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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.

Sandoz Inc.,

Defendant.

:

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 Sandoz Inc. (“Sandoz” or “Defendant”) 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 Sandoz’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”), 9,168,258 (“the ’258 patent”), 9,199,995 (“the ’995 patent”), 9,616,061 (“the ’061 patent”), 9,956,227 (“the ’227 patent”), 10,117,867 (“the ’867 patent”), 10,464,938 (“the ’938 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”), RE48,825 (“the RE ’825 patent”), and RE48,839 (“the RE ’839 patent”). These patents are referred to collectively herein as the “Patents-in-Suit.”

2. Sandoz notified Plaintiff by letter dated February 15, 2024 (“Sandoz’s Notice Letter”) that it had submitted to the FDA ANDA No. 218938 (“Sandoz’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, (“Sandoz’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 Sandoz is a corporation organized and existing under the laws of Delaware and having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

6. Upon information and belief, Sandoz is in the business of, among other things, importing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Sandoz knows and intends that upon approval of Sandoz’s ANDA, Sandoz will manufacture Sandoz’s ANDA Product and Sandoz will directly or indirectly market, sell, and distribute Sandoz’s ANDA Product throughout the United States, including in New Jersey.

Jurisdiction

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

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

9. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Sandoz.

10. Upon information and belief, Sandoz has a principal place of business in New Jersey, and is in the business of, among other things, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic versions of branded pharmaceutical products throughout the United States, including in New Jersey, through its own

actions and/or through the actions of its agents and subsidiaries, from which Sandoz derives a substantial portion of its revenue.

11. Upon information and belief, Sandoz is registered to do business in New Jersey under Entity Identification Number 0100097265 and is registered with the New Jersey Department of Health as a drug manufacturer and wholesaler under Registration Number 5003732.

12. Upon information and belief, Sandoz, through its own actions and/or through the actions of its agents and subsidiaries, has engaged in the research and development, and the preparation and filing, of Sandoz's ANDA; continues to engage in seeking FDA approval of Sandoz's ANDA; intends to engage in the commercial manufacture, marketing, offer for sale, sale, or importation of Sandoz's ANDA Product throughout the United States, including in New Jersey; and stands to benefit from the approval of Sandoz's ANDA.

13. Upon information and belief, Sandoz, through its own actions and/or through the actions of its agents and subsidiaries, prepared and submitted Sandoz's ANDA with certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

14. Upon information and belief, upon FDA approval of Sandoz's ANDA, Sandoz will market, offer to sell, sell, or distribute Sandoz's ANDA Product throughout the United States, including in New Jersey, consistently with Sandoz's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Sandoz 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, Sandoz's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. Upon information and belief, Sandoz's ANDA Product will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and/or 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 Sandoz's ANDA Product is approved before the Patents-in-Suit expire.

15. Upon information and belief, Sandoz derives substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and which are manufactured by Sandoz and/or for which Sandoz is the named applicant on approved ANDAs. Upon information and belief, various products for which Sandoz is the named applicant on approved ANDAs are available at retail pharmacies in New Jersey.

16. Sandoz 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. Upon information and belief, Sandoz is a corporation with a principal place of business in New Jersey, is registered 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, Sandoz develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

17. This Court also has personal jurisdiction over Sandoz because, among other things, upon information and belief: (1) Sandoz filed Sandoz's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product in the United States, including in New Jersey; and (2) upon approval of Sandoz's ANDA, Sandoz will directly, or indirectly through subsidiaries, intermediaries, distributors, retailers, or others, market, distribute, offer for sale, sell, and/or import Sandoz's

ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Sandoz's ANDA Product in New Jersey. Upon information and belief, upon approval of Sandoz's ANDA, Sandoz's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

18. This Court also has personal jurisdiction over Sandoz because Sandoz has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiff, which manufactures CAPLYTA® drug products for sale and use throughout the United States, including in New Jersey. As a result, the consequences of Sandoz's actions were, and will be, suffered in New Jersey. Sandoz knew or should have known that the consequences of its actions were, and will be, suffered in New Jersey. At the time Sandoz sent notice of the certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), it was reasonably foreseeable that Sandoz would be sued within 45 days in New Jersey, where Sandoz is located. Upon information and belief, Sandoz's actions will injure Plaintiff by displacing at least some, if not all, of Plaintiff's sales of CAPLYTA® drug products in New Jersey, as well as resulting in price erosion and loss of goodwill with the purchasers and distributors of CAPLYTA® drug products in New Jersey.

19. Sandoz is also subject to personal jurisdiction in New Jersey because it (1) engages in patent litigation concerning Sandoz's generic versions of branded pharmaceutical products in this District, (2) does not contest personal jurisdiction in this District, and (3) purposefully avails itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g., Astellas Pharma Inc. v. Sandoz, Inc.*, No. 23-cv-01214, ECF No. 17 (D.N.J.

May 1, 2023); *Aragon Pharms., Inc. v. Sandoz Inc.*, No. 22-cv-03044, ECF No. 23 (D.N.J. Aug. 1, 2022).

20. For the above reasons, it would not be unfair or unreasonable for Sandoz to litigate this action in this District, and the Court has personal jurisdiction over Sandoz.

Venue

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

22. Venue is proper in this district under 28 U.S.C. § 1391, at least because, upon information and belief, Sandoz resides in this district and a substantial part of the events and injury giving rise to Plaintiff's claims has and continues to occur in this district.

