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Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

INTRACELLULAR THERAPIES, INC.,

Plaintiff,

v.

AUROBINDO PHARMA LTD., AUROBINDO
PHARMA USA, INC., ALKEM
LABORATORIES LTD., DR. REDDY'S
LABORATORIES INC. DR. REDDY'S
LABORATORIES LTD., HETERO USA, INC.,
HETERO LABS LTD. UNIT-V, HETERO
LABS LTD., MSN LABORATORIES
PRIVATE LTD., SANDOZ INC., ZYDUS
PHARMACEUTICALS (USA) INC., and
ZYDUS LIFESCIENCES LTD.,

Defendants.

C.A. No. 3:24-cv-04264-MAS-JBD
(Consolidated)

(Filed Electronically)

DEFENDANTS' ANSWER TO PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT, AND COUNTERCLAIMS

Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively, “Aurobindo” or “Defendants”), through their undersigned attorneys, answer the Complaint for Patent Infringement (“Complaint”) filed in Civil Action No. 24-8848 (No. 24-8848, Dkt. 1)¹ by Plaintiff Intra-Cellular Therapies, Inc. (“ITCI” or “Plaintiff”) as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Aurobindo denies all allegations in ITCI’s Complaint except for those specifically admitted below.

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 Aurobindo’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, 42 mg, prior to the expiration of U.S. Patent Nos. 11,980,617 (“the ’617 patent”) and 12,070,459 (“the ’459 patent”) (collectively, the “Patents-in-Suit”).

ANSWER: Paragraph 1 states legal conclusions for which no response is required. To the extent a response is required, Aurobindo admits that ITCI’s Complaint purports to be 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.* Aurobindo further admits that it filed ANDA No. 219085 (“Aurobindo’s ANDA”) with the U.S. Food and Drug Administration (the “FDA”) to obtain approval for the commercial manufacture, use, and sale of generic

¹ Civil Action No. 24-8848 has since been consolidated with Civil Action No. 24-4264. See No. 24-4264, Dkt. 65.

lumateperone capsules, 42 mg (“Aurobindo’s ANDA Product”) in the United States, prior to the expiration of U.S. Patent Nos. 11,980,617 (“the ’617 patent”) and 12,070,459 (“the ’459 patent”). Aurobindo denies any remaining allegations in Paragraph 1 of the Complaint.

2. Aurobindo notified Plaintiff by letter dated February 12, 2024 (“Aurobindo’s Notice Letter”) that it had submitted to the FDA ANDA No. 219085 (“Aurobindo’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, 42 mg, (“Aurobindo’s ANDA Product”) prior to the expiration of the 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”), 11,690,842 (“the ’842 patent”), 11,753,419 (“the ’419 patent”), 11,806,348 (“the ’348 patent”), and RE48,839 (“the RE ’839 patent”).

ANSWER: Aurobindo admits that by letter dated February 12, 2024 (“Aurobindo’s Notice Letter”), Aurobindo notified ITCI that it had submitted to the FDA Aurobindo’s ANDA, seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo’s ANDA Product prior to the expiration of the ’227 patent, the ’345 patent, the ’009 patent, the ’951 patent, the ’842 patent, the ’419 patent, the ’348 patent, and the RE ’839 patent. Aurobindo denies any remaining allegations in Paragraph 2 of the Complaint.

3. On March 27, 2024, Plaintiff sued Aurobindo in this district for infringement of the patents identified in Aurobindo’s Notice Letter. *See* Civil Action No. 3:24-cv-04264-MAS-JBD, ECF No. 1.

ANSWER: Aurobindo admits that Plaintiff sued Aurobindo in this district for alleged infringement of the ’227 patent, the ’345 patent, the ’009 patent, the ’951 patent, the ’842 patent, the ’419 patent, the ’348 patent, and the RE ’839 patent. Aurobindo denies any remaining allegations in Paragraph 3 of the Complaint.

The Parties

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

ANSWER: In response to this paragraph, Aurobindo incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

5. 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.

ANSWER: Aurobindo admits that the Drugs@FDA database (<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm>) indicates that ITCI is the holder of NDA No. 209500. Aurobindo is without sufficient knowledge or information with which to form a belief as to the truth or accuracy of the remaining allegations in Paragraph 5 of the Complaint and, therefore, denies those allegations.

