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*and Zydus Lifesciences Limited*

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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|---|---|
| Intra-Cellular Therapies, Inc.,<br><br>*Plaintiff,*<br><br>v.<br><br>Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Ltd.,<br><br>*Defendants.* | Civil Action No. 3:24-04330 (MAS)(JBD)<br><br>*Document Electronically Filed* |

**ZYDUS PHARMACEUTICALS (USA) INC.'S AND ZYDUS LIFESCIENCES LIMITED'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFF'S COMPLAINT**

Defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Zydus Lifesciences Limited ("Zydus Lifesciences") (collectively, "Zydus" or "Defendants") for their Answer and Affirmative Defenses to the Complaint of Intra-Cellular Therapies, Inc. ("Intra-Cellular" or "Plaintiff") state as follows:

All averments not expressly admitted are denied.

## 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 Zydus'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. 10,695,345 ("the '345 patent"), 11,052,084 ("the '084 patent"), 11,690,842 ("the '842 patent"), 11,753,419 ("the '419 patent"), and 11,806,348 ("the '348 patent"). These patents are referred to collectively herein as the "Patents-in-Suit."

**ANSWER**: The allegations in paragraph 1 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus USA submitted Abbreviated New Drug Application ("ANDA") No. 218652 to the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, sale, and importation of lumateperone capsules, 10.5 mg, 21 mg, and 42 mg ("Zydus's Proposed ANDA Product") in or into the United States. Zydus further admits that ANDA No. 218652 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certifications") with respect to U.S. Patent Nos. 10,695,345 ("the '345 patent"), 11,052,084 ("the '084 patent"), 11,690,842 ("the '842 patent"), 11,753,419 ("the '419 patent"), and 11,806,348 ("the '348 patent") (collectively, the "Patents-In-Suit"). Zydus further admits that the Complaint purports to be a civil action alleging infringement of the Patents-In-Suit. Zydus denies all other allegations in paragraph 1.

2. Zydus notified Plaintiff by letter dated February 12, 2024 ("Zydus's Notice Letter") that it had submitted to the FDA ANDA No. 218652 ("Zydus'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, ("Zydus's ANDA Product") prior to the expiration of the Patents-in-Suit.

**ANSWER**: Zydus admits that Zydus USA transmitted its Notice Letter dated February 12, 2024 ("Notice Letter") to Plaintiff, notifying it that Zydus USA submitted ANDA No. 218652 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United

States. Zydus further admits that ANDA No. 218652 includes Paragraph IV Certifications with respect to the Patents-In-Suit. Zydus denies all other allegations in paragraph 2.

**The Parties**

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

**ANSWER**: Defendants restate and incorporate by reference their answers to each of the preceding paragraphs as if fully set forth herein.

4. Plaintiff Intra-Cellular Therapies ("ITCI") is a corporation organized and existing under the laws of Delaware and having a place of business at 430 East 29th Street, Suite 900, New York, NY 10016. ITCI is the holder of New Drug Application ("NDA") No. 209500 for the manufacture and sale of lumateperone capsules, 10.5 mg, 21 mg, and 42 mg, which have been approved by the FDA.

**ANSWER**: The allegations in paragraph 4 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") identifies "INTRA-CELLULAR THERAPIES INC" as Applicant Holder, "LUMATEPERONE TOSYLATE" as Active Ingredient, "CAPSULE" as Dosage Form, and "EQ 10.5MG BASE," "EQ 21MG BASE," and "EQ 42MG BASE," as Strength in connection with NDA No. 209500. Zydus lacks knowledge or information sufficient to form a belief regarding all other allegations in paragraph 4 and therefore denies them.

5. Upon information and belief, Defendant Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of New Jersey and having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

**ANSWER**: Admitted.

6. Upon information and belief, Defendant Zydus Lifesciences Ltd. is a corporation organized and existing under the laws of the Republic of India and having a principal place of business at Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, Ahmedabad, Gujarat, India, 382481.

**ANSWER**: Admitted.

7. Upon information and belief, Zydus Pharmaceuticals (USA) Inc. is the U.S. Regulatory Agent for Zydus Lifesciences Ltd.

**ANSWER**: Denied.

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

**ANSWER**: The allegations in paragraph 8 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus USA sells pharmaceutical products in the United States, including generic pharmaceutical products manufactured by Zydus Lifesciences. Zydus further admits that Zydus USA submitted ANDA No. 218652 to FDA seeking approval to engage in the manufacture, use, sale, and importation of Zydus's Proposed ANDA Product in or into the United States and that ANDA No. 218652 identifies Zydus Lifesciences as the manufacturer of Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 8.

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

**ANSWER**: The allegations in paragraph 9 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus USA sells pharmaceutical products in the United States, including generic pharmaceutical products manufactured by Zydus Lifesciences. Zydus further admits that Zydus USA submitted ANDA No. 218652 to FDA seeking approval to engage in the manufacture, use, sale, and importation of Zydus's Proposed ANDA Product in or into the United States and that ANDA No. 218652 identifies Zydus Lifesciences as

the manufacturer of Zydus's Proposed ANDA Product. Zydus further admits that Zydus USA is a wholly owned subsidiary of Zydus Lifesciences. Zydus denies all other allegations in paragraph 9.