23. Venue is proper in this district under 28 U.S.C. § 1400(b), at least because, upon information and belief, Sandoz has a principal place of business in New Jersey and has committed acts of infringement in New Jersey. Upon information and belief, among other things, (1) Sandoz prepared and/or submitted Sandoz's ANDA with Paragraph IV certifications in New Jersey, where Sandoz is located; and (2) upon approval of Sandoz's ANDA, Sandoz will market, distribute, offer for sale, sell, and/or import Sandoz's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Sandoz's ANDA Product in New Jersey.

24. Venue is proper in this district as to Sandoz because Sandoz (1) engages in patent litigation concerning Sandoz's generic versions of branded pharmaceutical products in this District, and (2) does not contest that venue is proper in this district. *See, e.g., Astellas Pharma Inc. v. Sandoz, Inc.*, No. 23-cv-01214, ECF No. 17 (D.N.J. May 1, 2023); *Aragon Pharms., Inc. v. Sandoz Inc.*, No. 22-cv-03044, ECF No. 23 (D.N.J. Aug. 1, 2022).

Factual Background

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

26. CAPLYTA®, lumateperone capsules, 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.

27. In Sandoz's Notice Letter, Sandoz stated that the subject of Sandoz's ANDA is lumateperone capsules, 10.5 mg, 21 mg, and 42 mg. In Sandoz's Notice Letter, Sandoz stated that Sandoz's ANDA was submitted under 21 U.S.C. § 355(j)(1) & (2)(a) and contended that Sandoz's ANDA contains bioavailability and/or bioequivalence studies for Sandoz's ANDA Product. Upon information and belief, Sandoz's ANDA Product is a generic version of CAPLYTA®.

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

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

30. Upon information and belief, Sandoz's ANDA Product is not publicly available, nor is ANDA No. 218938 accessible to the public.

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

32. In an exchange of correspondence, counsel for Plaintiff and counsel for Sandoz discussed the terms of Sandoz's Offer of Confidential Access. The parties did not agree on terms

under which Plaintiff could review, among other things, Sandoz's unredacted ANDA, any Drug Master File referred to therein, or all relevant characterization data. Sandoz further refused to produce samples of Sandoz's ANDA Product and other internal documents and material relevant to infringement.

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

Count I—Infringement of the RE '839 Patent

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

35. 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.

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

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

38. 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").

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

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

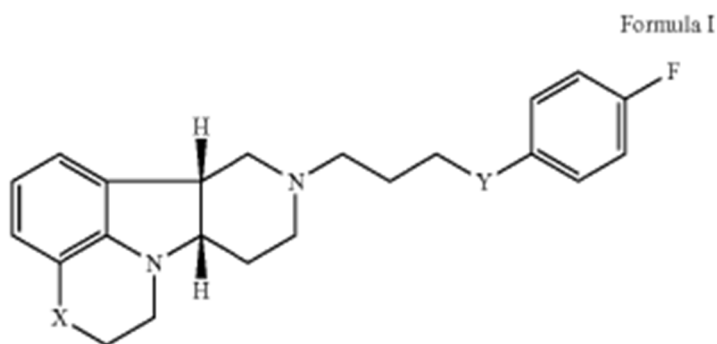
asserting that the RE '839 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

41. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

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

43. 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:



wherein X is O, —NH or —N(CH₃); 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.

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

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

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

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

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

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

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

51. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the RE '839 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon

information and belief, Sandoz plans and intends to, and will, contribute to infringement of the RE '839 patent immediately and imminently upon approval of Sandoz's ANDA.

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

53. The foregoing actions by Sandoz 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.

54. Upon information and belief, Sandoz 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.

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

56. Unless Sandoz 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

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

58. 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 Sandoz on the other regarding Sandoz'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.

59. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz 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 '258 Patent

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

61. The '258 patent, entitled "Methods and Compositions for Sleep Disorders and Other Disorders" (attached as Exhibit B), was duly and legally issued on October 27, 2015.

62. The inventors named on the '258 patent are Sharon Mates, Allen Fienberg, and Lawrence P. Wennogle.

63. Plaintiff is the owner and assignee of the '258 patent.

64. CAPLYTA® is covered by one or more claims of the '258 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

65. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz'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 Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '258 patent.

66. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '258 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications

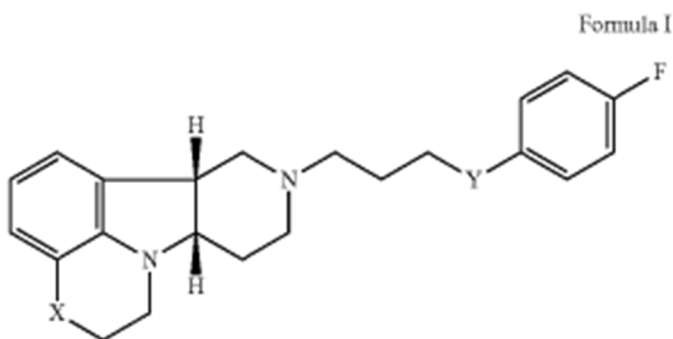
asserting that the '258 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

67. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

68. Upon information and belief, Sandoz's ANDA Product and the use of Sandoz's ANDA Product are covered by one or more claims of the '258 patent, either literally or under the doctrine of equivalents.

