on the '951 patent are Kimberly Vanover, Peng Li, Sharon Mates, Robert Davis, and Lawrence P. Wennogle.

114. Plaintiff is the owner and assignee of the '951 patent.

115. CAPLYTA® is covered by one or more claims of the '951 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

116. In Zydus's Second Notice Letter, Zydus notified Plaintiff of the submission of Zydus's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product prior to the expiration of the Patents-in-Suit, including the '951 patent.

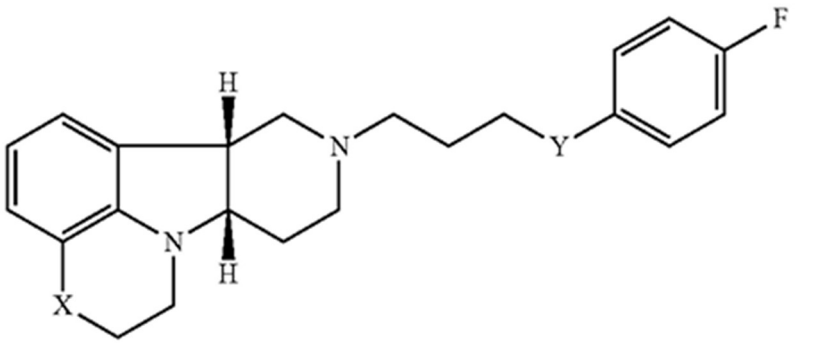
117. According to Zydus's First Notice Letter and Zydus's Second Notice Letter, Zydus's ANDA Product contains lumateperone.

118. Upon information and belief, the use of Zydus's ANDA Product in accordance with and as directed by Zydus's proposed labeling for that product would infringe one or more claims of the '951 patent.

119. As an example, claim 1 of the '951 patent recites:

> A method for the treatment of bipolar disorder I and/or bipolar II disorder comprising administering to a patient in need thereof an effective amount of a Compound of Formula I:

Formula I



wherein:

X is —N(CH_3)— and Y is —C(O)—;

in free or pharmaceutically acceptable salt form, wherein said Compound is not used in combination with another antipsychotic agent.

120. Upon information and belief, the use of Zydus's ANDA Product in accordance with and as directed by Zydus's proposed label would involve treating bipolar disorder I and/or bipolar II disorder, including by administering to the patient in need thereof an effective amount of a Formula I compound in free or pharmaceutically acceptable salt form and not in combination with another antipsychotic agent, as recited in claim 1.

121. Upon information and belief, Zydus's ANDA Product infringes one or more claims of the '951 patent, literally or under the doctrine of equivalents.

122. Zydus's submission of Zydus's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product before the expiration of the '951 patent was an act of infringement of the '951 patent under 35 U.S.C. § 271(e)(2)(A).

123. Upon information and belief, Zydus will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Product immediately and imminently upon approval of its ANDA.

124. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '951 patent.

125. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '951 patent.

126. Upon information and belief, Zydus plans and intends to, and will, actively induce infringement of the '951 patent when Zydus's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Zydus's activities will be done with knowledge of the '951 patent and specific intent to infringe that patent.

127. Upon information and belief, Zydus knows that Zydus's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '951 patent, that Zydus's ANDA Product is not a staple article or commodity of commerce, and that Zydus's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Zydus plans and intends to, and will, contribute to infringement of the '951 patent immediately and imminently upon approval of Zydus's ANDA.

128. Notwithstanding Zydus's knowledge of the claims of the '951 patent, Zydus has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Zydus's ANDA Product with its product labeling following FDA approval of Zydus's ANDA prior to the expiration of the '951 patent.

129. The foregoing actions by Zydus constitute and/or will constitute infringement of the '951 patent; active inducement of infringement of the '951 patent; and/or contribution to the infringement by others of the '951 patent.

130. Upon information and belief, Zydus has acted with full knowledge of the '951 patent and without a reasonable basis for believing that it would not be liable for infringement of the '951 patent; active inducement of infringement of the '951 patent; and/or contribution to the infringement by others of the '951 patent.

131. Plaintiff will be substantially and irreparably damaged by infringement of the '951 patent.

132. Unless Zydus is enjoined from infringing the '951 patent, actively inducing infringement of the '951 patent, and contributing to the infringement by others of the '951 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

COUNT VIII—DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '951 PATENT

133. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

134. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Zydus on the other regarding Zydus's infringement, active inducement of infringement, contribution to the infringement by others of the '951 patent, and/or the validity of the '951 patent.

135. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Zydus's ANDA Product with its proposed labeling, or any other Zydus drug product that is covered by or whose use is covered by the '951 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '951 patent, and that the claims of the '951 patent are not invalid.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

(a) A judgment that the Patents-in-Suit have been infringed under 35 U.S.C. § 271(e)(2) by Zydus's submission to the FDA of Zydus's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Zydus's ANDA Product, or any other drug product that infringes or the use of which infringes the Patents-in-Suit, be not earlier than the expiration dates of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Zydus, and all persons acting in concert with Zydus, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Zydus's ANDA Product, or any other drug product covered by or whose use is covered by the Patents-in-Suit, prior to the expiration of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale, or importation of Zydus's ANDA Product, or any other drug product covered by or whose use is covered by the Patents-in-Suit, prior to the expiration of said patents, will infringe, induce the infringement of, and contribute to infringement by others of said patents;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Dated: January 31, 2025

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LOCAL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy in this action is related to the following actions: *Intra-Cellular Therapies, Inc. v. Aurobindo Pharma Ltd. et al*, 3:24-cv-04264 (consolidated), pending before the United States District Court for the District of New Jersey, in which Plaintiff asserted claims of patent infringement against, *inter alia*, Defendants in connection with Defendants' submission of ANDA No. 218652; *Intra-Cellular Therapies, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al*, 3:24-cv-04330-MAS-JBD, before the United States District Court for the District of New Jersey, which has been consolidated with Case No. 3:24-cv-04264-MAS-JBD and in which Plaintiff asserted claims of patent infringement against Defendants in connection with Defendants' submission of ANDA No. 218652; *Intra-Cellular Therapies, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al*, 3:24-cv-08856-MAS-JBD, before the United States District Court for the District of New Jersey, which has been consolidated with Case No. 3:24-cv-04264-MAS-JBD and in which Plaintiff asserted claims of patent infringement against Defendants in connection with Defendants' submission of ANDA No. 218652; *Intra-Cellular Therapies, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al*, 3:24-cv-10240-MAS-JBD, before the United States District Court for the District of New Jersey, which has been consolidated with Case No. 3:24-cv-04264-MAS-JBD and in which Plaintiff asserted claims of patent infringement against Defendants in connection with Defendants' submission of ANDA No. 218652.

Dated: January 31, 2025

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LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

Dated: January 31, 2025

By: *s/Liza M. Walsh*

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