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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. 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"). These patents are referred to collectively herein as the "Patents-in-Suit."

2. Zydus notified Plaintiff by letter dated February 12, 2024 ("Zydus's 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 the Patents-in-Suit.

The Parties

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

4. Plaintiff Intra-Cellular Therapies ("ITCI") is a corporation organized and existing under the laws of Delaware and having a place of business at 430 East 29th Street, Suite 900, New York, NY 10016. 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.

5. 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.

6. 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.

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

8. 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.

9. 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.

10. 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

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

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

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

14. 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.

15. 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.

16. 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), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

17. Upon information and belief, Zydus, with knowledge of the Hatch-Waxman Act process, directed Zydus's Notice Letter to Plaintiff. Upon information and belief, Zydus knew when it did so that it was triggering the forty-five-day period for Plaintiff to bring an action for patent infringement under the Hatch-Waxman Act. Zydus has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Zydus's Notice Letter to Plaintiff it would be sued for patent infringement in New Jersey, where Zydus Pharmaceuticals (USA) Inc. is located and incorporated.

18. 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 expire.

19. 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

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

21. 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.

22. 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

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

24. 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.

25. In Zydus's 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 Notice Letter, Zydus stated that Zydus's ANDA was submitted under 21 U.S.C. § 355(j)(1) & (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®.

26. In Zydus's Notice Letter, Zydus stated that it had submitted Paragraph IV certifications to the FDA alleging that the Patents-in-Suit 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 the Patents-in-Suit.

27. The purpose of Zydus's submission of Zydus's ANDA was to obtain 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 Patents-in-Suit.

28. Upon information and belief, Zydus's ANDA Product is not publicly available, nor is ANDA No. 218652 accessible to the public.

29. In Zydus's Notice Letter, Zydus included an Offer of Confidential Access to a redacted version of Zydus's ANDA, and Zydus's offer was subject to various unreasonably restrictive conditions.

30. In an exchange of correspondence, counsel for Plaintiff and counsel for Zydus discussed the terms of Zydus's Offer of Confidential Access. The parties did not agree on terms under which Plaintiff could review, among other things, Zydus's unredacted ANDA, any Drug Master File referred to therein, or all relevant characterization data. Zydus further refused to produce samples of Zydus's ANDA Product and other internal documents and material relevant to infringement.

31. This action is being commenced within 45 days from the date Plaintiff received Zydus's Notice Letter.

Count I—Infringement of the '345 Patent

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

33. The '345 patent, entitled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" (attached as Exhibit A), was duly and legally issued on June 30, 2020.

34. The inventors named on the '345 patent are Peng Li and Robert Davis.

35. Plaintiff is the owner and assignee of the '345 patent.

36. CAPLYTA® is covered by one or more claims of the '345 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

37. In Zydus's 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 '345 patent.

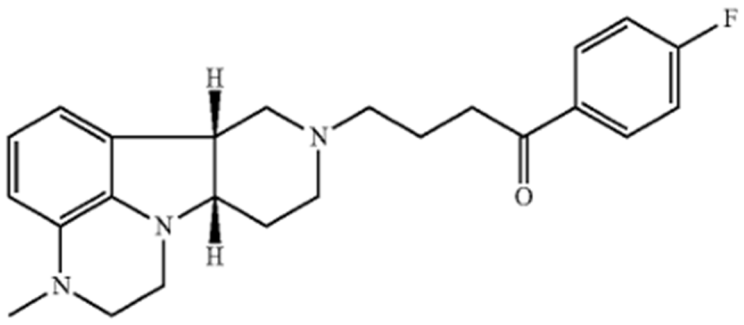
38. In Zydus's Notice Letter, Zydus also notified Plaintiff that, as part of its ANDA, Zydus had filed Paragraph IV certifications with respect to the '345 patent. Upon information and belief, Zydus submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '345 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product.