69. As an example, claim 1 of the '258 patent recites:

A pharmaceutical composition in oral unit dose form comprising an amount of 10 mg or less of a Compound of Formula I:



wherein X is O, —NH or —N(CH₃); and Y is —O— or —C(O)—, in free or pharmaceutically acceptable salt form, in combination or association with a pharmaceutically acceptable diluent or carrier, provided that in the case of a salt, the weight is calculated as the free base, where the amount of the Compound of Formula I:

- a) is sufficient to block the 5-HT_{2A} receptor; and
- b) either does not block, or minimally blocks the dopamine D₂ receptor.

70. Upon information and belief, Sandoz's ANDA Product contains a pharmaceutical composition in oral unit dose form containing an amount of 10 mg or less (calculated as the free base) of a Formula I compound (lumateperone) in pharmaceutically acceptable salt form in combination or association with a pharmaceutically acceptable diluent or carrier and in an amount that is sufficient to block the 5-HT_{2A} receptor and that does not block, or minimally blocks, the dopamine D2 receptor, as recited in claim 1.

71. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '258 patent, literally or under the doctrine of equivalents.

72. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '258 patent was an act of infringement of the '258 patent under 35 U.S.C. § 271(e)(2)(A).

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

74. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '258 patent.

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

76. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '258 patent when Sandoz's ANDA is approved, and plans and intends to, and

will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '258 patent and specific intent to infringe that patent.

77. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '258 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '258 patent immediately and imminently upon approval of Sandoz's ANDA.

78. Notwithstanding Sandoz's knowledge of the claims of the '258 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '258 patent.

79. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '258 patent; active inducement of infringement of the '258 patent; and/or contribution to the infringement by others of the '258 patent.

80. Upon information and belief, Sandoz has acted with full knowledge of the '258 patent and without a reasonable basis for believing that it would not be liable for infringement of the '258 patent; active inducement of infringement of the '258 patent; and/or contribution to the infringement by others of the '258 patent.

81. Plaintiff will be substantially and irreparably damaged by infringement of the '258 patent.

82. Unless Sandoz is enjoined from infringing the '258 patent, actively inducing infringement of the '258 patent, and contributing to the infringement by others of the '258 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count IV—Declaratory Judgment of Infringement of the '258 Patent

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

84. 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 Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '258 patent, and/or the validity of the '258 patent.

85. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '258 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '258 patent, and that the claims of the '258 patent are not invalid.

Count V—Infringement of the '061 Patent

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

87. The '061 patent, entitled "Methods and Compositions for Sleep Disorders and Other Disorders" (attached as Exhibit C), was duly and legally issued on April 11, 2017.

88. The inventors named on the '061 patent are Sharon Mates, Allen Fienberg, and Lawrence Wennogle.

89. Plaintiff is the owner and assignee of the '061 patent.

90. CAPLYTA® is covered by one or more claims of the '061 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

91. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz'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 Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '061 patent.

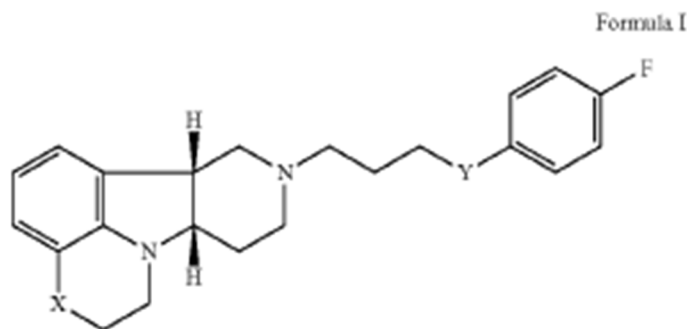
92. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '061 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '061 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

93. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

94. Upon information and belief, Sandoz's ANDA Product and the use of Sandoz's ANDA Product are covered by one or more claims of the '061 patent, either literally or under the doctrine of equivalents.

95. As an example, claim 1 of the '061 patent recites:

A pharmaceutical composition in oral unit dose form comprising an amount of from 0.1-20 mg of a Compound of Formula I:



wherein X is $\text{—N(CH}_3\text{)}$; and Y is —C(O)— , in free or pharmaceutically acceptable salt form, in combination or association with a pharmaceutically acceptable diluent or carrier,

provided that in the case of a salt, the weight is calculated as the free base.

96. Upon information and belief, Sandoz's ANDA Product contains a pharmaceutical composition in oral unit dose form containing an amount of from 0.1-20 mg (calculated as the free base) of a Formula I compound (lumateperone) in pharmaceutically acceptable salt form in combination or association with a pharmaceutically acceptable diluent or carrier, as recited in claim 1.

97. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '061 patent, literally or under the doctrine of equivalents.

98. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '061 patent was an act of infringement of the '061 patent under 35 U.S.C. § 271(e)(2)(A).

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

100. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '061 patent.

101. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '061 patent.

102. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '061 patent when Sandoz's ANDA is approved, and plans and intends to, and

will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '061 patent and specific intent to infringe that patent.

103. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '061 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '061 patent immediately and imminently upon approval of Sandoz's ANDA.

104. Notwithstanding Sandoz's knowledge of the claims of the '061 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '061 patent.

105. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '061 patent; active inducement of infringement of the '061 patent; and/or contribution to the infringement by others of the '061 patent.

106. Upon information and belief, Sandoz has acted with full knowledge of the '061 patent and without a reasonable basis for believing that it would not be liable for infringement of the '061 patent; active inducement of infringement of the '061 patent; and/or contribution to the infringement by others of the '061 patent.

