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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.

Alkem Laboratories Ltd.,

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 Alkem Laboratories Ltd. (“Alkem”) 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 Alkem’s submission of an Abbreviated New Drug Application (“ANDA”) to the U.S. Food and Drug Administration (“FDA”) seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of CAPLYTA® (lumateperone) capsules, 10.5 mg, 21 mg, and 42 mg, prior to the expiration of U.S. Patent Nos. 9,956,227 (“the ’227 patent”), 10,695,345 (“the ’345 patent”), 10,960,009 (“the ’009 patent”), 11,026,951 (“the ’951 patent”), 11,052,084 (“the ’084 patent”), 11,690,842 (“the ’842 patent”), 11,753,419 (“the ’419 patent”), 11,806,348 (“the ’348 patent”), and RE48,839 (“the RE ’839 patent”). These patents are referred to collectively herein as the “Patents-in-Suit.”

2. Alkem notified Plaintiff by letter dated February 16, 2024 (“Alkem’s Notice Letter”) that it had submitted to the FDA ANDA No. 219200 (“Alkem’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, (“Alkem’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 Alkem Laboratories Ltd. is a corporation organized and existing under the laws of the Republic of India and having a principal place of business at Alkem House, Senapati Bapat Marg Lower Parel, Mumbai, Maharashtra, India, 400013.

6. Upon information and belief, Alkem 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, Alkem knows and intends that upon approval of Alkem’s ANDA, Alkem will manufacture Alkem’s ANDA Product and Alkem will directly or indirectly market, sell, and distribute Alkem’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 Alkem.

10. Upon information and belief, Alkem 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 Alkem derives a substantial portion of its revenue.

11. Upon information and belief, Alkem, 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 Alkem's ANDA; continues to engage in seeking FDA approval of Alkem's ANDA; intends to engage in the commercial manufacture, marketing, offer for sale, sale, or importation of Alkem's ANDA Product throughout the United States, including in New Jersey; and stands to benefit from the approval of Alkem's ANDA.

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

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

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

manufactured by Alkem and/or for which Alkem is the named applicant on approved ANDAs. Upon information and belief, various products for which Alkem is the named applicant on approved ANDAs are available at retail pharmacies in New Jersey.

15. Alkem 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, Alkem 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.

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

17. This Court also has personal jurisdiction over Alkem because Alkem 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 Alkem's actions were, and will be, suffered in New Jersey. Alkem knew or should have known that the consequences of its actions were, and will be, suffered in New Jersey. At the time Alkem sent notice of the certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), it was reasonably foreseeable that Alkem would be sued within 45 days in New Jersey. Upon information and belief, Alkem'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.

18. Alkem is also subject to personal jurisdiction in New Jersey because it (1) engages in patent litigation concerning Alkem'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., Janssen Pharms., Inc. v. Alkem Lab'ys Ltd.*, No. 23-cv-02939, ECF No. 11 (D.N.J. July 20, 2023); *Jazz Pharms. Rsch. UK Ltd. v. Teva Pharms., Inc.*, No. 23-cv-00018, ECF No. 118 (D.N.J. Apr. 5, 2023).

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

Venue

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

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

Factual Background

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

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

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

25. In Alkem's Notice Letter, Alkem stated that it had submitted Paragraph IV certifications to the FDA alleging that the '345 patent, '951 patent, '084 patent, '842 patent, '419 patent, '348 patent, and RE '839 patent are invalid, unenforceable, and/or not infringed, and that Alkem is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Alkem's ANDA Product prior to the expiration of those patents.

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

27. Upon information and belief, Alkem's ANDA Product is not publicly available, nor is ANDA No. 219200 accessible to the public.

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

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

30. Nor could Plaintiff ascertain whether Alkem had filed Paragraph III certifications as to the Patents-in-Suit for which Alkem did not state that it had submitted Paragraph IV certifications (the '227 patent and '009 patent), or whether it instead provided a statement to the FDA regarding the '227 patent and '009 patent pursuant to 21 U.S.C. § 355(j)(2)(A)(viii).

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

Count I—Infringement of the RE '839 Patent

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

33. 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.

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

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

36. 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").

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

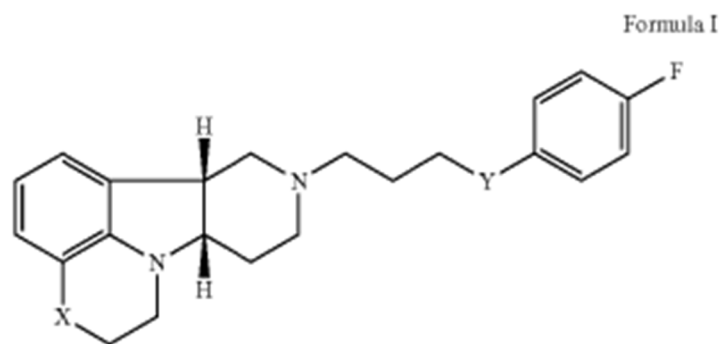
38. In Alkem's Notice Letter, Alkem also notified Plaintiff that, as part of its ANDA, Alkem had filed Paragraph IV certifications with respect to the RE '839 patent. Upon information and belief, Alkem submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the RE '839 patent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

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

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

41. 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.