39. According to Zydus's Notice Letter, Zydus's ANDA Product contains lumateperone.

40. Upon information and belief, Zydus's ANDA Product and the use of Zydus's ANDA Product are covered by one or more claims of the '345 patent, either literally or under the doctrine of equivalents.

41. As an example, claim 1 of the '345 patent recites:

> A pharmaceutical capsule for oral administration, comprising lumateperone:



> in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form; and

> wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium, 0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule.

42. Upon information and belief, Zydus's ANDA Product is a pharmaceutical capsule for oral administration comprising lumateperone mono-tosylate in solid crystal form in a blend with the specific excipients in the specific amounts recited in claim 1.

43. Upon information and belief, Zydus's ANDA Product infringes one or more claims of the '345 patent, literally or under the doctrine of equivalents.

44. 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 '345 patent was an act of infringement of the '345 patent under 35 U.S.C. § 271(e)(2)(A).

45. 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.

46. 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 '345 patent.

47. 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 '345 patent.

48. Upon information and belief, Zydus plans and intends to, and will, actively induce infringement of the '345 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 '345 patent and specific intent to infringe that patent.

49. 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 '345 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 '345 patent immediately and imminently upon approval of Zydus's ANDA.

50. Notwithstanding Zydus's knowledge of the claims of the '345 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 '345 patent.

51. The foregoing actions by Zydus constitute and/or will constitute infringement of the '345 patent; active inducement of infringement of the '345 patent; and/or contribution to the infringement by others of the '345 patent.

52. Upon information and belief, Zydus has acted with full knowledge of the '345 patent and without a reasonable basis for believing that it would not be liable for infringement of the '345 patent; active inducement of infringement of the '345 patent; and/or contribution to the infringement by others of the '345 patent.

53. Plaintiff will be substantially and irreparably damaged by infringement of the '345 patent.

54. Unless Zydus is enjoined from infringing the '345 patent, actively inducing infringement of the '345 patent, and contributing to the infringement by others of the '345 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count II—Declaratory Judgment of Infringement of the '345 Patent

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

56. 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 '345 patent, and/or the validity of the '345 patent.

57. 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 '345 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '345 patent, and that the claims of the '345 patent are not invalid.

Count III—Infringement of the '084 Patent

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

59. The '084 patent, entitled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" (attached as Exhibit B), was duly and legally issued on July 6, 2021.

60. The inventors named on the '084 patent are Peng Li and Robert Davis.

61. Plaintiff is the owner and assignee of the '084 patent.

62. CAPLYTA® is covered by one or more claims of the '084 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

63. In Zydus's 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 '084 patent.

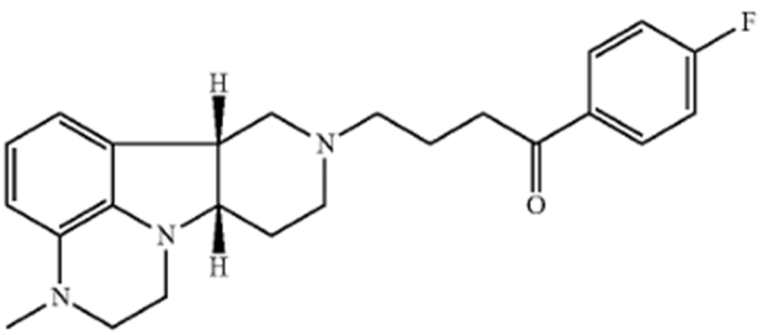
64. In Zydus's Notice Letter, Zydus also notified Plaintiff that, as part of its ANDA, Zydus had filed Paragraph IV certifications with respect to the '084 patent. Upon information and belief, Zydus submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '084 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product.

65. According to Zydus's Notice Letter, Zydus's ANDA Product contains lumateperone.

66. Upon information and belief, Zydus's ANDA Product and the use of Zydus's ANDA Product are covered by one or more claims of the '084 patent, either literally or under the doctrine of equivalents.