107. Plaintiff will be substantially and irreparably damaged by infringement of the '061 patent.

108. Unless Sandoz is enjoined from infringing the '061 patent, actively inducing infringement of the '061 patent, and contributing to the infringement by others of the '061 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count VI—Declaratory Judgment of Infringement of the '061 Patent

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

110. 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 Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '061 patent, and/or the validity of the '061 patent.

111. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '061 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '061 patent, and that the claims of the '061 patent are not invalid.

Count VII—Infringement of the '867 Patent

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

113. The '867 patent, entitled "Methods and Compositions for Sleep Disorders and Other Disorders" (attached as Exhibit D), was duly and legally issued on November 6, 2018.

114. The inventors named on the '867 patent are Sharon Mates, Allen Fienberg, and Lawrence P. Wennogle.

115. Plaintiff is the owner and assignee of the '867 patent.

116. CAPLYTA® is covered by one or more claims of the '867 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

117. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz'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 Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '867 patent.

118. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '867 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '867 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

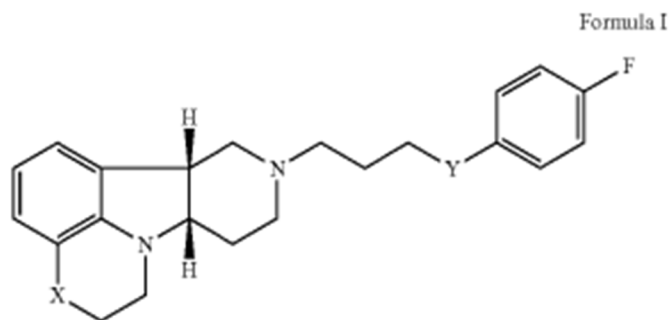
119. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

120. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe one or more claims of the '867 patent.

121. As an example, claim 1 of the '867 patent recites:

A method for the treatment of bipolar depression, comprising administering to a patient in need thereof a Compound of Formula

I:



wherein X is O, —NH or —N(CH₃); and Y is —O— or —C(O)—, in free or pharmaceutically acceptable salt form.

122. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed label would involve treating bipolar depression, including by administering to the patient in need thereof a free or pharmaceutically acceptable salt form of a Formula I compound, as recited in claim 1.

123. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '867 patent, literally or under the doctrine of equivalents.

124. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '867 patent was an act of infringement of the '867 patent under 35 U.S.C. § 271(e)(2)(A).

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

126. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '867 patent.

127. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '867 patent.

128. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '867 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '867 patent and specific intent to infringe that patent.

129. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '867 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '867 patent immediately and imminently upon approval of Sandoz's ANDA.

130. Notwithstanding Sandoz's knowledge of the claims of the '867 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '867 patent.

131. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '867 patent; active inducement of infringement of the '867 patent; and/or contribution to the infringement by others of the '867 patent.

132. Upon information and belief, Sandoz has acted with full knowledge of the '867 patent and without a reasonable basis for believing that it would not be liable for infringement of the '867 patent; active inducement of infringement of the '867 patent; and/or contribution to the infringement by others of the '867 patent.

133. Plaintiff will be substantially and irreparably damaged by infringement of the '867 patent.

134. Unless Sandoz is enjoined from infringing the '867 patent, actively inducing infringement of the '867 patent, and contributing to the infringement by others of the '867 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count VIII—Declaratory Judgment of Infringement of the '867 Patent

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

136. 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 Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '867 patent, and/or the validity of the '867 patent.

137. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '867 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '867 patent, and that the claims of the '867 patent are not invalid.

Count IX—Infringement of the '077 Patent

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

139. 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 E), was duly and legally issued on February 11, 2014.

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

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

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

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

144. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '077 patent. Upon information and belief, Sandoz 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 Sandoz's ANDA Product.

145. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

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

147. 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.

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

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

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

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

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

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

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

155. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '077 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon

information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '077 patent immediately and imminently upon approval of Sandoz's ANDA.

156. Notwithstanding Sandoz's knowledge of the claims of the '077 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '077 patent.

157. The foregoing actions by Sandoz 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.

158. Upon information and belief, Sandoz 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.

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

160. Unless Sandoz 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 X—Declaratory Judgment of Infringement of the '077 Patent

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

162. 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 Sandoz on the other regarding Sandoz's infringement, active inducement of

infringement, contribution to the infringement by others of the '077 patent, and/or the validity of the '077 patent.

163. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz 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 XI—Infringement of the '995 Patent

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

165. The '995 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 F), was duly and legally issued on December 1, 2015.

166. The inventors named on the '995 patent are John Tomesch and Lawrence P. Wennogle.

167. Plaintiff is the owner and assignee of the '995 patent.

168. CAPLYTA® is covered by one or more claims of the '995 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

169. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz'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 Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '995 patent.

170. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '995 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '995 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

171. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

172. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe one or more claims of the '995 patent.

173. As an example, claim 2 of the '995 patent recites:

A method for modulating 5-hydroxytryptamine 2A receptor activity in a patient, comprising administering to a patient in need thereof an effective amount 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 toluene sulfonic acid salt crystal, 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.

174. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed label would involve modulating 5-hydroxytryptamine

2A receptor activity in a patient, including by administering to the patient in need thereof an effective amount of the salt crystal recited in claim 2.

175. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '995 patent, literally or under the doctrine of equivalents.

176. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '995 patent was an act of infringement of the '995 patent under 35 U.S.C. § 271(e)(2)(A).

