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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") 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. 12,090,155 (the "'155 patent"), 12,122,792 (the "'792 patent"), and 12,128,043 (the "'043 patent") (collectively, 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 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").

3. On March 28, 2024, Plaintiff sued Sandoz in this district for infringement of the patents identified in Sandoz's Notice Letter. *See* Civil Action No. 3:24-cv-04327-MAS-JBD, ECF No. 1. That case is currently pending and has been consolidated with Civil Action No. 3:24-cv-04264. ECF No. 22.

4. On August 29, 2024, Plaintiff sued Sandoz in this district for infringement of U.S. Patent Nos. 11,980,617 ("the '617 patent") and 12,070,459 ("the '459 patent"). *See* Civil Action No. 3:24-cv-08855-MAS-JBD, ECF No. 1. That case is currently pending and has been consolidated with Civil Action No. 3:24-cv-04264. ECF No. 65.

The Parties

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

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

7. 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.

8. 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

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

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

11. 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.

12. 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.

13. 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.

14. 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.

15. 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) ("Paragraph IV certifications").

16. 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.

17. 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.

18. 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.

19. 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.

20. 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. It was reasonably foreseeable that Sandoz would be sued 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.

21. 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.*, *Intra-Cellular Therapies, Inc. v. Sandoz Inc.*, No. 3-24-cv-04327, ECF No. 10 (D.N.J. June 10, 2024); *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).

22. 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

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

24. 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.

25. 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.

26. 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.*, *Intra-Cellular Therapies, Inc. v. Sandoz Inc.*, No. 3-24-cv-04327, ECF No. 10 (D.N.J. June 10, 2024); *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

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

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

29. In 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®.

30. In Sandoz's Notice Letter, Sandoz stated that it had submitted Paragraph IV certifications to the FDA alleging that the '077 patent, '258 patent, '995 patent, '061 patent, '227 patent, '867 patent, '938 patent, '345 patent, '009 patent, '951 patent, '084 patent, '842 patent, '419 patent, '348 patent, RE '825 patent, and RE '839 patent 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 those patents.

31. The purpose of Sandoz's submission of Sandoz's ANDA was to obtain, *inter alia*, approval under the Federal Food, Drug, and Cosmetic Act (the "FDCA") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the '077 patent, '258 patent, '995 patent, '061 patent, '227 patent, '867 patent, '938 patent, '345 patent, '009 patent, '951 patent, '084 patent, '842 patent, '419 patent, '348 patent, RE '825 patent, and RE '839 patent. On information and belief, Sandoz intends to seek 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.

Count I—Infringement of the '155 Patent

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

33. The '155 patent, entitled "Methods" (attached as Exhibit A), was duly and legally issued on September 17, 2024.

34. The inventors named on the '155 patent are Sharon Mates, Robert Davis and Kimberly Vanover.

35. Plaintiff is the owner and assignee of the '155 patent.

36. CAPLYTA® is covered by one or more claims of the '155 patent, which is 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 Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was 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 '077 patent, '258 patent, '995 patent, '061 patent, '227 patent, '867 patent, '938 patent, '345

patent, ’009 patent, ’951 patent, ’084 patent, ’842 patent, ’419 patent, ’348 patent, RE ’825 patent, and RE ’839 patent. On information and belief, Sandoz intends to seek 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 ’155 patent.

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

39. 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 ’155 patent.

40. As an example, claim 1 of the ’155 patent recites:

> A method for the treatment of a major depressive episode associated with Bipolar II Disorder, comprising administering to a patient in need thereof, a therapeutically effective amount of lumateperone in mono-tosylate salt form, wherein the method comprises once daily administration of a tablet or capsule comprising about 60 mg of lumateperone mono-tosylate in combination or association with a pharmaceutically acceptable diluent or carrier.

41. As a further example, claim 22 of the ’155 patent recites:

> A method for the treatment of a depressive episode associated with Bipolar II Disorder, comprising administering to a patient in need thereof, a therapeutically effective amount of lumateperone in mono-tosylate salt form, wherein the method comprises once daily administration of a tablet or capsule comprising about 60 mg of lumateperone monotosylate in

combination or association with a pharmaceutically acceptable diluent or carrier.

42. 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 major depressive episode associated with Bipolar II Disorder, including by administering to a patient in need thereof a capsule comprising a therapeutically effective amount and about 60 mg of lumateperone mono-tosylate in combination or association with a pharmaceutically acceptable diluent or carrier, as recited in claim 1.

