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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 No. 11,980,617 ("the '617 patent") and 12,070,459 ("the '459 patent") (collectively, the "Patents-in-Suit").

2. Alkem notified Plaintiff by letter dated February 16, 2024 ("Alkem's First 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 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").

3. On March 28, 2024, Plaintiff sued Alkem in this district for infringement of the patents identified in Alkem's First Notice Letter. *See* Civil Action No. 3:24-cv-04312-MAS-JBD, ECF No. 1. That case has been consolidated with Civil Action No. 3:24-cv-04264. ECF No. 22.

4. Alkem further notified Plaintiff by letter dated August 2, 2024 ("Alkem's Second Notice Letter") that it was seeking approval from the FDA 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 '617 patent.

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 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.

7. 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.

8. 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

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 Alkem.

12. 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.

13. 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.

14. 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) ("Paragraph IV certifications").

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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 Labs. 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).

21. 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

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

23. 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

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

25. 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.

26. In Alkem's First Notice Letter and Alkem's Second 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 First 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®.

27. In Alkem's First 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.

28. In Alkem's Second Notice Letter, Alkem stated that it had submitted Paragraph IV certifications to the FDA alleging that the '617 patent is 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 the '617 patent.

29. The purpose of Alkem's submission of Alkem'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 Alkem's ANDA Product prior to the expiration of the '617 patent.

Count I—Infringement of the '617 Patent

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

31. The '617 patent, entitled "Methods of Treating Acute Depression and/or Acute Anxiety" (attached as Exhibit A), was duly and legally issued on May 14, 2024.

32. The inventors named on the '617 patent are Gretchen Snyder, Robert Davis, and Lawrence Wennogle.

33. Plaintiff is the owner and assignee of the '617 patent.

34. CAPLYTA® is covered by one or more claims of the '617 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").

35. In Alkem's First Notice Letter and Alkem's Second 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 '617 patent.

36. In Alkem's Second Notice Letter, Alkem also notified Plaintiff that, as part of its ANDA, Alkem had filed Paragraph IV certifications with respect to the '617 patent. Upon information and belief, Alkem submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '617 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.

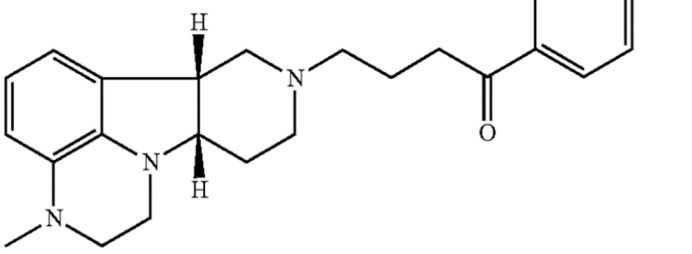
37. According to Alkem's First Notice Letter and Alkem's Second Notice Letter, Alkem's ANDA Product contains lumateperone.

38. 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 '617 patent.

39. As an example, claim 1 of the '617 patent recites:

> A method of treating acute depression and/or acute anxiety, comprising administering to a patient in need thereof, a therapeutically effective amount of a Compound of Formula I:

Formula I



> in free, or pharmaceutically acceptable salt form.

40. 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 acute depression and/or

acute anxiety, including by administering to the patient in need thereof a free or pharmaceutically acceptable salt form of a Formula I compound (which is lumateperone) in a therapeutically effective dose, as recited in claim 1.

41. 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 '617 patent, literally or under the doctrine of equivalents.

42. 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 '617 patent was an act of infringement of the '617 patent under 35 U.S.C. § 271(e)(2)(A).

43. 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.

44. 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 '617 patent.

45. 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 '617 patent.

46. Upon information and belief, Alkem plans and intends to, and will, actively induce infringement of the '617 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 '617 patent and specific intent to infringe that patent.

47. 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 '617 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 '617 patent immediately and imminently upon approval of Alkem's ANDA.

48. Notwithstanding Alkem's knowledge of the claims of the '617 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 '617 patent.

49. The foregoing actions by Alkem constitute and/or will constitute infringement of the '617 patent; active inducement of infringement of the '617 patent; and/or contribution to the infringement by others of the '617 patent.

50. Upon information and belief, Alkem has acted with full knowledge of the '617 patent and without a reasonable basis for believing that it would not be liable for infringement of the '617 patent; active inducement of infringement of the '617 patent; and/or contribution to the infringement by others of the '617 patent.

51. Plaintiff will be substantially and irreparably damaged by infringement of the '617 patent.

52. Unless Alkem is enjoined from infringing the '617 patent, actively inducing infringement of the '617 patent, and contributing to the infringement by others of the '617 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count II—Declaratory Judgment of Infringement of the '617 Patent

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

54. 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 '617 patent, and/or the validity of the '617 patent.