6. Upon information and belief, Defendant Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of the Republic of India and having a principal place of business at Plot No. 2, Maitrivihaar, Ameerpet, Hyderabad-500038, Telangana, India.

ANSWER: Aurobindo admits that Aurobindo Pharma Ltd. is a corporation existing under the laws of India, having a place of business at Plot No. 2, Maitrivihaar, Ameerpet, Hyderabad-500038, Telangana, India. Aurobindo denies any remaining allegations in Paragraph 6 of the Complaint.

7. Upon information and belief, Defendant Aurobindo Pharma USA, Inc., is a corporation organized and existing under the laws of Delaware and having a principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520-1401.

ANSWER: Aurobindo admits that Aurobindo Pharma USA, Inc., is a corporation organized under the laws of Delaware with a place of business located at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520. Aurobindo denies all remaining allegations in Paragraph 6 of the Complaint.

8. Upon information and belief, Aurobindo Pharma USA, Inc. is the U.S. Regulatory Agent for Aurobindo Pharma Ltd.

ANSWER: Aurobindo admits that Aurobindo Pharma USA, Inc. is the U.S.

Regulatory Agent of Aurobindo Pharma Ltd. for ANDA No. 219085.

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

ANSWER: Paragraph 9 states legal conclusions for which no response is required. To the extent a response is required, denied.

10. Upon information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Aurobindo's ANDA Product, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, Aurobindo Pharma USA, Inc. participated in, assisted, and cooperated with Aurobindo Pharma Ltd. in the acts complained of herein.

ANSWER: Paragraph 10 states legal conclusions for which no response is required. To the extent a response is required, denied.

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

ANSWER: Paragraph 11 states legal conclusions for which no response is required. To the extent a response is required, denied.

Jurisdiction

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

ANSWER: In response to this paragraph, Aurobindo incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

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

ANSWER: Paragraph 13 states legal conclusions for which no response is required.

To the extent a response is required, Aurobindo does not contest subject matter jurisdiction in this judicial district for the purposes of this action only. Aurobindo denies that the claims have merit or that ITCI is entitled to any relief on its claims or any other allegations of Paragraph 13. Aurobindo otherwise denies the allegations of Paragraph 13.

14. This Court has personal jurisdiction over each of Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc.

ANSWER: Paragraph 14 states legal conclusions for which no response is required.

To the extent a response is required, Aurobindo does not contest personal jurisdiction in this judicial district for the purposes of this action only. Aurobindo otherwise denies the allegations of Paragraph 14.

15. Aurobindo Pharma Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Aurobindo Pharma Ltd., itself and through its subsidiary Aurobindo Pharma USA, Inc., has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Aurobindo Pharma Ltd., itself and through its subsidiary Aurobindo Pharma USA, Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey and therefore transacts business within the State of New Jersey, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. In addition, Aurobindo Pharma Ltd. is subject to personal jurisdiction in New Jersey because, upon information and belief, it controls Aurobindo Pharma USA, Inc. and therefore the activities of Aurobindo Pharma USA, Inc. in this jurisdiction are attributed to Aurobindo Pharma Ltd.

ANSWER: Paragraph 15 states legal conclusions for which no response is required.

To the extent a response is required, Aurobindo does not contest personal jurisdiction in this judicial district for the purposes of this action only. Aurobindo otherwise denies the allegations of Paragraph 15.

16. Aurobindo Pharma USA, Inc. is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Aurobindo Pharma USA, Inc. is a corporation having a principal place of business in the State of New Jersey, is qualified to do business in New Jersey, and has appointed a registered agent for

service of process in New Jersey. It therefore has consented to general jurisdiction in New Jersey. In addition, upon information and belief, Aurobindo Pharma USA, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey and therefore transacts business within the State of New Jersey related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

ANSWER: Paragraph 16 states legal conclusions for which no response is required.

To the extent a response is required, Aurobindo does not contest personal jurisdiction in this judicial district for the purposes of this action only. Aurobindo otherwise denies the allegations of Paragraph 16.

17. Aurobindo has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certifications"), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

ANSWER: Paragraph 17 states legal conclusions for which no response is required.

To the extent a response is required, Aurobindo does not contest personal jurisdiction in this judicial district for the purposes of this action only. Aurobindo otherwise denies the allegations of Paragraph 17.