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

178. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '995 patent.

179. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '995 patent.

180. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '995 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '995 patent and specific intent to infringe that patent.

181. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '995 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's

ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '995 patent immediately and imminently upon approval of Sandoz's ANDA.

182. Notwithstanding Sandoz's knowledge of the claims of the '995 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '995 patent.

183. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '995 patent; active inducement of infringement of the '995 patent; and/or contribution to the infringement by others of the '995 patent.

184. Upon information and belief, Sandoz has acted with full knowledge of the '995 patent and without a reasonable basis for believing that it would not be liable for infringement of the '995 patent; active inducement of infringement of the '995 patent; and/or contribution to the infringement by others of the '995 patent.

185. Plaintiff will be substantially and irreparably damaged by infringement of the '995 patent.

186. Unless Sandoz is enjoined from infringing the '995 patent, actively inducing infringement of the '995 patent, and contributing to the infringement by others of the '995 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count XII—Declaratory Judgment of Infringement of the '995 Patent

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

188. 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 Sandoz on the other regarding Sandoz's infringement, active inducement of

infringement, contribution to the infringement by others of the '995 patent, and/or the validity of the '995 patent.

189. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '995 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '995 patent, and that the claims of the '995 patent are not invalid.

Count XIII—Infringement of the RE '825 Patent

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

191. The RE '825 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 Salt Crystal Forms" (attached as Exhibit G), was duly and legally issued on November 23, 2021.

192. The inventors named on the RE '825 patent are John Tomesch and Lawrence P. Wennogle.

193. Plaintiff is the owner and assignee of the RE '825 patent.

194. CAPLYTA® is covered by one or more claims of the RE '825 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

195. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz'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 Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the RE '825 patent.

196. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the RE '825 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the RE '825 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

197. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

198. Upon information and belief, Sandoz's ANDA Product and the use of Sandoz's ANDA Product are covered by one or more claims of the RE '825 patent, either literally or under the doctrine of equivalents.

199. As an example, claim 1 of the RE '825 patent recites:

A 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 crystal form, wherein said salt crystal form exhibits an X-ray powder diffraction pattern comprising at least two peaks 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°±0.2° 2θ.

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

201. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the RE '825 patent, literally or under the doctrine of equivalents.

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

ANDA Product before the expiration of the RE '825 patent was an act of infringement of the RE '825 patent under 35 U.S.C. § 271(e)(2)(A).

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

204. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the RE '825 patent.

205. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the RE '825 patent.

206. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the RE '825 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the RE '825 patent and specific intent to infringe that patent.

207. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the RE '825 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the RE '825 patent immediately and imminently upon approval of Sandoz's ANDA.

208. Notwithstanding Sandoz's knowledge of the claims of the RE '825 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import

Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the RE '825 patent.

209. The foregoing actions by Sandoz constitute and/or will constitute infringement of the RE '825 patent; active inducement of infringement of the RE '825 patent; and/or contribution to the infringement by others of the RE '825 patent.

210. Upon information and belief, Sandoz has acted with full knowledge of the RE '825 patent and without a reasonable basis for believing that it would not be liable for infringement of the RE '825 patent; active inducement of infringement of the RE '825 patent; and/or contribution to the infringement by others of the RE '825 patent.

211. Plaintiff will be substantially and irreparably damaged by infringement of the RE '825 patent.

212. Unless Sandoz is enjoined from infringing the RE '825 patent, actively inducing infringement of the RE '825 patent, and contributing to the infringement by others of the RE '825 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count XIV—Declaratory Judgment of Infringement of the RE '825 Patent

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

214. 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 Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the RE '825 patent, and/or the validity of the RE '825 patent.

215. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the RE '825 patent, will infringe, induce

infringement of, and contribute to the infringement by others of the RE '825 patent, and that the claims of the RE '825 patent are not invalid.

Count XV—Infringement of the '938 Patent

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

217. The '938 patent, entitled “Pharmaceutical Compositions Comprising ((6bR,10aS)-1-(4-fluorophenyl)-4-(3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3',4':4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)butan-1-one or Pharmaceutically Acceptable Salts Thereof” (attached as Exhibit H), was duly and legally issued on November 5, 2019.

218. The inventors named on the '938 patent are John Charles Tomesch, Peng Li, Wei Yao, Qiang Zhang, James David Beard, Andrew S. Thompson, Hua Cheng, and Lawrence P. Wennogle.

219. Plaintiff is the owner and assignee of the '938 patent.

220. CAPLYTA® is covered by one or more claims of the '938 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

221. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz'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 Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '938 patent.

222. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '938 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '938 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

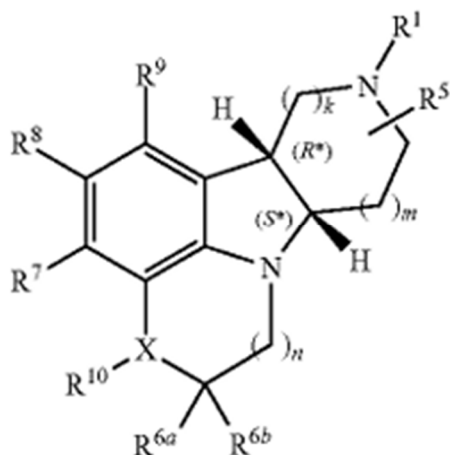
223. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

224. Upon information and belief, Sandoz's ANDA Product and the use of Sandoz's ANDA Product are covered by one or more claims of the '938 patent, either literally or under the doctrine of equivalents.