10. Upon information and belief, following any FDA approval of Zydus's ANDA, Zydus Lifesciences Ltd. and Zydus Pharmaceuticals (USA) Inc. will act in concert to distribute and sell Zydus's ANDA Product throughout the United States, including within New Jersey.

**ANSWER**: The allegations in paragraph 10 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus USA sells pharmaceutical products in the United States, including generic pharmaceutical products manufactured by Zydus Lifesciences. Zydus further admits that Zydus USA submitted ANDA No. 218652 to FDA seeking approval to engage in the manufacture, use, sale, and importation of Zydus's Proposed ANDA Product in or into the United States and that ANDA No. 218652 identifies Zydus Lifesciences as the manufacturer of Zydus's Proposed ANDA Product. Zydus further admits that Zydus USA is a wholly owned subsidiary of Zydus Lifesciences. Zydus denies all other allegations in paragraph 10.

**Jurisdiction**

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

**ANSWER**: Defendants restate and incorporate by reference their answers to each of the preceding paragraphs as if fully set forth herein.

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

**ANSWER**: The allegations in paragraph 12 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest subject matter jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Defendants in this case and

solely as they apply to Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 12.

13. This Court has personal jurisdiction over each of Zydus Lifesciences Ltd. and Zydus Pharmaceuticals (USA) Inc.

**ANSWER**: The allegations in paragraph 13 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Defendants in this case and solely as they apply to Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 13.

14. Zydus Lifesciences Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Zydus Lifesciences Ltd., itself and through its subsidiary Zydus Pharmaceuticals (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, Zydus Lifesciences Ltd., itself and through its subsidiary Zydus Pharmaceuticals (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, Zydus Lifesciences Ltd. is subject to personal jurisdiction in New Jersey because, upon information and belief, it controls Zydus Pharmaceuticals (USA) Inc. and therefore the activities of Zydus Pharmaceuticals (USA) Inc. in this jurisdiction are attributed to Zydus Lifesciences Ltd.

**ANSWER**: The allegations in paragraph 14 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus Lifesciences does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Zydus Lifesciences in this case and solely as they apply to Zydus's Proposed ANDA Product. Zydus admits that Zydus USA is a wholly owned subsidiary of Zydus Lifesciences. Zydus further admits that Zydus Lifesciences develops and manufactures pharmaceutical products, including generic drugs. Zydus further admits that Zydus USA imports, offers to sell, and/or sells pharmaceutical

products, including generic drugs, in or into the United States. Zydus denies all other allegations in paragraph 14.

15. Zydus Pharmaceuticals (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. Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey, has 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, Zydus Pharmaceuticals (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**: The allegations in paragraph 15 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus USA does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Zydus USA in this case and solely as they apply to Zydus's Proposed ANDA Product. Zydus admits that Zydus USA is a corporation organized and existing under the laws of the State of New Jersey, has 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. Zydus further admits that Zydus USA imports, offers to sell, and/or sells pharmaceutical products, including generic drugs, in or into the United States. Zydus denies all other allegations in paragraph 15.

16. Zydus 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), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

**ANSWER**: The allegations in paragraph 16 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus USA has submitted ANDAs to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture,

use, sale, and importation of pharmaceutical products in or into the United States, that certain of those ANDAs included Paragraph IV Certifications in connection with which Zydus USA has sent Notice Letters, and that Zydus USA has engaged in patent litigation arising from Zydus USA's submission of certain ANDAs. Zydus denies all other allegations in Paragraph 16.

17. Upon information and belief, Zydus, with knowledge of the Hatch-Waxman Act process, directed Zydus's Notice Letter to Plaintiff. Upon information and belief, Zydus knew when it did so that it was triggering the forty-five-day period for Plaintiff to bring an action for patent infringement under the Hatch-Waxman Act. Zydus has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Zydus's Notice Letter to Plaintiff it would be sued for patent infringement in New Jersey, where Zydus Pharmaceuticals (USA) Inc. is located and incorporated.

**ANSWER**: The allegations in paragraph 17 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus USA transmitted its Notice Letter dated February 12, 2024 to Intra-Cellular Therapies, Inc., notifying it that Zydus USA submitted ANDA No. 218652 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that Plaintiff filed the Complaint alleging infringement of the Patents-In-Suit on March 28, 2024. Zydus further admits that it has been a litigant in connection with other infringement actions under the Hatch-Waxman Act. Zydus denies all other allegations in paragraph 17.

18. Upon information and belief, if Zydus's ANDA is approved, Zydus will directly or indirectly manufacture, market, sell, and/or distribute Zydus's ANDA Product within the United States, including in New Jersey, consistent with Zydus's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Zydus 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, Zydus's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. Upon information and belief, Zydus'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 Zydus's ANDA Product is approved before the patents expire.