18. Upon information and belief, Aurobindo, with knowledge of the Hatch-Waxman Act process, directed Aurobindo's Notice Letter to Plaintiff. Aurobindo has been a litigant in connection with other infringement actions under the Hatch-Waxman Act. It was reasonably foreseeable that Aurobindo would be sued in New Jersey, where Aurobindo Pharma USA, Inc. is located.

ANSWER: Paragraph 18 states legal conclusions for which no response is required.

To the extent a response is required, Aurobindo does not contest personal jurisdiction in this judicial district for the purposes of this action only. Aurobindo otherwise denies the allegations of Paragraph 18.

19. Upon information and belief, if Aurobindo's ANDA is approved, Aurobindo will directly or indirectly manufacture, market, sell, and/or distribute Aurobindo's ANDA Product within the United States, including in New Jersey, consistent with Aurobindo's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and

belief, Aurobindo 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, Aurobindo's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. Upon information and belief, Aurobindo's ANDA Product will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the Patents-in-Suit in the event that Aurobindo's ANDA Product is approved before the Patents-in-Suit expire.

ANSWER: Paragraph 19 states legal conclusions for which no response is required.

To the extent a response is required, Aurobindo does not contest personal jurisdiction in this judicial district for the purposes of this action only. Aurobindo otherwise denies the allegations of Paragraph 19.

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

ANSWER: Paragraph 20 states legal conclusions for which no response is required.

To the extent a response is required, Aurobindo does not contest personal jurisdiction in this judicial district for the purposes of this action only. Aurobindo otherwise denies the allegations of Paragraph 20.

Venue

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

ANSWER: In response to this paragraph, Aurobindo incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

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

ANSWER: Paragraph 22 states legal conclusions for which no response is required.

To the extent a response is required, Aurobindo does not contest venue in this judicial district for the purposes of this action only. Aurobindo otherwise denies the allegations of Paragraph 22.

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

ANSWER: Paragraph 23 states legal conclusions for which no response is required.

To the extent a response is required, Aurobindo does not contest venue in this judicial district for the purposes of this action only. Aurobindo otherwise denies the allegations of Paragraph 23.

Factual Background

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

ANSWER: In response to this paragraph, Aurobindo incorporates by reference the preceding paragraphs of this Answer 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.

ANSWER: Aurobindo admits that the prescribing information for Caplyta® speaks for itself. Aurobindo denies any remaining allegations of Paragraph 25 of the Complaint.

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

ANSWER: Aurobindo refers to its Notice Letter for a complete and accurate statement of its contents. Aurobindo denies any remaining allegations in Paragraph 26 of the Complaint.

27. In Aurobindo's Notice Letter, Aurobindo stated that it had submitted Paragraph IV certifications to the FDA alleging that the '227 patent, the '345 patent, the '009 patent, the '951 patent, the '842 patent, the '419 patent, the '348 patent, and the RE '839 patent are invalid, unenforceable, and/or not infringed, and that Aurobindo is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Aurobindo's ANDA Product prior to the expiration of those patent.

ANSWER: Aurobindo refers to its Notice Letter for a complete and accurate statement of its contents. Aurobindo denies any remaining allegations in Paragraph 27 of the Complaint.

28. The purpose of Aurobindo's submission of Aurobindo'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 Aurobindo's ANDA Product prior to the expiration of the Patents-in-Suit. On information and belief, Aurobindo intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Aurobindo's ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Paragraph 28 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Aurobindo admits that Aurobindo filed its ANDA seeking approval from the FDA to commercially market generic versions of Caplyta® prior to the expiration of the Patents-in-Suit. Aurobindo denies any remaining allegations of Paragraph 28 of the Complaint.

Count I—Infringement of the '617 Patent

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

ANSWER: In response to this paragraph, Aurobindo incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

30. 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.

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, Aurobindo admits that the '617 patent bears the title "Methods of Treating Acute Depression and/or Acute Anxiety." Aurobindo admits that the '617

patent, on its face, bears an issue date of May 14, 2024. Aurobindo admits that Exhibit A attached to the Complaint purports to be a copy of the '617 patent. Aurobindo denies any remaining allegations in Paragraph 30 of the Complaint, and specifically denies that the '617 patent was "duly and legally issued."

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

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is required, Aurobindo admits, on its face, that the '617 patent identifies Gretchen Snyder, Robert Davis, and Lawrence Wennogle as the inventors. Aurobindo denies any remaining allegations in Paragraph 31 of the Complaint.

