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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. Hetero USA, Inc., Hetero Labs Ltd. Unit-V, and Hetero Labs 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 Hetero USA, Inc., Hetero Labs Ltd. Unit-V, and Hetero Labs Ltd. (collectively, "Hetero") 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 Hetero'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. 8,648,077 ("the '077 patent"), 9,956,227 ("the '227 patent"), 10,695,345 ("the '345 patent"), 10,960,009 ("the '009 patent"), 11,026,951 ("the '951 patent"), 11,052,084 ("the '084 patent"), 11,690,842 ("the '842 patent"), 11,753,419 ("the '419 patent"), 11,806,348 ("the '348 patent"), and RE48,839 ("the RE '839 patent"). These patents are referred to collectively herein as the "Patents-in-Suit."

2. Hetero notified Plaintiff by letter dated February 20, 2024 ("Hetero's Notice Letter") that it had submitted to the FDA ANDA No. 219142 ("Hetero'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, ("Hetero'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 Hetero USA, Inc., is a corporation organized and existing under the laws of Delaware and having a principal place of business at 1035 Centennial Ave, Piscataway, New Jersey 08854.

6. Upon information and belief, defendant Hetero Labs Ltd., Unit-V is a division of Hetero Labs Ltd., having a principal place of business at Sy. No.: 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepally Village, Mahabubnagar, Telangana, India, 509301.

7. Upon information and belief, Defendant Hetero Labs Ltd. is a corporation organized and existing under the laws of the Republic of India and having a principal place of business at 7-2-a2, Hetero Corporate Industrial Estate, Sanathnagar, Hyderabad, Telangana, India, 500018.

8. Upon information and belief, Hetero USA Inc. is the U.S. Regulatory Agent for Hetero Labs Ltd., Unit-V, which is a division of Hetero Labs Ltd.

9. Upon information and belief, Hetero Labs Ltd., Hetero Labs Ltd., Unit-V, and Hetero USA Inc. acted in concert to prepare and submit Hetero's ANDA to the FDA. Upon information and belief, Hetero Labs Ltd., Hetero Labs Ltd., Unit-V, and Hetero USA Inc. know and intend that upon approval of Hetero's ANDA, Hetero Labs Ltd. and/or Hetero Labs Ltd., Unit-V will manufacture Hetero's ANDA Product, and Hetero USA Inc. will directly or indirectly market, sell, and distribute Hetero's ANDA Product throughout the United States, including in New Jersey.

10. Upon information and belief, Hetero Labs Ltd., Hetero Labs Ltd., Unit-V, and Hetero USA Inc. are agents of each other and/or operate in concert as integrated parts of the same

business group, including with respect to Hetero's ANDA Product, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, Hetero USA Inc. participated in, assisted, and cooperated with Hetero Labs Ltd. and Hetero Labs Ltd., Unit-V in the acts complained of herein.

11. Upon information and belief, following any FDA approval of Hetero's ANDA, Hetero Labs Ltd., Hetero Labs Ltd., Unit-V, and Hetero USA Inc. will act in concert to distribute and sell Hetero's ANDA Product throughout the United States, including within New Jersey.

Jurisdiction

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

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

14. This Court has personal jurisdiction over each of Hetero Labs Ltd., Hetero Labs Ltd., Unit-V, and Hetero USA Inc.

15. Hetero Labs Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Hetero Labs Ltd., itself and through its subsidiary Hetero 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, Hetero Labs Ltd., itself and through its subsidiary Hetero 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, Hetero Labs Ltd. is subject to personal jurisdiction in New Jersey because, upon information and belief, it controls Hetero USA Inc. and therefore the activities of Hetero USA Inc. in this jurisdiction are attributed to Hetero Labs Ltd.

16. Hetero Labs Ltd., Unit-V is subject to personal jurisdiction in New Jersey because, among other things, Hetero Labs Ltd., Unit-V, itself and through its agent Hetero 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, Hetero Labs Ltd., Unit-V, itself and through its agent Hetero 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, Hetero Labs Ltd., Unit-V is subject to personal jurisdiction in New Jersey because, upon information and belief, it controls Hetero USA Inc. and therefore the activities of Hetero USA Inc. in this jurisdiction are attributed to Hetero Labs Ltd., Unit-V.

17. Hetero 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. Hetero USA Inc. is a corporation having 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, Hetero 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.