67. As an example, claim 1 of the '084 patent recites:

> A pharmaceutical capsule for oral administration, comprising lumateperone:



in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form; and

wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium, 0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule,

wherein the capsule comprises the lumateperone mono-tosylate in an amount equivalent to 0.01 to 30 mg of lumateperone free base.

68. Upon information and belief, Zydus's ANDA Product is a pharmaceutical capsule for oral administration comprising 0.01 to 30 mg of lumateperone mono-tosylate in solid crystal form (measured as the free base) and the specific excipients in the specific amounts recited in claim 1.

69. Upon information and belief, Zydus's ANDA Product infringes one or more claims of the '084 patent, literally or under the doctrine of equivalents.

70. 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 '084 patent was an act of infringement of the '084 patent under 35 U.S.C. § 271(e)(2)(A).

71. 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.

72. 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 '084 patent.

73. 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 '084 patent.

74. Upon information and belief, Zydus plans and intends to, and will, actively induce infringement of the '084 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 '084 patent and specific intent to infringe that patent.

75. 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 '084 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 '084 patent immediately and imminently upon approval of Zydus's ANDA.

76. Notwithstanding Zydus's knowledge of the claims of the '084 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 '084 patent.

77. The foregoing actions by Zydus constitute and/or will constitute infringement of the '084 patent; active inducement of infringement of the '084 patent; and/or contribution to the infringement by others of the '084 patent.

78. Upon information and belief, Zydus has acted with full knowledge of the '084 patent and without a reasonable basis for believing that it would not be liable for infringement of the '084 patent; active inducement of infringement of the '084 patent; and/or contribution to the infringement by others of the '084 patent.

79. Plaintiff will be substantially and irreparably damaged by infringement of the '084 patent.

80. Unless Zydus is enjoined from infringing the '084 patent, actively inducing infringement of the '084 patent, and contributing to the infringement by others of the '084 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count IV—Declaratory Judgment of Infringement of the '084 Patent

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

82. 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 '084 patent, and/or the validity of the '084 patent.

83. 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 '084 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '084 patent, and that the claims of the '084 patent are not invalid.

Count V—Infringement of the '842 Patent

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

85. The ’842 patent, entitled “Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate” (attached as Exhibit C), was duly and legally issued on July 4, 2023.

86. The inventors named on the ’842 patent are Peng Li and Robert Davis.

87. Plaintiff is the owner and assignee of the ’842 patent.

88. CAPLYTA® is covered by one or more claims of the ’842 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

89. In Zydus’s 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 ’842 patent.

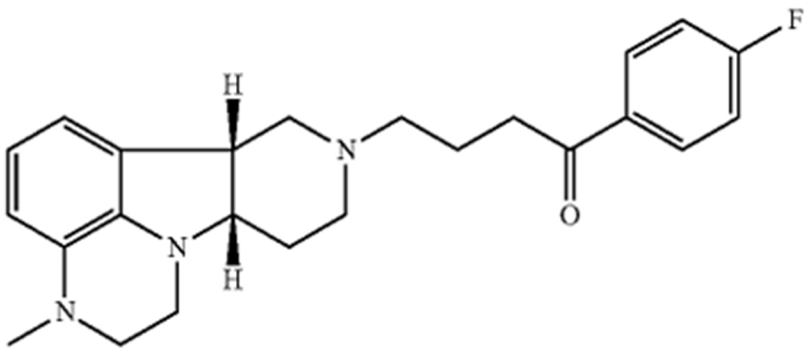
90. In Zydus’s Notice Letter, Zydus also notified Plaintiff that, as part of its ANDA, Zydus had filed Paragraph IV certifications with respect to the ’842 patent. Upon information and belief, Zydus submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the ’842 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Zydus’s ANDA Product.

91. According to Zydus’s Notice Letter, Zydus’s ANDA Product contains lumateperone.

92. Upon information and belief, Zydus’s ANDA Product and the use of Zydus’s ANDA Product are covered by one or more claims of the ’842 patent, either literally or under the doctrine of equivalents.