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

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent an answer is required, Aurobindo admits that the '617 patent identifies Plaintiff as the assignee. Aurobindo denies any remaining allegations in Paragraph 32 of the Complaint.

33. 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").

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. To the extent an answer is required, Aurobindo admits that the '617 patent has been listed in connection with the New Drug Application ("NDA") for CAPLYTA® in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the Orange Book"). Aurobindo denies any remaining allegations in Paragraph 33 of the Complaint.

34. In Aurobindo's Notice Letter, Aurobindo notified Plaintiff of the submission of Aurobindo'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 Aurobindo's ANDA Product prior to the expiration of the '617 patent.

ANSWER: Aurobindo refers to its Notice Letter for a complete and accurate statement of its contents. Aurobindo denies any remaining allegations in Paragraph 34 of the Complaint.

35. According to Aurobindo's Notice Letter, Aurobindo's ANDA Product contains lumateperone.

ANSWER: Admitted.

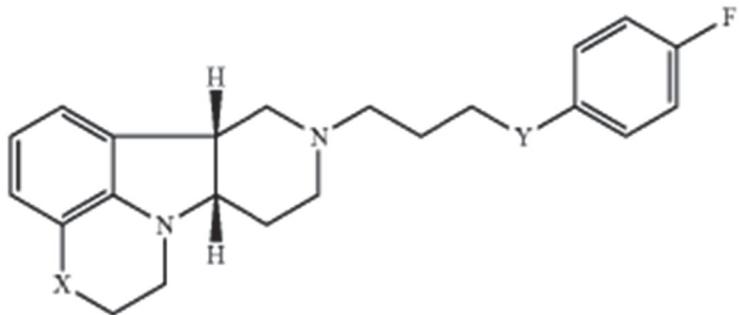
36. Upon information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '617 patent.

ANSWER: Denied.

37. 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.

ANSWER: Aurobindo admits ITCI purports to recite claim 1 of the '617 patent.

Aurobindo denies any remaining allegations in Paragraph 37 of the Complaint.

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

ANSWER: Paragraph 38 states legal conclusions for which no response is required.

To the extent a response is required, Aurobindo admits that its proposed label speaks for itself.

Aurobindo denies any remaining allegations in Paragraph 38 of the Complaint.

39. Upon information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed product labeling would infringe one or more claims of the '617 patent, literally or under the doctrine of equivalents.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Aurobindo lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 41 and therefore denies any allegations of Paragraph 41.

42. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '617 patent.

ANSWER: Denied.

43. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '617 patent.

ANSWER: Denied.

44. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '617 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Aurobindo's activities will be done with knowledge of the '617 patent and specific intent to infringe that patent.

ANSWER: Denied.

45. Upon information and belief, Aurobindo knows that Aurobindo's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '617 patent, that Aurobindo's ANDA Product is not a staple article or commodity of commerce, and that Aurobindo's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '617 patent immediately and imminently upon approval of Aurobindo's ANDA.

ANSWER: Denied.

46. Notwithstanding Aurobindo's knowledge of the claims of the '617 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's ANDA Product with its product labeling following FDA approval of Aurobindo's ANDA prior to the expiration of the '617 patent.

ANSWER: Denied.

47. The foregoing actions by Aurobindo 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.

ANSWER: Denied.

48. Upon information and belief, Aurobindo 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.

ANSWER: Denied.

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

ANSWER: Denied.

50. Unless Aurobindo 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.

ANSWER: Denied.

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

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

ANSWER: In response to this paragraph, Aurobindo incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

52. 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 Aurobindo on the other regarding Aurobindo's infringement, active inducement of infringement, contribution to the infringement by others of the '617 patent, and/or the validity of the '617 patent.

ANSWER: Paragraph 52 states legal conclusions for which no response is required.

To the extent a response is required, Aurobindo admits that ITCI purports there is a case of actual controversy between ITCI and Aurobindo. Aurobindo specifically denies any allegation of infringement, active inducement of infringement, or contributory infringement of the '617 patent. Aurobindo specifically denies the '617 patent is valid. Aurobindo denies any remaining allegations of Paragraph 52 of the Complaint.

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

ANSWER: Denied.