55. 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 '617 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '617 patent, and that the claims of the '617 patent are not invalid.

Count III—Infringement of the '459 Patent

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

57. The '459 patent, entitled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" (attached as Exhibit B), was duly and legally issued on August 27, 2024.

58. The inventors named on the '459 patent are Peng Li and Robert Davis.

59. Plaintiff is the owner and assignee of the '459 patent.

60. CAPLYTA® is covered by one or more claims of the '459 patent, which will be listed in connection with CAPLYTA® in the Orange Book.

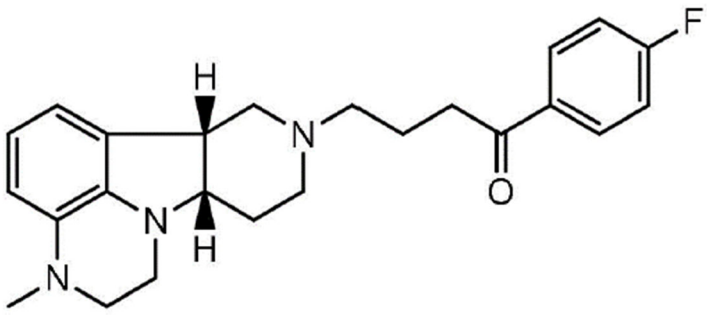
61. In Alkem's First Notice Letter and Alkem's Second Notice Letter, Alkem notified Plaintiff of the submission of Alkem's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's ANDA Product prior to the expiration of the '459 patent.

62. According to Alkem's First Notice Letter and Alkem's Second Notice Letter, Alkem's ANDA Product contains lumateperone.

63. 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 '459 patent.

64. As an example, claim 1 of the '459 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 of about 60 mg lumateperone mono-tosylate 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, and one or more pharmaceutically acceptable diluents or carriers comprising one or more of (a) diluent/filler, (b) binder, (c) disintegrant, (d) lubricant, or (e) a glidant, and wherein administration of an oral dose of a single capsule under fasting conditions provides a maximal plasma concentration of lumateperone of 15-55 ng/mL, and/or a time to

maximal plasma concentration of lumateperone of 0.7 to 1.5 hours, and/or an area under the plasma concentration curve (AUC) extrapolated to infinity (AUC(0-inf)) of 51 to 135 hours-ng/mL.

65. 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 one or more of the specific diluents or carriers in the specific amounts recited in claim 1. Upon information and belief, administration of an oral dose of a single capsule of Alkem's ANDA Product under fasting conditions will provide a maximal plasma concentration of lumateperone and/or time to maximal plasma concentration of lumateperone and/or area under the plasma concentration curve extrapolated to infinity within the specific ranges recited in claim 1.

66. Upon information and belief, Alkem's ANDA Product infringes one or more claims of the '459 patent, literally or under the doctrine of equivalents.

67. 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 '459 patent was an act of infringement of the '459 patent under 35 U.S.C. § 271(e)(2)(A).

68. 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.

69. 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 '459 patent.

70. 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 '459 patent.

71. Upon information and belief, Alkem plans and intends to, and will, actively induce infringement of the '459 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 '459 patent and specific intent to infringe that patent.

72. 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 '459 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 '459 patent immediately and imminently upon approval of Alkem's ANDA.

73. Notwithstanding Alkem's knowledge of the claims of the '459 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 '459 patent.

74. The foregoing actions by Alkem constitute and/or will constitute infringement of the '459 patent; active inducement of infringement of the '459 patent; and/or contribution to the infringement by others of the '459 patent.

75. Upon information and belief, Alkem has acted with full knowledge of the '459 patent and without a reasonable basis for believing that it would not be liable for infringement of the '459 patent; active inducement of infringement of the '459 patent; and/or contribution to the infringement by others of the '459 patent.

76. Plaintiff will be substantially and irreparably damaged by infringement of the '459 patent.

77. Unless Alkem is enjoined from infringing the '459 patent, actively inducing infringement of the '459 patent, and contributing to the infringement by others of the '459 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Count IV—Declaratory Judgment of Infringement of the '459 Patent

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

79. 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 '459 patent, and/or the validity of the '459 patent.

80. 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 '459 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '459 patent, and that the claims of the '459 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 patent, 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: August 29, 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. 219200; *Intra-Cellular Therapies, Inc. v. Alkem Laboratories, Ltd. et al*, 3:24-cv-04312-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. 219200.

Dated: August 29, 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: August 29, 2024

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