93. As an example, claim 1 of the ’842 patent recites:

A pharmaceutical capsule for oral administration, comprising lumateperone:



in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form; and

wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium, 0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule, and

wherein a single capsule dissolves in 500 mL of 0.1N aqueous hydrochloric acid to the extent of at least 85% after 15 minutes, and/or to the extent of at least 92% after 30 minutes, and/or to the extent of at least 94% after 45 minutes.

94. Upon information and belief, Zydus's ANDA Product is a pharmaceutical capsule for oral administration comprising lumateperone mono-tosylate in solid crystal form and the specific excipients in the specific amounts recited in claim 1 and possessing the specific dissolution profile recited in claim 1.

95. Upon information and belief, Zydus's ANDA Product infringes one or more claims of the '842 patent, literally or under the doctrine of equivalents.

96. 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 '842 patent was an act of infringement of the '842 patent under 35 U.S.C. § 271(e)(2)(A).

97. 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.

98. 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 '842 patent.

99. 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 '842 patent.

100. Upon information and belief, Zydus plans and intends to, and will, actively induce infringement of the '842 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 '842 patent and specific intent to infringe that patent.

101. 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 '842 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 '842 patent immediately and imminently upon approval of Zydus's ANDA.

102. Notwithstanding Zydus's knowledge of the claims of the '842 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 '842 patent.

103. The foregoing actions by Zydus constitute and/or will constitute infringement of the '842 patent; active inducement of infringement of the '842 patent; and/or contribution to the infringement by others of the '842 patent.

104. Upon information and belief, Zydus has acted with full knowledge of the '842 patent and without a reasonable basis for believing that it would not be liable for infringement of the '842 patent; active inducement of infringement of the '842 patent; and/or contribution to the infringement by others of the '842 patent.

105. Plaintiff will be substantially and irreparably damaged by infringement of the '842 patent.

106. Unless Zydus is enjoined from infringing the '842 patent, actively inducing infringement of the '842 patent, and contributing to the infringement by others of the '842 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count VI—Declaratory Judgment of Infringement of the '842 Patent

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

108. 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 '842 patent, and/or the validity of the '842 patent.

109. 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 '842 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '842 patent, and that the claims of the '842 patent are not invalid.

Count VII—Infringement of the '348 Patent

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

111. The '348 patent, entitled "Methods of Treatment Using Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" (attached as Exhibit D), was duly and legally issued on November 7, 2023.

112. The inventors named on the '348 patent are Peng Li and Robert Davis.

113. Plaintiff is the owner and assignee of the '348 patent.

114. CAPLYTA® is covered by one or more claims of the '348 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

115. In Zydus's 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 '348 patent.

116. In Zydus's Notice Letter, Zydus also notified Plaintiff that, as part of its ANDA, Zydus had filed Paragraph IV certifications with respect to the '348 patent. Upon information and belief, Zydus submitted its ANDA to the FDA containing Paragraph IV certifications asserting

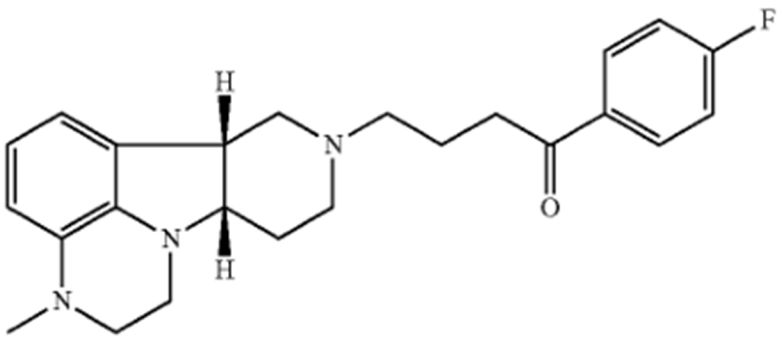
that the '348 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product.