43. 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 depressive episode associated with Bipolar II Disorder, including by administering to a patient in need thereof a capsule comprising about a therapeutically effective amount and 60 mg of lumateperone mono-tosylate in combination or association with a pharmaceutically acceptable diluent or carrier, as recited in claim 22.

44. 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 '155 patent, literally or under the doctrine of equivalents.

45. 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 '155 patent was an act of infringement of the '155 patent under 35 U.S.C. § 271(e)(2)(A).

46. 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.

47. 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 '155 patent.

48. 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 '155 patent.

49. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '155 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 '155 patent and specific intent to infringe that patent.

50. 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 '155 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 '155 patent immediately and imminently upon approval of Sandoz's ANDA.

51. Notwithstanding Sandoz's knowledge of the claims of the '155 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 '155 patent.

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

53. Upon information and belief, Sandoz has acted with full knowledge of the '155 patent and without a reasonable basis for believing that it would not be liable for infringement of the '155 patent; active inducement of infringement of the '155 patent; and/or contribution to the infringement by others of the '155 patent.

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

55. Unless Sandoz is enjoined from infringing the '155 patent, actively inducing infringement of the '155 patent, and contributing to the infringement by others of the '155 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count II—Declaratory Judgment of Infringement of the '155 Patent

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

57. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '155 patent, and/or the validity of the '155 patent.

58. 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 '155 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '155 patent, and that the claims of the '155 patent are not invalid.

Count III—Infringement of the '792 Patent

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

60. The ’792 patent, entitled “Pharmaceutical Compositions Comprising 4-((6bR,10aS)-3-methyl2,3,6b,9,10,10a-hexahydro-1H-pyrido[3',4':4,5]pyrrolo[1,2,3-de]quinoxalin8(7H)-yl)-1-(4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3',4':4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)phenyl)butan-1-one for Treating Conditions of the Central Nervous System and Cardiac Disorders” (attached as Exhibit B), was duly and legally issued on October 22, 2024.

61. The inventors named on the ’792 patent are Peng Li, Robert Davis, and Kimberly Vanover.

62. Plaintiff is the owner and assignee of the ’792 patent.

63. CAPLYTA® is covered by one or more claims of the ’792 patent, which will be listed in connection with CAPLYTA® in the Orange Book.

64. 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 engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product prior to the expiration of the ’077 patent, ’258 patent, ’995 patent, ’061 patent, ’227 patent, ’867 patent, ’938 patent, ’345 patent, ’009 patent, ’951 patent, ’084 patent, ’842 patent, ’419 patent, ’348 patent, RE ’825 patent, and RE ’839 patent. On information and belief, Sandoz intends to seek 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 ’792 patent.

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

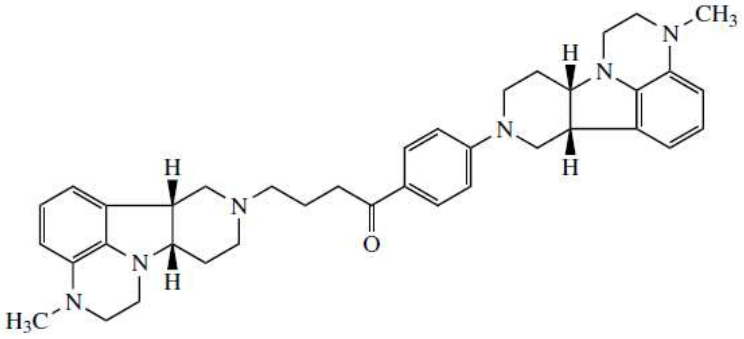
66. Upon information and belief, the use of Sandoz’s ANDA Product in accordance with and as directed by Sandoz’s proposed labeling for that product would infringe one or more claims of the ’792 patent.

67. As an example, claim 1 of the '792 patent recites:

A pharmaceutical composition comprising a pharmaceutically acceptable diluent or carrier in admixture with:

(i) a compound of Formula I:

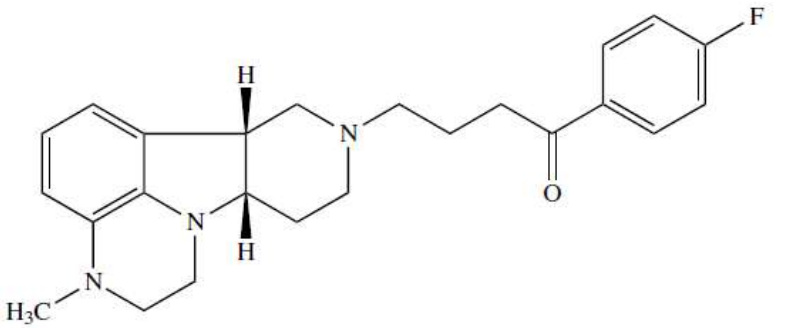
Formula I



in free base or pharmaceutically acceptable salt form; and

(ii) a compound of Formula II:

Formula II



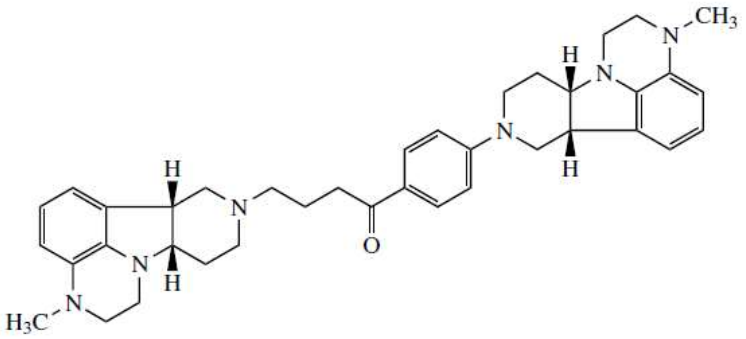
in free base or pharmaceutically acceptable salt form.

68. As an example, claim 29 of the '792 patent recites:

A pharmaceutical composition comprising:

1) a compound of Formula I:

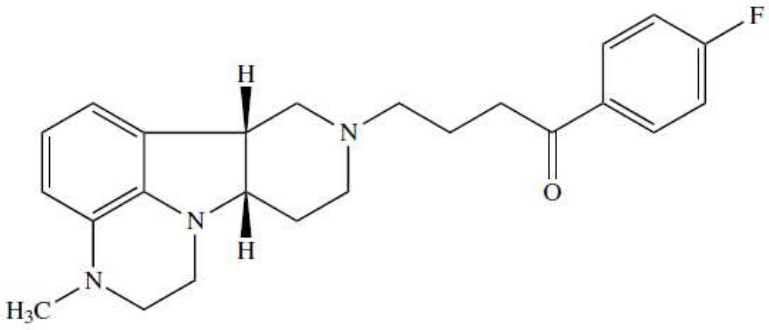
Formula I



in free base or pharmaceutically acceptable salt form; and

(ii) a compound of Formula II:

Formula II



in toluenesulfonic acid addition salt form;

wherein the pharmaceutical composition comprises the compound of Formula I and the compound of Formula II in a weight ratio in the range of from 1:200 to 1:2000.

69. Upon information and belief, Sandoz's ANDA Product is a pharmaceutical composition comprising a pharmaceutically acceptable diluent or carrier in admixture with a compound of Formula I in free base or pharmaceutically acceptable salt form and a compound of Formula II in free base or pharmaceutically acceptable salt form, as recited in claim 1.

70. Upon information and belief, Sandoz's ANDA Product is a pharmaceutical composition comprising a compound of Formula I in free base or pharmaceutically acceptable salt

form and a compound of Formula II in toluenesulfonic acid addition salt form in a weight ratio between 1:200 to 1:2000, as recited in claim 29.

71. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '792 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 '792 patent was an act of infringement of the '792 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 '792 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 '792 patent.

76. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '792 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 '792 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 '792 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 '792 patent immediately and imminently upon approval of Sandoz's ANDA.

78. Notwithstanding Sandoz's knowledge of the claims of the '792 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 '792 patent.

79. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '792 patent; active inducement of infringement of the '792 patent; and/or contribution to the infringement by others of the '792 patent.

80. Upon information and belief, Sandoz has acted with full knowledge of the '792 patent and without a reasonable basis for believing that it would not be liable for infringement of the '792 patent; active inducement of infringement of the '792 patent; and/or contribution to the infringement by others of the '792 patent.

81. Plaintiff will be substantially and irreparably damaged by infringement of the '792 patent.

82. Unless Sandoz is enjoined from infringing the '792 patent, actively inducing infringement of the '792 patent, and contributing to the infringement by others of the '792 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count IV—Declaratory Judgment of Infringement of the '792 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 '792 patent, and/or the validity of the '792 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 '792 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '792 patent, and that the claims of the '792 patent are not invalid.

Count V—Infringement of the '043 Patent

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

87. The '043 patent, entitled "Pharmaceutical Capsules Comprising Lumateperone Mono-Tosylate" (attached as Exhibit C), was duly and legally issued on October 29, 2024.

88. The inventors named on the '043 patent are Robert Davis and Peng Li.

89. Plaintiff is the owner and assignee of the '043 patent.

90. CAPLYTA® is covered by one or more claims of the '043 patent, which will be listed in connection with CAPLYTA® in the Orange Book.