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

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

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

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

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

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

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

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

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

51. The foregoing actions by Alkem 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.

52. Upon information and belief, Alkem 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.

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

54. Unless Alkem 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

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

56. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Alkem on the other regarding Alkem'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.

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

Count III—Infringement of the '227 Patent

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

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

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

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

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

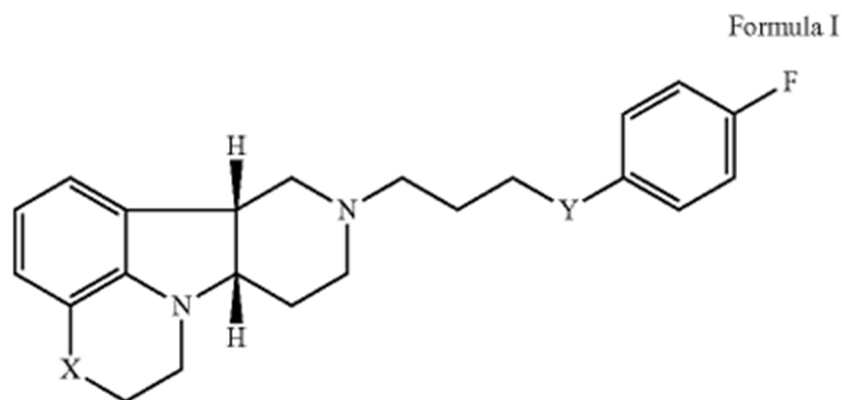
63. In Alkem's Notice Letter, Alkem notified Plaintiff of the submission of Alkem's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's ANDA Product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

64. According to Alkem's Notice Letter, Alkem's ANDA Product contains lumateperone.

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

66. 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.

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

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

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

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

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

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

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

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

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

76. The foregoing actions by Alkem 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.

77. Upon information and belief, Alkem 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.

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

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

Count IV—Declaratory Judgment of Infringement of the '227 Patent

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

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

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

Count V—Infringement of the '009 Patent

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

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

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

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

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

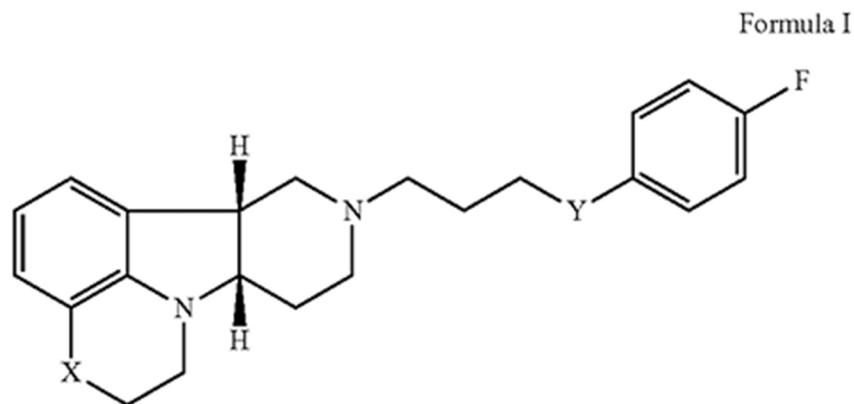
88. In Alkem’s Notice Letter, Alkem notified Plaintiff of the submission of Alkem’s ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem’s ANDA Product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

89. According to Alkem’s Notice Letter, Alkem’s ANDA Product contains lumateperone.

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

91. 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.