Count III—Infringement of the '459 Patent

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

ANSWER: In response to this paragraph, Aurobindo incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

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

ANSWER: Paragraph 55 contains legal conclusions to which no answer is required.

To the extent an answer is required, Aurobindo admits that the '459 patent bears the title "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate." Aurobindo admits that the '459 patent, on its face, bears an issue date of August 27, 2024. Aurobindo admits that Exhibit B attached to the Complaint purports to be a copy of the '459 patent. Aurobindo

denies any remaining allegations in Paragraph 55 of the Complaint, and specifically denies that the '459 patent was "duly and legally issued."

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

ANSWER: Paragraph 56 contains legal conclusions to which no answer is required.

To the extent an answer is required, Aurobindo admits, on its face, that the '459 patent identifies Peng Li and Robert Davis as the inventors. Aurobindo denies any remaining allegations of Paragraph 56 of the Complaint.

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

ANSWER: Paragraph 57 contains legal conclusions to which no answer is required.

To the extent an answer is required, Aurobindo admits that the '459 patent identifies Plaintiff as the assignee. Aurobindo denies any remaining allegations in Paragraph 57 of the Complaint.

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

ANSWER: Paragraph 58 contains legal conclusions to which no answer is required.

To the extent an answer is required, Aurobindo admits that the '459 patent has been listed in connection with the NDA for CAPLYTA® in the Orange Book. Aurobindo denies any remaining allegations in Paragraph 58 of the Complaint.

59. In Aurobindo's Notice Letter, Aurobindo notified Plaintiff of the submission of Aurobindo'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 Aurobindo's ANDA Product prior to the expiration of the '459 patent.

ANSWER: Aurobindo refers to its Notice Letter for a complete and accurate statement of its contents. Aurobindo denies any remaining allegations in Paragraph 59 of the Complaint.

60. According to Aurobindo's Notice Letter, Aurobindo's ANDA Product contains lumateperone.

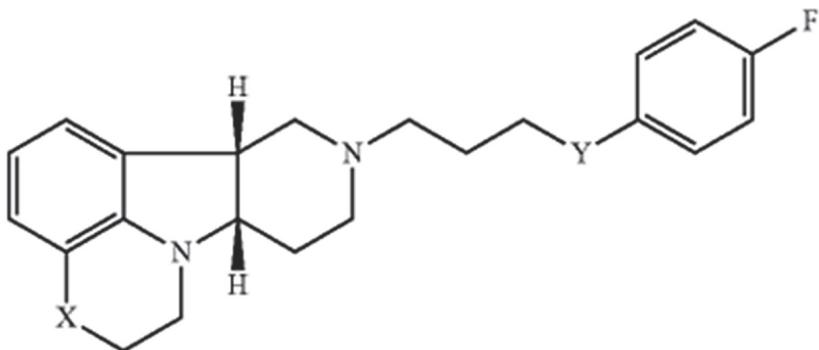
ANSWER: Admitted.

61. Upon information and belief, the use of Aurobindo's ANDA Product in accordance with and as directed by Aurobindo's proposed labeling for that product would infringe one or more claims of the '459 patent.

ANSWER: Denied.

62. As an example, claim 1 of the '459 patent recites:
A pharmaceutical capsule for oral administration, comprising lumateperone:

Formula I



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..

ANSWER: Aurobindo admits ITCI purports to recite claim 1 of the '459 patent.

Aurobindo denies any remaining allegations in Paragraph 62 of the Complaint.

63. Upon information and belief, Aurobindo'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 Aurobindo'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.

ANSWER: Paragraph 63 states legal conclusions for which no response is required.

To the extent a response is required, denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Aurobindo lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 66 and therefore denies any allegations of Paragraph 66.

67. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '459 patent.

ANSWER: Denied.

68. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Aurobindo's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '459 patent.

ANSWER: Denied.

69. Upon information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '459 patent when Aurobindo's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Aurobindo's activities will be done with knowledge of the '459 patent and specific intent to infringe that patent.

ANSWER: Denied.

70. Upon information and belief, Aurobindo knows that Aurobindo's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '459 patent, that Aurobindo's ANDA Product is not a staple article or commodity of commerce, and that Aurobindo's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '459 patent immediately and imminently upon approval of Aurobindo's ANDA.

ANSWER: Denied.