117. According to Zydus's 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 '348 patent.

119. As an example, claim 1 of the '348 patent recites:

> A method for the treatment of a disease or disorder involving or mediated by the 5-HT_{2A} receptor, serotonin transporter (SERT), and/or dopamine D1/D2 receptor signaling pathways, comprising administering to a patient in need thereof a pharmaceutical capsule for oral administration, comprising lumateperone:



> in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form; and
>
> wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium,

0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule,

wherein the capsule comprises the lumateperone mono-tosylate in an amount equivalent to 0.01 to 30 mg or 35 to 45 mg of lumateperone free base.

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 a disease or disorder involving or mediated by the 5-HT_{2A} receptor, serotonin transporter (SERT), and/or dopamine D1/D2 receptor signaling pathways, including by administering to the patient in need thereof a pharmaceutical capsule for oral administration comprising 0.01 to 30 mg or 35 to 45 mg of lumateperone mono-tosylate in solid crystal form (measured as the free base) and the specific excipients in the specific amounts recited in claim 1.

121. Upon information and belief, Zydus's ANDA Product infringes one or more claims of the '348 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 '348 patent was an act of infringement of the '348 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 '348 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 '348 patent.

126. Upon information and belief, Zydus plans and intends to, and will, actively induce infringement of the '348 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 '348 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 '348 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 '348 patent immediately and imminently upon approval of Zydus's ANDA.

128. Notwithstanding Zydus's knowledge of the claims of the '348 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 '348 patent.

129. The foregoing actions by Zydus constitute and/or will constitute infringement of the '348 patent; active inducement of infringement of the '348 patent; and/or contribution to the infringement by others of the '348 patent.

130. Upon information and belief, Zydus has acted with full knowledge of the '348 patent and without a reasonable basis for believing that it would not be liable for infringement of the '348 patent; active inducement of infringement of the '348 patent; and/or contribution to the infringement by others of the '348 patent.

131. Plaintiff will be substantially and irreparably damaged by infringement of the ’348 patent.

132. Unless Zydus is enjoined from infringing the ’348 patent, actively inducing infringement of the ’348 patent, and contributing to the infringement by others of the ’348 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count VIII—Declaratory Judgment of Infringement of the ’348 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 ’348 patent, and/or the validity of the ’348 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 ’348 patent, will infringe, induce infringement of, and contribute to the infringement by others of the ’348 patent, and that the claims of the ’348 patent are not invalid.

Count IX—Infringement of the ’419 Patent

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

137. The ’419 patent, entitled “4-((6br,10as)-3-methyl-2,3,6b,9,10,10a-hexahydro-1h-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7h)-yl)-1-(4-((6br,10as)-3-methyl-2,3,6b,9,10,10a-hexahydro-1h-pyrido[3′4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7h)-yl)phenyl)butan-1-one for Treating Conditions of the Central Nervous System and Cardiac Disorders” (attached as Exhibit E), was duly and legally issued on September 12, 2023.

138. The inventors named on the '419 patent are Peng Li, Robert E. Davis, and Kimberly Vanover.

139. Plaintiff is the owner and assignee of the '419 patent.

140. CAPLYTA® is covered by one or more claims of the '419 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

141. In Zydus's 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 '419 patent.

142. In Zydus's Notice Letter, Zydus also notified Plaintiff that, as part of its ANDA, Zydus had filed Paragraph IV certifications with respect to the '419 patent. Upon information and belief, Zydus submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '419 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.