225. As an example, claim 1 of the '938 patent recites:

A pharmaceutical composition comprising toluenesulfonic acid and the compound of Formula 2J:

Formula 2J



or a pharmaceutically acceptable salt thereof,

wherein:

k is 1;

m is 1;

n is 1;

R¹ is 4-(4-fluorophenyl)-4-oxobutyl;

R⁵ is H;

R^{6a} and R^{6b} are independently H;

R^7 , R^8 and R^9 are independently H;

R^{10} is CH_3 ; and

X is —N—.

226. Upon information and belief, Sandoz's ANDA Product is a pharmaceutical composition comprising toluenesulfonic acid and the Formula 2J compound recited in claim 1.

227. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '938 patent, literally or under the doctrine of equivalents.

228. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '938 patent was an act of infringement of the '938 patent under 35 U.S.C. § 271(e)(2)(A).

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

230. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '938 patent.

231. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '938 patent.

232. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '938 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '938 patent and specific intent to infringe that patent.

233. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '938 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '938 patent immediately and imminently upon approval of Sandoz's ANDA.

234. Notwithstanding Sandoz's knowledge of the claims of the '938 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '938 patent.

235. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '938 patent; active inducement of infringement of the '938 patent; and/or contribution to the infringement by others of the '938 patent.

236. Upon information and belief, Sandoz has acted with full knowledge of the '938 patent and without a reasonable basis for believing that it would not be liable for infringement of the '938 patent; active inducement of infringement of the '938 patent; and/or contribution to the infringement by others of the '938 patent.

237. Plaintiff will be substantially and irreparably damaged by infringement of the '938 patent.

238. Unless Sandoz is enjoined from infringing the '938 patent, actively inducing infringement of the '938 patent, and contributing to the infringement by others of the '938 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count XVI—Declaratory Judgment of Infringement of the '938 Patent

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

240. 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 Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '938 patent, and/or the validity of the '938 patent.

241. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '938 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '938 patent, and that the claims of the '938 patent are not invalid.

Count XVII—Infringement of the '227 Patent

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

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

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

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

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

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

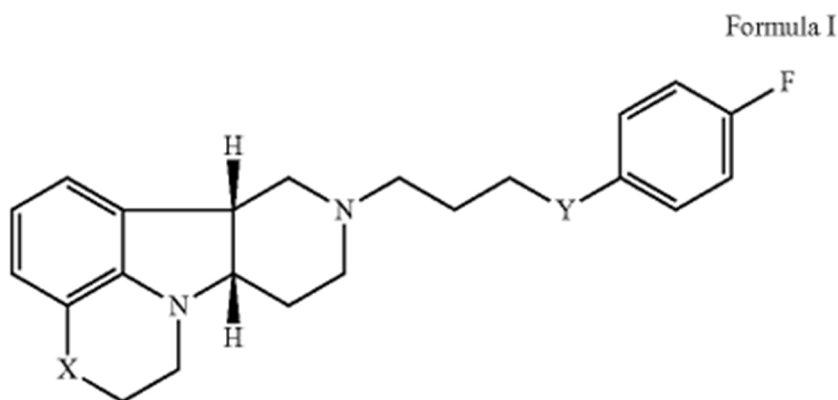
248. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '227 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '227 patent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

249. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

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

251. 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:



wherein:

X is —O—, —NH— or —N(CH₃)—;

Y is —O—, —C(R₂)(OH)—, —C(R₃)(OR₁) or —C(O)—; and

R₁ is —C₁₋₆ alkyl or —C(O)—C₁₋₂₁ alkyl, optionally saturated or unsaturated and optionally substituted with one or more hydroxyl or C₁₋₂₂ alkoxy groups wherein such compound hydrolyzes to form the residue of a natural or unnatural, saturated or unsaturated fatty acid;

R₂ is H or —C₁₋₆ alkyl; and

R₃ is H or —C₁₋₆ alkyl;

in free or pharmaceutically acceptable salt form;

wherein the patient significantly improves on the Prosocial PANSS

Factor change from baseline.

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

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

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

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

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

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

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

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

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

261. The foregoing actions by Sandoz 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.

262. Upon information and belief, Sandoz 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.

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

264. Unless Sandoz 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 XVIII—Declaratory Judgment of Infringement of the '227 Patent

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

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

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

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

269. The '009 patent, entitled “Methods of Treating Schizophrenia and Depression” (attached as Exhibit J), was duly and legally issued on March 30, 2021.

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

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

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

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

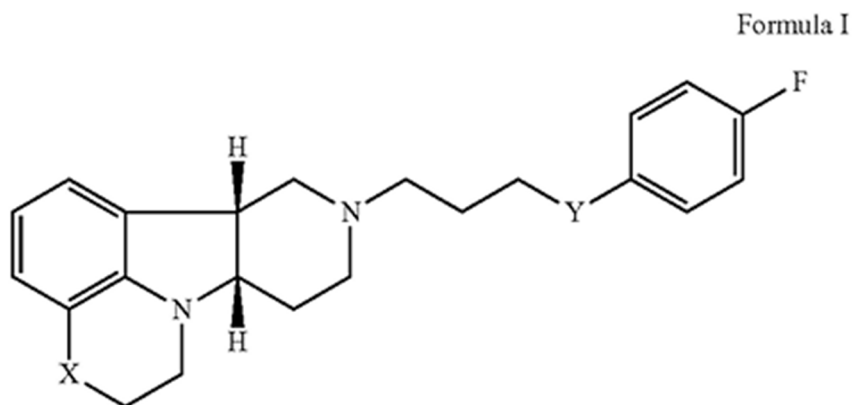
274. In Sandoz’s Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '009 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '009 patent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

275. According to Sandoz’s Notice Letter, Sandoz’s ANDA Product contains lumateperone.

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

277. 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:



wherein:

X is —N(CH₃)— 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.