71. Notwithstanding Aurobindo's knowledge of the claims of the '459 patent, Aurobindo has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aurobindo's ANDA Product with its product labeling following FDA approval of Aurobindo's ANDA prior to the expiration of the '459 patent.

ANSWER: Denied.

72. The foregoing actions by Aurobindo 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.

ANSWER: Denied.

73. Upon information and belief, Aurobindo 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.

ANSWER: Denied.

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

ANSWER: Denied.

75. Unless Sandoz [sic] 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.

ANSWER: Denied.

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

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

ANSWER: In response to this paragraph, Aurobindo incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

77. 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 Aurobindo on the other regarding Aurobindo's infringement, active inducement of infringement, contribution to the infringement by others of the '459 patent, and/or the validity of the '459 patent.

ANSWER: Paragraph 77 states legal conclusions for which no response is required.

To the extent a response is required, Aurobindo admits that ITCI purports there is a case of actual controversy between ITCI and Aurobindo. Aurobindo specifically denies any allegation of infringement, active inducement of infringement, or contributory infringement of the '459 patent. Aurobindo specifically denies the '459 patent is valid. Aurobindo denies any remaining allegations of Paragraph 77 of the Complaint.

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

ANSWER: Denied.

PRAYER FOR RELIEF

Aurobindo denies that Plaintiff is entitled to any of the requested relief or any other relief against Aurobindo.

AFFIRMATIVE AND OTHER DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiff, Aurobindo avers and asserts the following separate defenses to the Complaint:

First Defense (Failure to State a Claim)

Plaintiff fails to state a claim upon which relief can be granted.

Second Defense (Non-infringement of U.S. Patent No. 11,980,617)

Aurobindo does not, has not, and will not infringe, literally or under the doctrine of equivalents, any valid and enforceable claim of the '617 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

Third Defense (Invalidity of U.S. Patent No. 11,980,617)

Each claim of the '617 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code § 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, or any judicially created bases for invalidation, including obviousness-type double patenting.

Fourth Defense (Non-infringement of U.S. Patent No. 12,070,459)

Aurobindo does not, has not, and will not infringe, literally or under the doctrine of equivalents, any valid and enforceable claim of the '459 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

Fifth Defense (Invalidity of U.S. Patent No. 12,070,459)

Each claim of the '459 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code § 101, *et seq.*, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, or any judicially created bases for invalidation, including obviousness-type double patenting.

Sixth Defense (Prosecution History Estoppel)

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the '617 patent and the '459 patent, Plaintiff is estopped from maintaining that any valid or enforceable claim of the '617 patent and the '459 patent is infringed by the product that is the subject of Aurobindo's ANDA.

RESERVATION OF DEFENSES

Aurobindo reserves the right to assert additional defenses as may be warranted by discovery or further factual investigation in this action.

AUROBINDO'S COUNTERCLAIMS

Defendants and Counterclaim-Plaintiffs Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc., (collectively, “Aurobindo” or “Counterclaim-Plaintiffs”) assert the following counterclaims against Plaintiff and Counterclaim-Defendant Intra-Cellular Therapies, Inc. (“ITCI” or “Counterclaim-Defendant”).

NATURE OF THE COUNTERCLAIMS

1. This is an action for declaratory relief seeking a declaration of noninfringement and invalidity of U.S. Patent Nos. 11,980,617 (“the ’617 patent”) and 12,070,459 (“the ’459 patent”) (collectively, the “Patents-in-Suit”).

2. As set forth below, Aurobindo Pharma Ltd. submitted Abbreviated New Drug Application (“ANDA”) No. 219085, containing, *inter alia*, certifications under 21 C.F.R. § 314.94(a)(12)(i)(A)(4) and 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV”) of the Drug Price Competition and Patent Term Restoration Act of 1984 as to the Patents-in-Suit, to the United States Food and Drug Administration (the “FDA”) seeking approval to market generic 42 mg lumateperone capsules.

3. ITCI filed a Complaint for Patent Infringement (the “Complaint”) in this Court alleging that Aurobindo’s act of submitting ANDA No. 219085 infringes the Patents-in-Suit and that Aurobindo’s intended commercial manufacture, use, sale, offer for sale, or importation of the product described in ANDA No. 219085 will infringe the Patents-in-Suit.