18. Hetero 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.

19. Upon information and belief, Hetero, with knowledge of the Hatch-Waxman Act process, directed Hetero's Notice Letter to Plaintiff. Upon information and belief, Hetero 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. Hetero has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Hetero's Notice Letter to Plaintiff it would be sued for patent infringement in New Jersey, where Hetero USA Inc. is located.

20. Upon information and belief, if Hetero's ANDA is approved, Hetero will directly or indirectly manufacture, market, sell, and/or distribute Hetero's ANDA Product within the United States, including in New Jersey, consistent with Hetero's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Hetero 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, Hetero's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. Upon information and belief, Hetero'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 Hetero's ANDA Product is approved before the patents expire.

21. Upon information and belief, Hetero derives substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and which are

manufactured by Hetero and/or Hetero USA Inc., Hetero Labs Ltd., Unit-V, or Hetero Labs Ltd. Upon information and belief, various products for which Hetero Labs Ltd., Hetero Labs Ltd., Unit-V, or Hetero USA Inc. is the named applicant on approved ANDAs are available at retail pharmacies in New Jersey.

Venue

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

23. Venue is proper in this district as to Hetero USA Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Hetero USA Inc. is a corporation having a principal place of business in the State of New Jersey and is subject to personal jurisdiction in this judicial district.

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

25. Venue is proper in this district as to Hetero Labs Ltd. pursuant to 28 U.S.C. §§ 1391 and/or 1400(b) because, *inter alia*, Hetero Labs 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

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

27. 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.

28. In Hetero's Notice Letter, Hetero stated that the subject of Hetero's ANDA is lumateperone capsules, 10.5 mg, 21 mg, and 42 mg. In Hetero's Notice Letter, Hetero stated that Hetero's ANDA was submitted under 21 U.S.C. § 355(j)(1) & (2)(a). Upon information and belief,

Hetero's ANDA contains bioavailability and/or bioequivalence studies for Hetero's ANDA Product. Upon information and belief, Hetero's ANDA Product is a generic version of CAPLYTA®.

29. In Hetero's Notice Letter, Hetero 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 Hetero is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Product prior to the expiration of the Patents-in-Suit.

30. The purpose of Hetero's submission of Hetero'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 Hetero's ANDA Product prior to the expiration of the Patents-in-Suit.

31. Upon information and belief, Hetero's ANDA Product is not publicly available, nor is ANDA No. 219142 accessible to the public.

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

33. Counsel for Plaintiff contacted Hetero to discuss the terms of Hetero's Offer of Confidential Access, but Hetero never responded. The parties therefore could not agree on terms under which Plaintiff could review, among other things, Hetero's unredacted ANDA, any Drug Master File referred to therein, or all relevant characterization data, or under which Hetero could produce samples of Hetero's ANDA Product and other internal documents and material relevant to infringement.

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

Count I—Infringement of the RE '839 Patent

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

36. 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.

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

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

39. 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").

40. In Hetero's Notice Letter, Hetero notified Plaintiff of the submission of Hetero'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 Hetero's ANDA Product prior to the expiration of the Patents-in-Suit, including the RE '839 patent.

41. In Hetero's Notice Letter, Hetero also notified Plaintiff that, as part of its ANDA, Hetero had filed Paragraph IV certifications with respect to the RE '839 patent. Upon information and belief, Hetero 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 Hetero's ANDA Product.

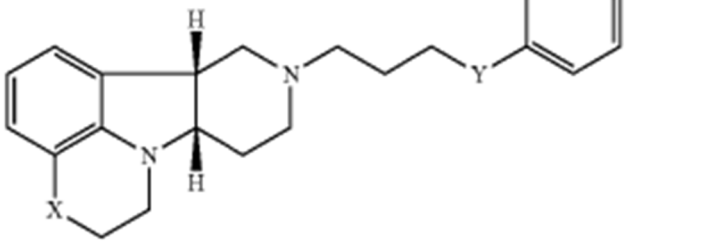
42. According to Hetero's Notice Letter, Hetero's ANDA Product contains lumateperone.

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

44. 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.

45. Upon information and belief, the use of Hetero's ANDA Product in accordance with and as directed by Hetero'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.

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

47. Hetero's submission of Hetero's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero'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).

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

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

50. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Hetero'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.

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

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

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

54. The foregoing actions by Hetero 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.

55. Upon information and belief, Hetero 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.

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

57. Unless Hetero 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

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

59. 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 Hetero on the other regarding Hetero'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.

60. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Product with its proposed labeling, or any other Hetero 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 '077 Patent

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

62. The '077 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-fluorophenyl)-1-butanone Toluenesulfonic Acid Addition Salt and Salt Crystals" (attached as Exhibit B), was duly and legally issued on February 11, 2014.

63. The inventors named on the '077 patent are John Tomesch and Lawrence P. Wennogle.

64. Plaintiff is the owner and assignee of the '077 patent.

65. CAPLYTA® is covered by one or more claims of the '077 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

66. In Hetero's Notice Letter, Hetero notified Plaintiff of the submission of Hetero'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 Hetero's ANDA Product prior to the expiration of the Patents-in-Suit, including the '077 patent.

67. In Hetero's Notice Letter, Hetero also notified Plaintiff that, as part of its ANDA, Hetero had filed Paragraph IV certifications with respect to the '077 patent. Upon information and belief, Hetero submitted its ANDA to the FDA containing Paragraph IV certifications

asserting that the '077 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Hetero's ANDA Product.

68. According to Hetero's Notice Letter, Hetero's ANDA Product contains lumateperone.

69. Upon information and belief, Hetero's ANDA Product and the use of Hetero's ANDA Product are covered by one or more claims of the '077 patent, either literally or under the doctrine of equivalents.

70. As an example, claim 1 of the '077 patent recites:

> A toluenesulfonic acid addition salt crystal of 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-fluorophenyl)-1-butanone, wherein said salt crystal exhibits an X-ray powder diffraction pattern comprising at least two peaks having 2-theta values selected from the group consisting of 5.68°, 12.11°, 16.04°, 17.03°, 18.16°, 19.00°, 21.67°, 22.55°, 23.48° and 24.30°, wherein the X-ray powder diffraction data is collected on a diffractometer operating with a copper anode with a nickel filter.

71. Upon information and belief, Hetero's ANDA Product contains a crystalline form of the compound recited in claim 1.

72. Upon information and belief, Hetero's ANDA Product infringes one or more claims of the '077 patent, literally or under the doctrine of equivalents.

73. Hetero's submission of Hetero's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero's

ANDA Product before the expiration of the '077 patent was an act of infringement of the '077 patent under 35 U.S.C. § 271(e)(2)(A).

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

75. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '077 patent.

76. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '077 patent.

77. Upon information and belief, Hetero plans and intends to, and will, actively induce infringement of the '077 patent when Hetero's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Hetero's activities will be done with knowledge of the '077 patent and specific intent to infringe that patent.

78. Upon information and belief, Hetero knows that Hetero's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '077 patent, that Hetero's ANDA Product is not a staple article or commodity of commerce, and that Hetero's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Hetero plans and intends to, and will, contribute to infringement of the '077 patent immediately and imminently upon approval of Hetero's ANDA.

79. Notwithstanding Hetero's knowledge of the claims of the '077 patent, Hetero has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Hetero's

ANDA Product with its product labeling following FDA approval of Hetero's ANDA prior to the expiration of the '077 patent.

80. The foregoing actions by Hetero constitute and/or will constitute infringement of the '077 patent; active inducement of infringement of the '077 patent; and/or contribution to the infringement by others of the '077 patent.

81. Upon information and belief, Hetero has acted with full knowledge of the '077 patent and without a reasonable basis for believing that it would not be liable for infringement of the '077 patent; active inducement of infringement of the '077 patent; and/or contribution to the infringement by others of the '077 patent.

82. Plaintiff will be substantially and irreparably damaged by infringement of the '077 patent.

83. Unless Hetero is enjoined from infringing the '077 patent, actively inducing infringement of the '077 patent, and contributing to the infringement by others of the '077 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count IV—Declaratory Judgment of Infringement of the '077 Patent

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

85. 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 Hetero on the other regarding Hetero's infringement, active inducement of infringement, contribution to the infringement by others of the '077 patent, and/or the validity of the '077 patent.

86. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Product with its proposed labeling, or any other Hetero drug product that is covered by or whose use is covered by the '077 patent, will infringe, induce

infringement of, and contribute to the infringement by others of the '077 patent, and that the claims of the '077 patent are not invalid.

Count V—Infringement of the '227 Patent

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

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

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

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

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

92. In Hetero's Notice Letter, Hetero notified Plaintiff of the submission of Hetero'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 Hetero's ANDA Product prior to the expiration of the Patents-in-Suit, including the '227 patent.

93. In Hetero's Notice Letter, Hetero also notified Plaintiff that, as part of its ANDA, Hetero had filed Paragraph IV certifications with respect to the '227 patent. Upon information and belief, Hetero 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 Hetero's ANDA Product.