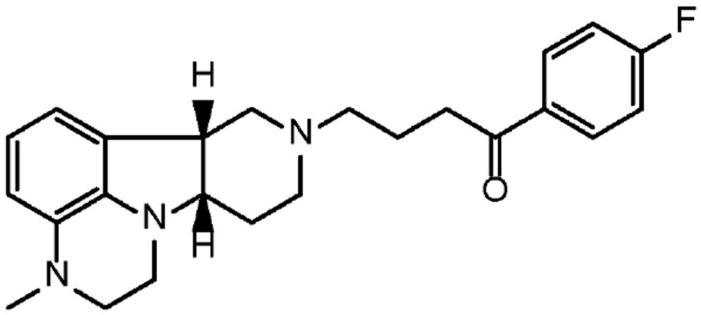
91. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the '077 patent, '258 patent, '995 patent, '061 patent, '227 patent, '867 patent, '938 patent, '345 patent, '009 patent, '951 patent, '084 patent, '842 patent, '419 patent, '348 patent, RE '825 patent, and RE '839 patent. On information and belief, Sandoz intends to seek 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 '043 patent.

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

93. 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 '043 patent.

94. As an example, claim 1 of the '043 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; wherein the capsule comprises the lumateperone mono-tosylate in an amount equivalent to 35 to 45 mg lumateperone free base, and wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, and one or more pharmaceutically acceptable diluents or carriers, wherein the one or more pharmaceutically acceptable diluents or carriers comprises one or more of (a) diluent/filler, (b) binder, (c) disintegrant, (d) lubricant, or (e) glidant, and wherein
>
> a single pharmaceutical capsule dissolves in 500 mL of 0. lN 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.

95. 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 one or more of the specific diluents or carriers in the specific amounts recited in claim 1. Upon information and belief, a single capsule of Sandoz's ANDA Product dissolves in 500 mL of 0. lN aqueous hydrochloric acid according to one or more of the parameters recited in claim 1.

96. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '043 patent, literally or under the doctrine of equivalents.

97. 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 '043 patent was an act of infringement of the '043 patent under 35 U.S.C. § 271(e)(2)(A).

98. 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.

99. 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 '043 patent.

100. 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 '043 patent.

101. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '043 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 '043 patent and specific intent to infringe that patent.

102. 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 '043 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 '043 patent immediately and imminently upon approval of Sandoz's ANDA.

103. Notwithstanding Sandoz's knowledge of the claims of the '043 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 '043 patent.

104. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '043 patent; active inducement of infringement of the '043 patent; and/or contribution to the infringement by others of the '043 patent.

105. Upon information and belief, Sandoz has acted with full knowledge of the '043 patent and without a reasonable basis for believing that it would not be liable for infringement of the '043 patent; active inducement of infringement of the '043 patent; and/or contribution to the infringement by others of the '043 patent.

106. Plaintiff will be substantially and irreparably damaged by infringement of the '043 patent.

107. Unless Sandoz is enjoined from infringing the '043 patent, actively inducing infringement of the '043 patent, and contributing to the infringement by others of the '043 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count VI—Declaratory Judgment of Infringement of the '043 Patent

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

109. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '043 patent, and/or the validity of the '043 patent.

110. 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 '043 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '043 patent, and that the claims of the '043 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: November 1, 2024

By: *s/Liza M. Walsh*

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LOCAL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy in this action is related to the following actions: *Intra-Cellular Therapies, Inc. v. Aurobindo Pharma Ltd. et al*, 3:24-cv-04264 (consolidated), pending before the United States District Court for the District of New Jersey, in which Plaintiff asserted claims of patent infringement against, *inter alia*, Defendant in connection with Defendant's submission of ANDA No. 218938; *Intra-Cellular Therapies, Inc. v. Sandoz Inc.*, 3:24-cv-04327-MAS-JBD, before the United States District Court for the District of New Jersey, which has been consolidated with Case No. 3:24-cv-04264-MAS-JBD and in which Plaintiff asserted claims of patent infringement against Defendant in connection with Defendant's submission of ANDA No. 218938; *Intra-Cellular Therapies, Inc. v. Sandoz Inc.*, 3:24-cv-08855-MAS-JBD, before the United States District Court for the District of New Jersey, which has been consolidated with Case No. 3:24-cv-04264-MAS-JBD and in which Plaintiff asserted claims of patent infringement against Defendant in connection with Defendant's submission of ANDA No. 218938.

Dated: November 1, 2024

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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: November 1, 2024

By: *s/Liza M. Walsh*

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