4. ITCI has alleged in this action that Aurobindo has infringed the Patents-in-Suit under 35 U.S.C. § 271(e)(2) by filing ANDA No. 219085 and that Aurobindo’s manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the proposed generic drug described in ANDA No. 219085 would directly infringe, induce others’ direct infringement of, and contribute to infringement of the Patents-in-Suit in violation of

35 U.S.C. § 271(a)–(c). Aurobindo denies that its filing of ANDA No. 219085 was an act of infringement under 35 U.S.C. § 271(e)(2) and denies that Aurobindo’s manufacture, use, offer for sale, sale, or importation of the proposed generic drug product described in its ANDA would constitute direct, induced, or contributory infringement of the Patents-in-Suit. ITCI’s lawsuit has restrained the free exploitation of Aurobindo’s noninfringing drug product by excluding Aurobindo from entering the market for the proposed generic drug product described in ANDA No. 219085.

5. Based on ITCI’s filing of its Complaint against Aurobindo asserting infringement of the Patents-in-Suit, and Aurobindo’s denial thereof, an actual controversy exists between Aurobindo and ITCI as to whether Aurobindo infringes any valid claim of the Patents-in-Suit.

6. Unless enjoined, ITCI will continue to assert that Aurobindo infringes the Patents-in-Suit and will continue to impair Aurobindo’s ability to market Aurobindo’s generic 42 mg lumateperone capsules, causing irreparable harm to Aurobindo’s business.

THE PARTIES

7. Aurobindo Pharma Ltd. is a corporation existing under the laws of India, having a place of business at Plot No. 2, Maitrivihaar, Ameerpet, Hyderabad-500038, Telangana, India.

8. Aurobindo Pharma USA, Inc. is a corporation existing under the laws of Delaware, having a place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

9. On information and belief, 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, New York 10016.

10. ITCI is the entity that filed the Complaint in Civil Action No. 3:24-cv-8848 (which was subsequently consolidated with this action) on or about August 29, 2024.

JURISDICTION AND VENUE

11. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, under the United States Patent Laws, 35 U.S.C. § 1 *et seq.*, and under 21 U.S.C. § 355(j)(5)(C).

12. This Court has subject matter jurisdiction based on 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 21 U.S.C. § 355(j)(5)(C).

13. This Court has personal jurisdiction over ITCI because, among other reasons, ITCI consented to jurisdiction by suing Aurobindo in this District.

14. This Court is the proper venue under 28 U.S.C. §§ 1391 and 1400(b) and 21 U.S.C. § 355(j)(5)(C)(i)(II).

THE PATENTS-IN-SUIT AND CAPLYTA®

15. The face of the '617 patent, titled "Methods of Treating Acute Depression and/or Acute Anxiety," indicates that the '617 patent issued on May 14, 2024 from U.S. Patent Application No. 16/981,639 filed on March 15, 2019.

16. On information and belief, ITCI purports to be the owner by assignment of the '617 patent.

17. The face of the '459 patent, titled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate," indicates that the '459 patent issued on August 27, 2024 from U.S. Patent Application No. 18/504,345 filed on November 8, 2023.

18. On information and belief, ITCI purports to be the owner by assignment of the '459 patent.

19. On information and belief, ITCI purports to be the present holder of New Drug Application ("NDA") No. 209500 for CAPLYTA® (lumateperone) capsules, 10.5 mg, 21 mg, and 42 mg.

20. On information and belief, CAPLYTA® is the trademark under which ITCI markets lumateperone capsules 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.

21. Under 21 U.S.C. § 355, an NDA holder must provide to the FDA the patent number and expiration date of any patent(s) that the holder believes “claims the drug for which the applicant submitted the application” or which “claims a method of using such drug.” See 21 U.S.C. § 355(b)(1)(A)(viii)(I)–(II). The FDA publishes these patent(s) in an electronic, publicly available database called *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the “Orange Book”).

22. The Patents-in-Suit are listed in the Orange Book in connection with CAPLYTA®.

AUROBINDO'S ANDA

23. Aurobindo Pharma Ltd. submitted ANDA No. 219085 (“Aurobindo’s ANDA”) to the FDA seeking approval to market the proposed generic 42 mg lumateperone capsules.

24. Aurobindo’s ANDA No. 219085 contains, or will contain, *inter alia*, Paragraph IV certifications under 21 C.F.R. § 314.94(a)(12)(i)(A)(4) and 21 U.S.C. §355(j)(2)(A)(vii)(IV) requesting FDA approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Aurobindo’s generic 42 mg lumateperone capsules prior to the expiration of the Patents-in-Suit.

25. Pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Aurobindo provided notice of its Paragraph IV certifications to ITCI in a letter dated February 12, 2024 (“Aurobindo’s Notice Letter”) that it had submitted to the FDA ANDA No. 219085 with respect to 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”), 11,690,842 (“the ’842 patent”), 11,753,419 (“the ’419 patent”), 11,806,348 (“the ’348 patent”), and RE48,839 (“the RE ’839 patent”).

26. On August 29, 2024, ITCI filed its Complaint, alleging infringement of the Patents-in-Suit by Aurobindo.

27. The present lawsuit by ITCI impairs Aurobindo’s ability to obtain approval of its ANDA No. 219085 and to market its generic 42 mg lumateperone capsules.

COUNT I
(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’617 PATENT)

28. Aurobindo realleges and incorporates by reference, as though fully set forth herein, the foregoing paragraphs of the Counterclaims.

29. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Aurobindo regarding whether the filing of Aurobindo’s ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Aurobindo’s ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the ’617 patent.

30. Aurobindo does not, has not, and will not infringe, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’617 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

31. Aurobindo is entitled to a declaration by the Court that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claims of the ’617 patent and is not liable for such infringement.

COUNT II
(DECLARATORY JUDGMENT OF INVALIDITY OF THE ’617 PATENT)

32. Aurobindo realleges and incorporates by reference, as though fully set forth herein, the foregoing paragraphs of the Counterclaims.

33. The '617 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 or under a judicially-created basis for invalidation or unenforceability, including obviousness-type double patenting.

34. Accordingly, there is an actual, immediate, and justiciable controversy between the parties regarding whether the claims of the '617 patent are invalid.

35. Aurobindo is entitled to a declaration by the Court that one or more claims of the '617 patent is invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity, including obviousness-type double patenting.

36. Aurobindo is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT III
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '459 PATENT

37. Aurobindo realleges and incorporates by reference, as though fully set forth herein, the foregoing paragraphs of the Counterclaims.

38. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Aurobindo regarding whether the filing of Aurobindo's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Aurobindo's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '459 patent.

39. Aurobindo does not, has not, and will not infringe, literally or under the doctrine of equivalents, any valid and enforceable claim of the '459 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

40. Aurobindo is entitled to a declaration by the Court that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claims of the '459 patent and is not liable for such infringement.

COUNT IV
(DECLARATORY JUDGMENT OF INVALIDITY OF THE '459 PATENT)

41. Aurobindo realleges and incorporates by reference, as though fully set forth herein, the foregoing paragraphs of the Counterclaims.

42. The '459 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 or under a judicially-created basis for invalidation or unenforceability, including obviousness-type double patenting.

43. Accordingly, there is an actual, immediate, and justiciable controversy between the parties regarding whether the claims of the '459 patent are invalid.

44. Aurobindo is entitled to a declaration by the Court that one or more claims of the '459 patent is invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity, including obviousness-type double patenting.

45. Aurobindo is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

PRAYER FOR RELIEF

WHEREFORE, Aurobindo prays that the Court enter judgment in its favor against ITCI as follows:

- (a) Declaring that the claims of the Patents-in-Suit are invalid;

- (b) Declaring that no valid claim of the Patents-in-Suit is or would be infringed by the manufacture, use, sale, offer for sale, and/or importation of Aurobindo's ANDA Product pursuant to ANDA No. 219085;
- (c) That an order be entered dismissing ITCI's Complaint with prejudice and entering judgment in favor of Aurobindo;
- (d) Finding this case exceptional within the meaning of 35 U.S.C. § 285, awarding Aurobindo reasonable attorney fees and costs incurred in prosecuting this action; and
- (e) Granting Aurobindo such other and further relief as the Court deems just and appropriate.

Dated: November 12, 2024

Respectfully submitted,



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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc., through their counsel, certify that the matter in controversy is not related to any action other than those that have been consolidated with this lead case.

Dated: November 12, 2024



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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on November 12, 2024, a true and correct copy of the foregoing DEFENDANTS' ANSWER TO PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT, AND COUNTERCLAIMS was filed via ECF and was served via electronic mail upon:

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