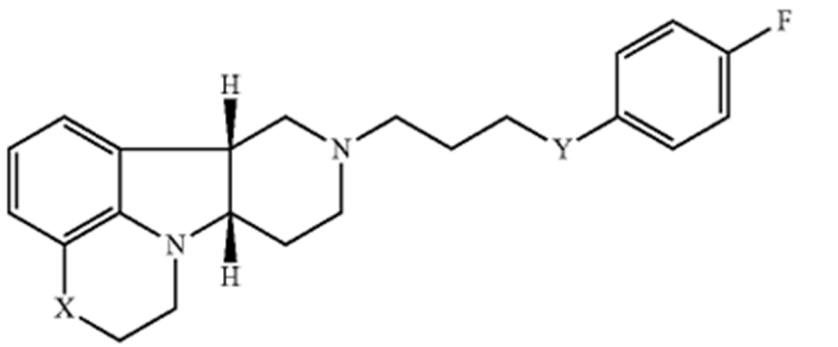
94. According to Hetero's Notice Letter, Hetero's ANDA Product contains lumateperone.

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

96. 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.

97. Upon information and belief, the use of Hetero's ANDA Product in accordance with and as directed by Hetero'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.

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

99. Hetero's submission of Hetero's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero'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).

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

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

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

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

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

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

106. The foregoing actions by Hetero 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.

107. Upon information and belief, Hetero 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.

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

109. Unless Hetero 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 VI—Declaratory Judgment of Infringement of the '227 Patent

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

111. 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 Hetero on the other regarding Hetero's infringement, active inducement of infringement, contribution to the infringement by others of the '227 patent, and/or the validity of the '227 patent.

112. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Product with its proposed labeling, or any other Hetero 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 VII—Infringement of the '009 Patent

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

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

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

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

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

118. In Hetero's Notice Letter, Hetero notified Plaintiff of the submission of Hetero'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 Hetero's ANDA Product prior to the expiration of the Patents-in-Suit, including the '009 patent.

119. In Hetero's Notice Letter, Hetero also notified Plaintiff that, as part of its ANDA, Hetero had filed Paragraph IV certifications with respect to the '009 patent. Upon information and belief, Hetero 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 Hetero's ANDA Product.

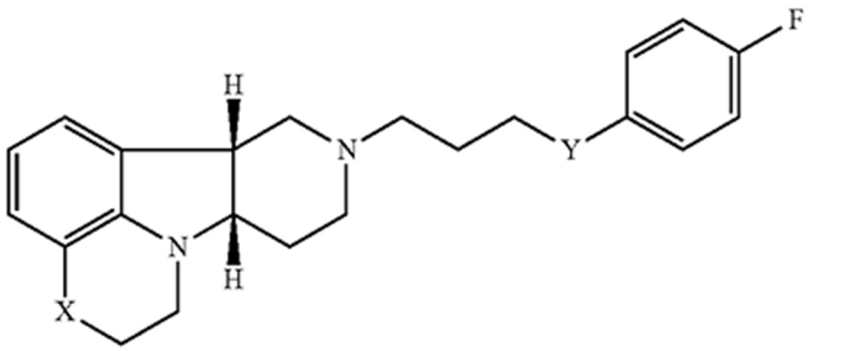
120. According to Hetero's Notice Letter, Hetero's ANDA Product contains lumateperone.

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

122. 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.

123. Upon information and belief, the use of Hetero's ANDA Product in accordance with and as directed by Hetero'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.

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

125. Hetero's submission of Hetero's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero'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).

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

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

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

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

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

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

132. The foregoing actions by Hetero 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.

133. Upon information and belief, Hetero 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.

134. Plaintiff will be substantially and irreparably damaged by infringement of the ’009 patent.

135. Unless Hetero 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 VIII—Declaratory Judgment of Infringement of the ’009 Patent

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

137. 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 Hetero on the other regarding Hetero’s infringement, active inducement of infringement, contribution to the infringement by others of the ’009 patent, and/or the validity of the ’009 patent.

138. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Hetero’s ANDA Product with its proposed labeling, or any other Hetero 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 IX—Infringement of the '951 Patent

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

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

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

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

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

144. In Hetero's Notice Letter, Hetero notified Plaintiff of the submission of Hetero'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 Hetero's ANDA Product prior to the expiration of the Patents-in-Suit, including the '951 patent.