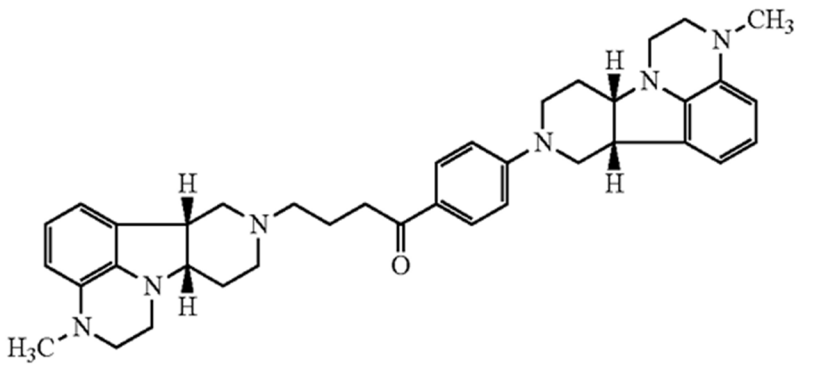
143. According to Zydus's Notice Letter, Zydus's ANDA Product contains lumateperone.

144. Upon information and belief, Zydus's ANDA Product and the use of Zydus's ANDA Product are covered by one or more claims of the '419 patent, either literally or under the doctrine of equivalents.

145. As an example, claim 1 of the '419 patent recites:

A compound of Formula I:

Formula I



in free base or pharmaceutically acceptable salt form.

146. Upon information and belief, Zydus's ANDA Product contains a Formula I compound in free or pharmaceutically acceptable salt form, as recited in claim 1.

147. Upon information and belief, Zydus's ANDA Product infringes one or more claims of the '419 patent, literally or under the doctrine of equivalents.

148. 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 '419 patent was an act of infringement of the '419 patent under 35 U.S.C. § 271(e)(2)(A).

149. 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.

150. 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 '419 patent.

151. 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 '419 patent.

152. Upon information and belief, Zydus plans and intends to, and will, actively induce infringement of the '419 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 '419 patent and specific intent to infringe that patent.

153. 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 '419 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 '419 patent immediately and imminently upon approval of Zydus's ANDA.

154. Notwithstanding Zydus's knowledge of the claims of the '419 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 '419 patent.

155. The foregoing actions by Zydus constitute and/or will constitute infringement of the '419 patent; active inducement of infringement of the '419 patent; and/or contribution to the infringement by others of the '419 patent.

156. Upon information and belief, Zydus has acted with full knowledge of the '419 patent and without a reasonable basis for believing that it would not be liable for infringement of the '419 patent; active inducement of infringement of the '419 patent; and/or contribution to the infringement by others of the '419 patent.

157. Plaintiff will be substantially and irreparably damaged by infringement of the '419 patent.

158. Unless Zydus is enjoined from infringing the '419 patent, actively inducing infringement of the '419 patent, and contributing to the infringement by others of the '419 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count X—Declaratory Judgment of Infringement of the '419 Patent

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

160. 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 '419 patent, and/or the validity of the '419 patent.

161. 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 '419 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '419 patent, and that the claims of the '419 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: March 28, 2024

By: *s/Liza M. Walsh*

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LOCAL RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is related to the following actions:

- *Intra-Cellular Therapies, Inc. v. Aurobindo Pharma Ltd. et al*, Civil Action No. 24-4264 (MAS/JBD);
- *Intra-Cellular Therapies, Inc. v. Alkem Laboratories Ltd.*, Civil Action No. 24-4312;
- *Intra-Cellular Therapies, Inc. v. Dr. Reddy's Laboratories Inc., et al*, Civil Action No. 24-4314;
- *Intra-Cellular Therapies, Inc. v. Hetero USA, Inc., et al*, Civil Action No. 24-4317;
- *Intra-Cellular Therapies, Inc. v. MSN Laboratories Private Ltd.*, Civil Action No. 24-4325; and
- *Intra-Cellular Therapies, Inc. v. Sandoz Inc.*, Civil Action No. 24-4327.

Dated: March 28, 2024

By: *s/Liza M. Walsh*

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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: March 28, 2024

By: *s/Liza M. Walsh*
Liza M. Walsh
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