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

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

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

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

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

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

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

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

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

287. The foregoing actions by Sandoz 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.

288. Upon information and belief, Sandoz 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.

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

290. Unless Sandoz 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 XX—Declaratory Judgment of Infringement of the '009 Patent

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

292. 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 Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '009 patent, and/or the validity of the '009 patent.

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

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

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

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

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

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

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

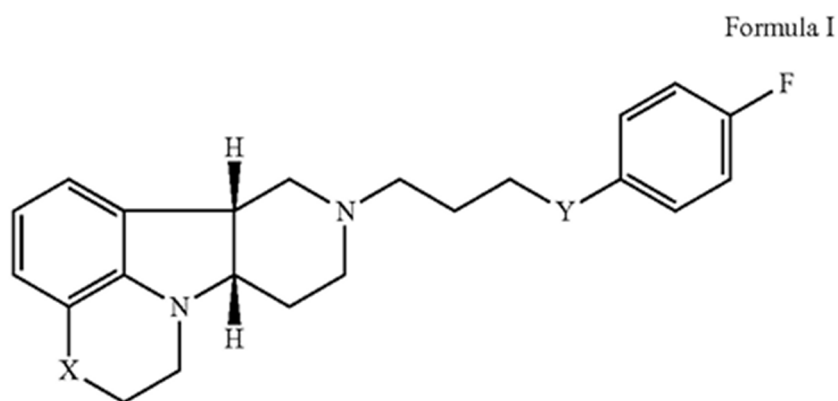
300. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '951 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '951 patent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

301. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

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

303. 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:



wherein:

X is $\text{—N(CH}_3\text{)—}$ and Y is —C(O)— ;

in free or pharmaceutically acceptable salt form, wherein said

Compound is not used in combination with another antipsychotic agent.

304. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed label would involve treating bipolar disorder I and/or bipolar II disorder, including by administering to the patient in need thereof an effective amount

of a Formula I compound in free or pharmaceutically acceptable salt form and not in combination with another antipsychotic agent, as recited in claim 1.

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

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

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

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

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

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

311. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '951 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's

ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '951 patent immediately and imminently upon approval of Sandoz's ANDA.

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

313. The foregoing actions by Sandoz 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.

314. Upon information and belief, Sandoz 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.

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

316. Unless Sandoz 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 XXII—Declaratory Judgment of Infringement of the '951 Patent

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

318. 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 Sandoz on the other regarding Sandoz's infringement, active inducement of

infringement, contribution to the infringement by others of the '951 patent, and/or the validity of the '951 patent.

319. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz 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 XXIII—Infringement of the '345 Patent

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

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

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

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

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

325. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz'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 Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '345 patent.

326. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '345 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications

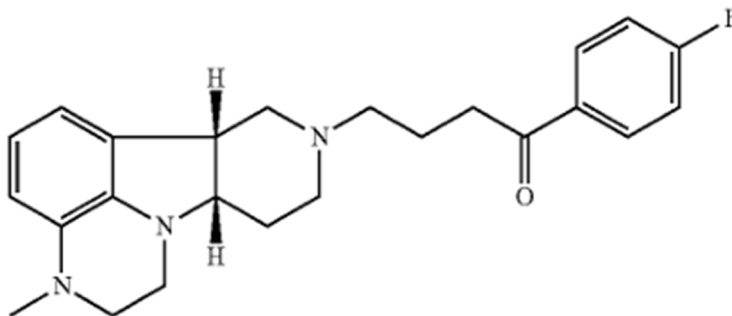
asserting that the '345 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

327. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

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

329. 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.

330. Upon information and belief, Sandoz'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.

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

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

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

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

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

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

337. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '345 patent, that

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

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

339. The foregoing actions by Sandoz 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.

340. Upon information and belief, Sandoz 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.

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

342. Unless Sandoz 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 XXIV—Declaratory Judgment of Infringement of the '345 Patent

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

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

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

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

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

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

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

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

351. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz'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 Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '084 patent.

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

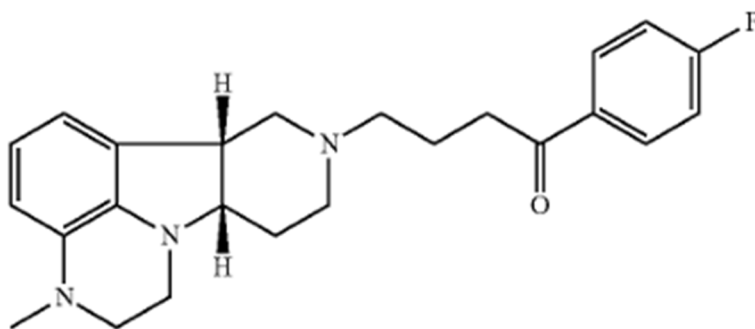
and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '084 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

353. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

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

355. 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.

356. Upon information and belief, Sandoz'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.

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

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

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

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

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

362. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '084 patent when Sandoz's ANDA is approved, and plans and intends to, and

will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '084 patent and specific intent to infringe that patent.