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

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

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

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

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

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

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

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

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

101. The foregoing actions by Alkem 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.

102. Upon information and belief, Alkem 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.

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

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

Count VI—Declaratory Judgment of Infringement of the '009 Patent

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

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

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

Count VII—Infringement of the '951 Patent

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

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

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

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

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

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

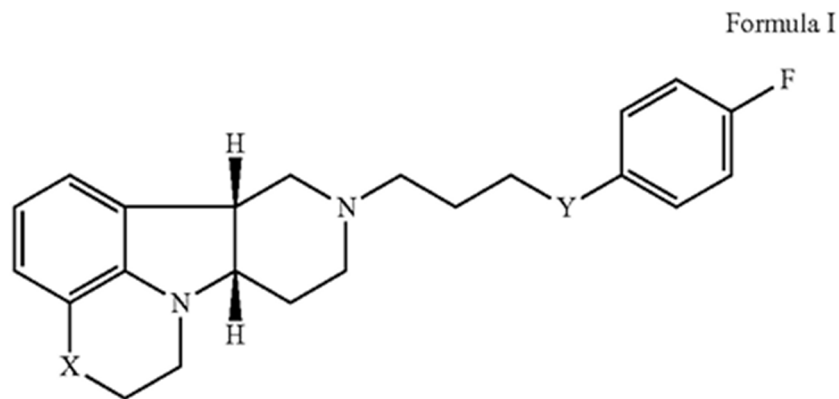
114. In Alkem’s Notice Letter, Alkem also notified Plaintiff that, as part of its ANDA, Alkem had filed Paragraph IV certifications with respect to the '951 patent. Upon information and belief, Alkem submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '951 patent is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

115. According to Alkem’s Notice Letter, Alkem’s ANDA Product contains lumateperone.

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

117. 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 —N(CH₃)— and Y is —C(O)—;

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

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

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

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

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

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

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

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

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

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

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

127. The foregoing actions by Alkem 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.

128. Upon information and belief, Alkem 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.

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

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

Count VIII—Declaratory Judgment of Infringement of the '951 Patent

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

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

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

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

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

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

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

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

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

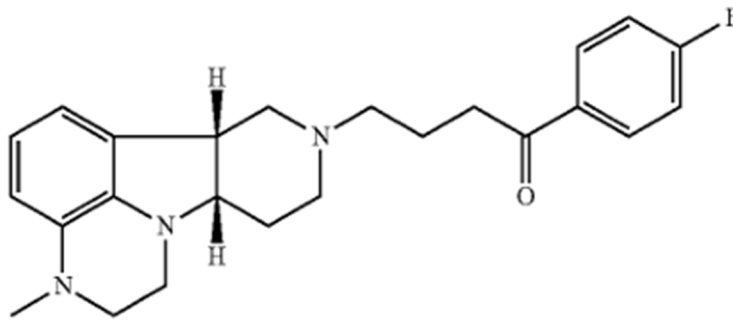
140. In Alkem's Notice Letter, Alkem also notified Plaintiff that, as part of its ANDA, Alkem had filed Paragraph IV certifications with respect to the '345 patent. Upon information and belief, Alkem submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '345 patent is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

141. According to Alkem's Notice Letter, Alkem's ANDA Product contains lumateperone.

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

143. 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.

144. Upon information and belief, Alkem'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.

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

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

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

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

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

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

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

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

153. The foregoing actions by Alkem 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.

154. Upon information and belief, Alkem 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.

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

156. Unless Alkem 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 X—Declaratory Judgment of Infringement of the '345 Patent

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

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

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

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

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

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

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

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

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

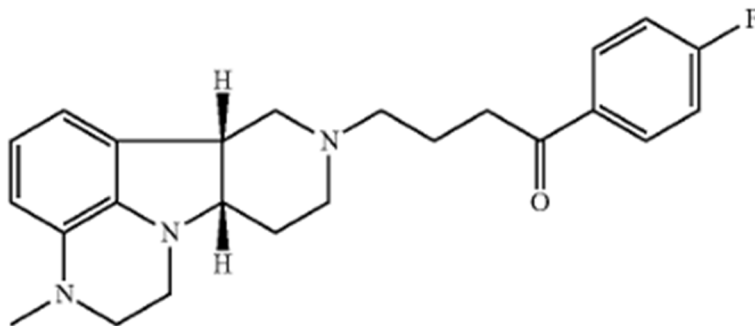
166. In Alkem's Notice Letter, Alkem also notified Plaintiff that, as part of its ANDA, Alkem had filed Paragraph IV certifications with respect to the '084 patent. Upon information and belief, Alkem submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '084 patent is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

167. According to Alkem's Notice Letter, Alkem's ANDA Product contains lumateperone.

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

169. 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.