145. In Hetero's Notice Letter, Hetero also notified Plaintiff that, as part of its ANDA, Hetero had filed Paragraph IV certifications with respect to the '951 patent. Upon information and belief, Hetero submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '951 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Hetero's ANDA Product.

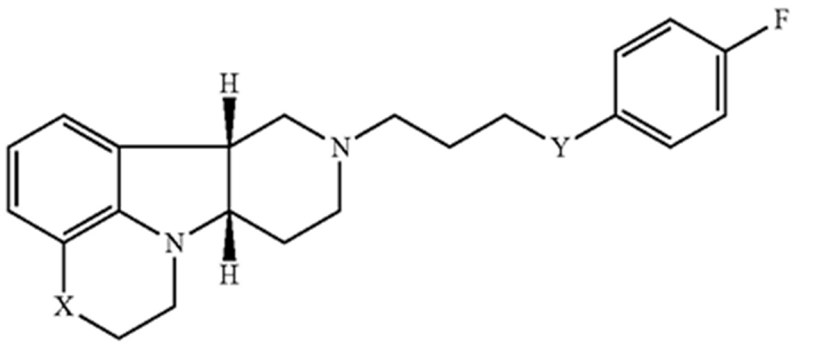
146. According to Hetero's Notice Letter, Hetero's ANDA Product contains lumateperone.

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

148. 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(CH3)— and Y is —C(O)—;
>
> in free or pharmaceutically acceptable salt form, wherein said Compound is not used in combination with another antipsychotic agent.

149. Upon information and belief, the use of Hetero’s ANDA Product in accordance with and as directed by Hetero’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.

150. Upon information and belief, Hetero’s ANDA Product infringes one or more claims of the ’951 patent, literally or under the doctrine of equivalents.

151. Hetero’s submission of Hetero’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero’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).

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

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

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

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

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

157. Notwithstanding Hetero's knowledge of the claims of the '951 patent, Hetero has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Hetero's

ANDA Product with its product labeling following FDA approval of Hetero's ANDA prior to the expiration of the '951 patent.

158. The foregoing actions by Hetero 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.

159. Upon information and belief, Hetero 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.

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

161. Unless Hetero 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 X—Declaratory Judgment of Infringement of the '951 Patent

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

163. 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 Hetero on the other regarding Hetero's infringement, active inducement of infringement, contribution to the infringement by others of the '951 patent, and/or the validity of the '951 patent.

164. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Product with its proposed labeling, or any other Hetero 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.

Count XI—Infringement of the ’345 Patent

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

166. The ’345 patent, entitled “Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate” (attached as Exhibit F), was duly and legally issued on June 30, 2020.

167. The inventors named on the ’345 patent are Peng Li and Robert Davis.

168. Plaintiff is the owner and assignee of the ’345 patent.

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

170. In Hetero’s Notice Letter, Hetero notified Plaintiff of the submission of Hetero’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 Hetero’s ANDA Product prior to the expiration of the Patents-in-Suit, including the ’345 patent.

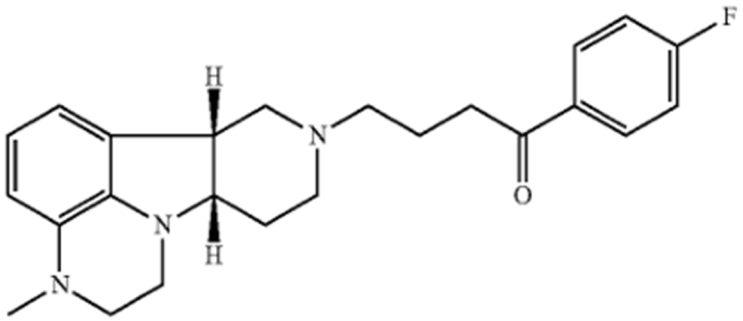
171. In Hetero’s Notice Letter, Hetero also notified Plaintiff that, as part of its ANDA, Hetero had filed Paragraph IV certifications with respect to the ’345 patent. Upon information and belief, Hetero submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the ’345 patent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

172. According to Hetero’s Notice Letter, Hetero’s ANDA Product contains lumateperone.

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

174. 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.

175. Upon information and belief, Hetero'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.

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

177. Hetero's submission of Hetero's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero'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).

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

179. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '345 patent.

180. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '345 patent.

181. Upon information and belief, Hetero plans and intends to, and will, actively induce infringement of the '345 patent when Hetero's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Hetero's activities will be done with knowledge of the '345 patent and specific intent to infringe that patent.