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

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

365. The foregoing actions by Sandoz 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.

366. Upon information and belief, Sandoz 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.

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

368. Unless Sandoz 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 XXVI—Declaratory Judgment of Infringement of the '084 Patent

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

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

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

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

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

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

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

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

377. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz'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 Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '842 patent.

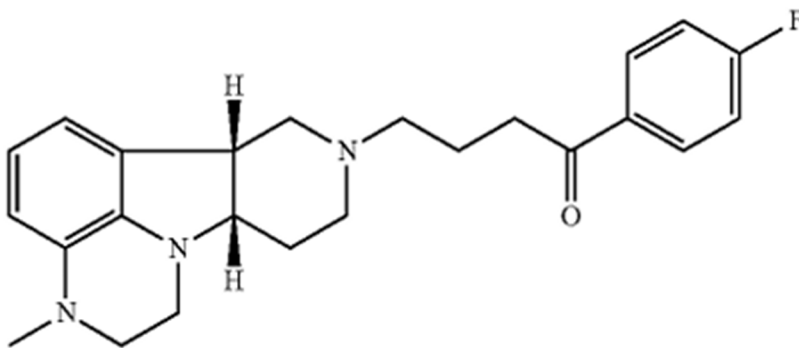
378. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '842 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '842 patent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

379. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

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

381. 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.

382. Upon information and belief, Sandoz'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.

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

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

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

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

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

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

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

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

391. The foregoing actions by Sandoz 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.

392. Upon information and belief, Sandoz 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.

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

394. Unless Sandoz 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 XXVIII—Declaratory Judgment of Infringement of the '842 Patent

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

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

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

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

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

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

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

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

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

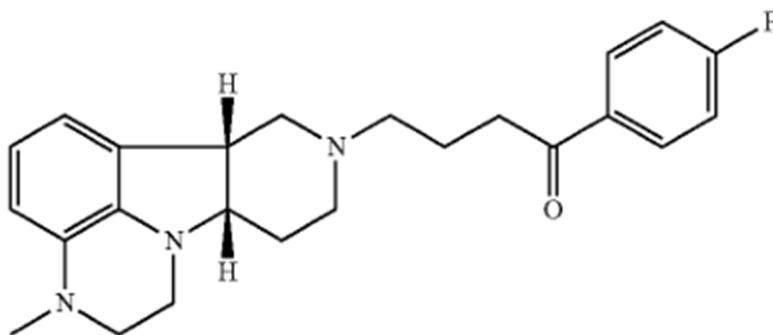
404. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '348 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '348 patent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

405. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

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

407. 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.

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

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

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

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

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

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

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

415. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '348 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '348 patent immediately and imminently upon approval of Sandoz's ANDA.

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

417. The foregoing actions by Sandoz 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.

418. Upon information and belief, Sandoz 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.

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

420. Unless Sandoz 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 XXX—Declaratory Judgment of Infringement of the '348 Patent

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

422. 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 Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '348 patent, and/or the validity of the '348 patent.

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

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

425. The '419 patent, entitled "4-((6b,10a)-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-((6b,10a)-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 P), was duly and legally issued on September 12, 2023.

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

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

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

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

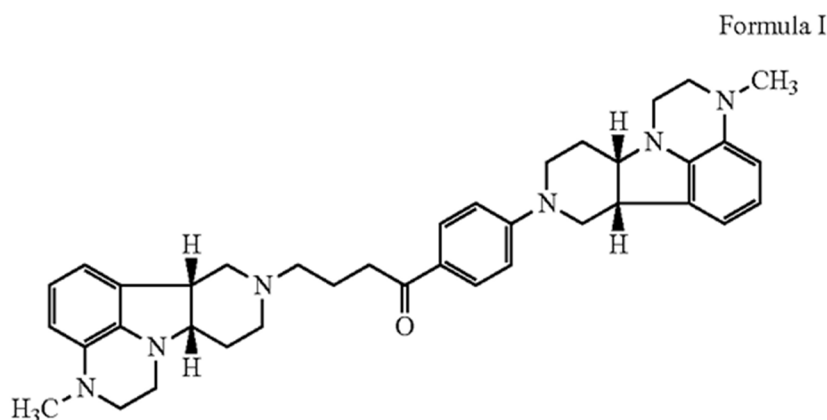
430. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '419 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '419 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

431. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

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

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

A compound of Formula I:



in free base or pharmaceutically acceptable salt form.

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

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

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

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

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

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

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

441. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '419 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon

information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '419 patent immediately and imminently upon approval of Sandoz's ANDA.

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

443. The foregoing actions by Sandoz 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.

444. Upon information and belief, Sandoz 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.

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

446. Unless Sandoz 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 XXXII—Declaratory Judgment of Infringement of the '419 Patent

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

448. 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 Sandoz on the other regarding Sandoz's infringement, active inducement of

infringement, contribution to the infringement by others of the '419 patent, and/or the validity of the '419 patent.

449. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz 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 Sandoz's submission to the FDA of Sandoz's ANDA;
- (b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Sandoz'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 Sandoz, and all persons acting in concert with Sandoz, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz'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 Sandoz'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

Liza M. Walsh

Katelyn O'Reilly

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
- *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; and
- *Intra-Cellular Therapies, Inc. v. MSN Laboratories Private Ltd.*, Civil Action No. 24-4325.

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

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