170. Upon information and belief, Alkem'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.

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

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

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

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

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

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

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

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

179. The foregoing actions by Alkem 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.

180. Upon information and belief, Alkem 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.

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

182. Unless Alkem 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 XII—Declaratory Judgment of Infringement of the '084 Patent

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

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

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

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

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

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

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

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

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

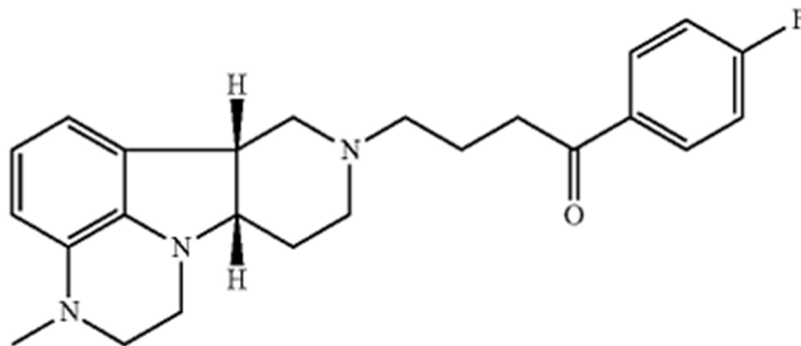
192. In Alkem's Notice Letter, Alkem also notified Plaintiff that, as part of its ANDA, Alkem had filed Paragraph IV certifications with respect to the '842 patent. Upon information and belief, Alkem submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '842 patent is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

193. According to Alkem's Notice Letter, Alkem's ANDA Product contains lumateperone.

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

195. 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.

196. Upon information and belief, Alkem'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.

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

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

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

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

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

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

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

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

205. The foregoing actions by Alkem 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.

206. Upon information and belief, Alkem 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.

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

208. Unless Alkem 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 XIV—Declaratory Judgment of Infringement of the '842 Patent

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

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

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

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

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

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

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

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

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

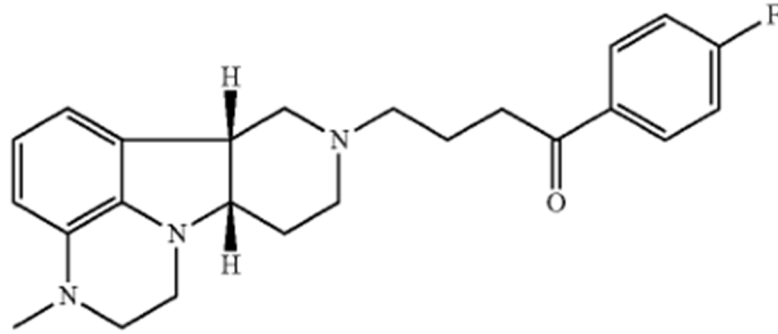
218. In Alkem's Notice Letter, Alkem also notified Plaintiff that, as part of its ANDA, Alkem had filed Paragraph IV certifications with respect to the '348 patent. Upon information and belief, Alkem submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '348 patent is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

219. According to Alkem's Notice Letter, Alkem's ANDA Product contains lumateperone.

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

221. 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.

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

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

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

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

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

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

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

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

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

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

231. The foregoing actions by Alkem 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.

232. Upon information and belief, Alkem 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.

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

234. Unless Alkem 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 XVI—Declaratory Judgment of Infringement of the '348 Patent

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

236. 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 Alkem on the other regarding Alkem's infringement, active inducement of

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

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

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

239. The '419 patent, entitled "4-(((6r,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-(((6r,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 I), was duly and legally issued on September 12, 2023.

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

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

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

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

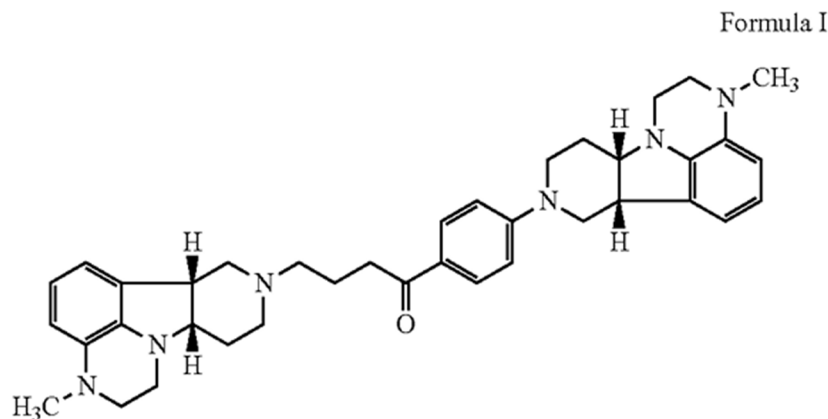
244. In Alkem's Notice Letter, Alkem also notified Plaintiff that, as part of its ANDA, Alkem had filed Paragraph IV certifications with respect to the '419 patent. Upon information and belief, Alkem submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '419 patent is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

245. According to Alkem's Notice Letter, Alkem's ANDA Product contains lumateperone.

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

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

A compound of Formula I:



in free base or pharmaceutically acceptable salt form.

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

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

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

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

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

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

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

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

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

257. The foregoing actions by Alkem 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.

258. Upon information and belief, Alkem 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.

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

260. Unless Alkem 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 XVIII—Declaratory Judgment of Infringement of the '419 Patent

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

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

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

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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).

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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