182. Upon information and belief, Hetero knows that Hetero's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '345 patent, that Hetero's ANDA Product is not a staple article or commodity of commerce, and that Hetero's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Hetero plans and intends to, and will, contribute to infringement of the '345 patent immediately and imminently upon approval of Hetero's ANDA.

183. Notwithstanding Hetero's knowledge of the claims of the '345 patent, Hetero has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Hetero's ANDA Product with its product labeling following FDA approval of Hetero's ANDA prior to the expiration of the '345 patent.

184. The foregoing actions by Hetero 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.

185. Upon information and belief, Hetero 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.

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

187. Unless Hetero 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 XII—Declaratory Judgment of Infringement of the '345 Patent

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

189. 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 Hetero on the other regarding Hetero's infringement, active inducement of infringement, contribution to the infringement by others of the '345 patent, and/or the validity of the '345 patent.

190. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Product with its proposed labeling, or any other Hetero 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 XIII—Infringement of the '084 Patent

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

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

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

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

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

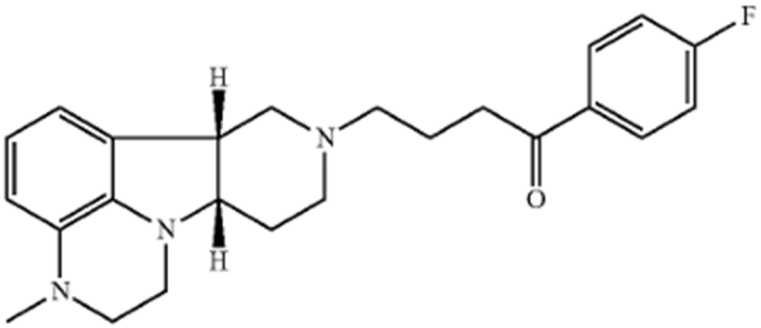
196. In Hetero's Notice Letter, Hetero notified Plaintiff of the submission of Hetero's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero's ANDA Product prior to the expiration of the Patents-in-Suit, including the '084 patent.

197. In Hetero's Notice Letter, Hetero also notified Plaintiff that, as part of its ANDA, Hetero had filed Paragraph IV certifications with respect to the '084 patent. Upon information and belief, Hetero 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 Hetero's ANDA Product.

198. According to Hetero's Notice Letter, Hetero's ANDA Product contains lumateperone.

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

200. 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.

201. Upon information and belief, Hetero'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.

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

203. Hetero's submission of Hetero's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero'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).

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

205. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '084 patent.

206. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '084 patent.

207. Upon information and belief, Hetero plans and intends to, and will, actively induce infringement of the '084 patent when Hetero's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Hetero's activities will be done with knowledge of the '084 patent and specific intent to infringe that patent.

208. Upon information and belief, Hetero knows that Hetero's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '084 patent, that Hetero's ANDA Product is not a staple article or commodity of commerce, and that Hetero's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Hetero plans and intends to, and will, contribute to infringement of the '084 patent immediately and imminently upon approval of Hetero's ANDA.

209. Notwithstanding Hetero's knowledge of the claims of the '084 patent, Hetero has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Hetero's ANDA Product with its product labeling following FDA approval of Hetero's ANDA prior to the expiration of the '084 patent.

210. The foregoing actions by Hetero 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.

211. Upon information and belief, Hetero 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.

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

213. Unless Hetero 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 XIV—Declaratory Judgment of Infringement of the '084 Patent

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

215. 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 Hetero on the other regarding Hetero's infringement, active inducement of infringement, contribution to the infringement by others of the '084 patent, and/or the validity of the '084 patent.

216. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Product with its proposed labeling, or any other Hetero 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 XV—Infringement of the '842 Patent

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

218. The '842 patent, entitled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" (attached as Exhibit H), was duly and legally issued on July 4, 2023.

219. The inventors named on the '842 patent are Peng Li and Robert Davis.

220. Plaintiff is the owner and assignee of the '842 patent.

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

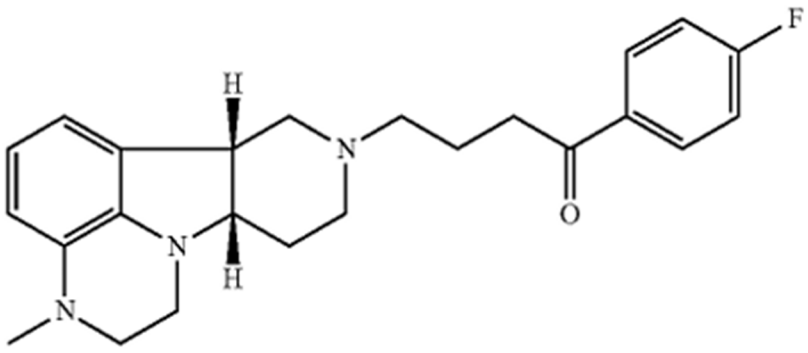
222. In Hetero's Notice Letter, Hetero notified Plaintiff of the submission of Hetero's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero's ANDA Product prior to the expiration of the Patents-in-Suit, including the '842 patent.

223. In Hetero's Notice Letter, Hetero also notified Plaintiff that, as part of its ANDA, Hetero had filed Paragraph IV certifications with respect to the '842 patent. Upon information and belief, Hetero 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 Hetero's ANDA Product.

224. According to Hetero's Notice Letter, Hetero's ANDA Product contains lumateperone.

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

226. 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.

227. Upon information and belief, Hetero'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.

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

229. Hetero's submission of Hetero's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero'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).

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

231. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '842 patent.

232. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '842 patent.

233. Upon information and belief, Hetero plans and intends to, and will, actively induce infringement of the '842 patent when Hetero's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Hetero's activities will be done with knowledge of the '842 patent and specific intent to infringe that patent.

234. Upon information and belief, Hetero knows that Hetero's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '842 patent, that Hetero's ANDA Product is not a staple article or commodity of commerce, and that Hetero's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Hetero plans and intends to, and will, contribute to infringement of the '842 patent immediately and imminently upon approval of Hetero's ANDA.

235. Notwithstanding Hetero's knowledge of the claims of the '842 patent, Hetero has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Hetero's ANDA Product with its product labeling following FDA approval of Hetero's ANDA prior to the expiration of the '842 patent.

236. The foregoing actions by Hetero 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.

237. Upon information and belief, Hetero 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.

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

239. Unless Hetero 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 XVI—Declaratory Judgment of Infringement of the '842 Patent

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

241. 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 Hetero on the other regarding Hetero's infringement, active inducement of infringement, contribution to the infringement by others of the '842 patent, and/or the validity of the '842 patent.

242. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Product with its proposed labeling, or any other Hetero 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 XVII—Infringement of the '348 Patent

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

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

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

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

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

248. In Hetero's Notice Letter, Hetero notified Plaintiff of the submission of Hetero'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 Hetero's ANDA Product prior to the expiration of the Patents-in-Suit, including the '348 patent.

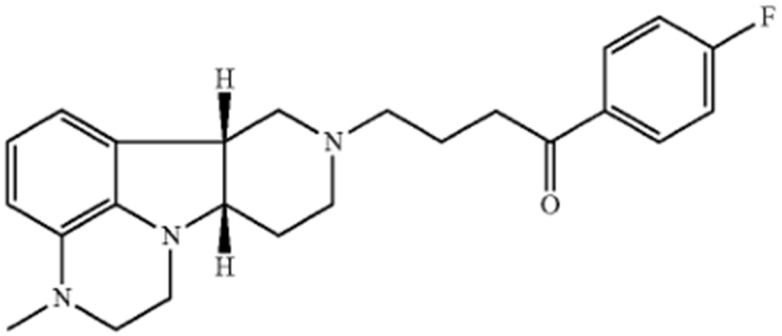
249. In Hetero's Notice Letter, Hetero also notified Plaintiff that, as part of its ANDA, Hetero had filed Paragraph IV certifications with respect to the '348 patent. Upon information and belief, Hetero submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '348 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Hetero's ANDA Product.

250. According to Hetero's Notice Letter, Hetero's ANDA Product contains lumateperone.

251. Upon information and belief, the use of Hetero's ANDA Product in accordance with and as directed by Hetero's proposed labeling for that product would infringe one or more claims of the '348 patent.

252. 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.

253. Upon information and belief, the use of Hetero's ANDA Product in accordance with and as directed by Hetero'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.

254. Upon information and belief, Hetero's ANDA Product infringes one or more claims of the '348 patent, literally or under the doctrine of equivalents.

255. Hetero's submission of Hetero's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero'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).

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

257. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '348 patent.

258. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '348 patent.

259. Upon information and belief, Hetero plans and intends to, and will, actively induce infringement of the '348 patent when Hetero's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Hetero's activities will be done with knowledge of the '348 patent and specific intent to infringe that patent.

260. Upon information and belief, Hetero knows that Hetero's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '348 patent, that Hetero's ANDA Product is not a staple article or commodity of commerce, and that Hetero's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon

information and belief, Hetero plans and intends to, and will, contribute to infringement of the '348 patent immediately and imminently upon approval of Hetero's ANDA.

261. Notwithstanding Hetero's knowledge of the claims of the '348 patent, Hetero has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Hetero's ANDA Product with its product labeling following FDA approval of Hetero's ANDA prior to the expiration of the '348 patent.

262. The foregoing actions by Hetero 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.

263. Upon information and belief, Hetero 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.

264. Plaintiff will be substantially and irreparably damaged by infringement of the '348 patent.

265. Unless Hetero 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 XVIII—Declaratory Judgment of Infringement of the '348 Patent

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

267. 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 Hetero on the other regarding Hetero's infringement, active inducement of

infringement, contribution to the infringement by others of the '348 patent, and/or the validity of the '348 patent.

268. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Product with its proposed labeling, or any other Hetero 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 XIX—Infringement of the '419 Patent

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

270. 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 J), was duly and legally issued on September 12, 2023.

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

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

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

274. In Hetero's Notice Letter, Hetero notified Plaintiff of the submission of Hetero'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 Hetero's ANDA Product prior to the expiration of the Patents-in-Suit, including the '419 patent.

275. In Hetero's Notice Letter, Hetero also notified Plaintiff that, as part of its ANDA, Hetero had filed Paragraph IV certifications with respect to the '419 patent. Upon information and belief, Hetero 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 Hetero's ANDA Product.

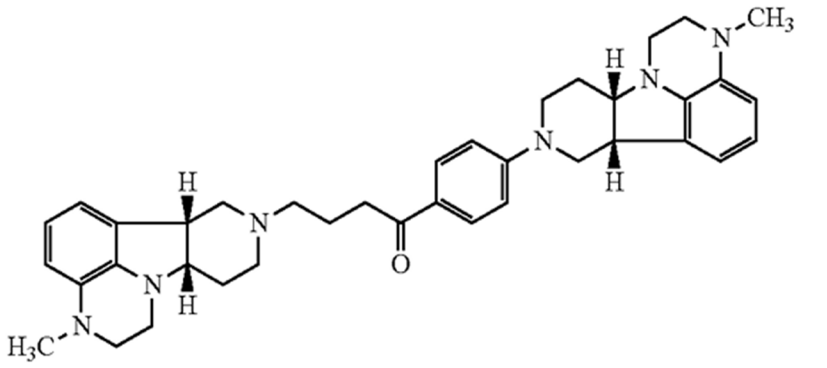
276. According to Hetero's Notice Letter, Hetero's ANDA Product contains lumateperone.

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

278. 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.

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

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

281. Hetero's submission of Hetero's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hetero'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).

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

283. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '419 patent.

284. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '419 patent.

285. Upon information and belief, Hetero plans and intends to, and will, actively induce infringement of the '419 patent when Hetero's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Hetero's activities will be done with knowledge of the '419 patent and specific intent to infringe that patent.

286. Upon information and belief, Hetero knows that Hetero's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '419 patent, that Hetero's ANDA Product is not a staple article or commodity of commerce, and that Hetero's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Hetero plans and intends to, and will, contribute to infringement of the '419 patent immediately and imminently upon approval of Hetero's ANDA.

287. Notwithstanding Hetero's knowledge of the claims of the '419 patent, Hetero has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Hetero's ANDA Product with its product labeling following FDA approval of Hetero's ANDA prior to the expiration of the '419 patent.

288. The foregoing actions by Hetero 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.

289. Upon information and belief, Hetero 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.

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

291. Unless Hetero 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 XX—Declaratory Judgment of Infringement of the '419 Patent

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

293. 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 Hetero on the other regarding Hetero's infringement, active inducement of infringement, contribution to the infringement by others of the '419 patent, and/or the validity of the '419 patent.

294. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Product with its proposed labeling, or any other Hetero 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 Hetero's submission to the FDA of Hetero's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Hetero'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 Hetero, and all persons acting in concert with Hetero, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Hetero'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 Hetero'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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Lauren R. Malakoff
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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; and
- *Intra-Cellular Therapies, Inc. v. Dr. Reddy's Laboratories Inc., et al*, Civil Action No. 24-4314.

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*
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Lauren R. Malakoff
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