**ANSWER**: The allegations in paragraph 18 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus USA sells pharmaceutical products in the United States, including generic pharmaceutical products manufactured by Zydus Lifesciences. Zydus further admits that Zydus USA submitted ANDA No. 218652 to FDA seeking approval to engage in the manufacture, use, sale, and importation of Zydus's Proposed ANDA Product in or into the United States. Zydus admits that Zydus USA's principal place of business is in New Jersey. Zydus lacks knowledge or information sufficient to form a belief regarding the allegations in the third and fourth sentences and therefore denies them. Zydus denies all other allegations in Paragraph 18.

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

**ANSWER**: The allegations in paragraph 19 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that Zydus USA sells pharmaceutical products in the United States, including generic pharmaceutical products manufactured by Zydus Lifesciences. Zydus lacks knowledge or information sufficient to form a belief regarding all other allegations in Paragraph 19 and therefore denies them.

**Venue**

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

**ANSWER**: Defendants restate and incorporate by reference their answers to each of the preceding paragraphs as if fully set forth herein.

21. Venue is proper in this district as to Zydus Pharmaceuticals (USA) Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Zydus Pharmaceuticals (USA) Inc. is a corporation organized and existing under the laws of the State of New Jersey, has a principal place of business in the State of New Jersey, and is subject to personal jurisdiction in this judicial district.

**ANSWER**: The allegations in paragraph 21 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this Court solely for the limited purpose of Plaintiff's claims against Zydus USA in this case and solely as they apply to Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 21.

22. Venue is proper in this district as to Zydus Lifesciences Ltd. pursuant to 28 U.S.C. §§ 1391 and/or 1400(b) because, *inter alia*, Zydus Lifesciences 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**: The allegations in paragraph 22 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this Court solely for the limited purpose of Plaintiff's claims against Zydus Lifesciences in this case and solely as they apply to Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 22.

## Factual Background

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

**ANSWER**: Defendants restate and incorporate by reference their answers to each of the preceding paragraphs as if fully set forth herein.

24. 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**: Zydus admits that FDA's Orange Book lists "CAPLYTA" as the Proprietary Name and "LUMATEPERONE TOSYLATE" as the Active Ingredient for NDA No. 209500. Zydus further admits that the CAPLYTA® prescribing information, revised June 2023, states, in part:

**----------INDICATIONS AND USAGE----------**

CAPLYTA is an atypical antipsychotic indicated for the treatment of:

- Schizophrenia in adults. (1)
- Depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate. (1)

Zydus denies all other allegations in paragraph 24.

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

**ANSWER**: Zydus admits that Zydus USA submitted ANDA No. 218652 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States and that ANDA No. 218652 identifies CAPLYTA as the Reference Listed Drug. Zydus further admits that Zydus USA's Notice Letter states in part that ANDA No. 218652 contains data from bioavailability or bioequivalence studies to obtain approval to engage in the commercial manufacture, use, sale, and importation of lumateperone capsules, 10.5 mg, 21 mg, and 42 mg. Zydus denies all other allegations in paragraph 25.

26. In Zydus's Notice Letter, Zydus stated that it had submitted Paragraph IV certifications to the FDA alleging that the Patents-in-Suit are invalid, unenforceable, and/or not infringed, and that Zydus is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Zydus's ANDA Product prior to the expiration of the Patents-in-Suit.

**ANSWER**: Zydus admits that Zydus USA's Notice Letter states that ANDA No. 218652 includes Paragraph IV Certifications with respect to the Patents-in-Suit stating that, in the opinion of Zydus and to the best of its knowledge, no valid and enforceable claim of the Patents-in-Suit will be infringed by the importation, manufacture, use, sale of, or offer to sell within the United States of Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 26.

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

**ANSWER**: Zydus admits that Zydus USA submitted ANDA No. 218652 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes Paragraph IV Certifications with respect to the Patents-in-Suit. Zydus denies all other allegations in paragraph 27.

28. Upon information and belief, Zydus's ANDA Product is not publicly available, nor is ANDA No. 218652 accessible to the public.

**ANSWER**: Admitted.

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

**ANSWER**: The allegations in paragraph 29 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that pursuant to 21 U.S.C. § 355(j)(5)(C), Zydus USA offered Plaintiff confidential access to ANDA No. 218652. Zydus denies all other allegations in paragraph 29.

30. In an exchange of correspondence, counsel for Plaintiff and counsel for Zydus discussed the terms of Zydus's Offer of Confidential Access. The parties did not agree on terms under which Plaintiff could review, among other things, Zydus's unredacted ANDA, any Drug Master File referred to therein, or all relevant characterization data. Zydus further refused to produce samples of Zydus's ANDA Product and other internal documents and material relevant to infringement.

**ANSWER**: The allegations in paragraph 30 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that pursuant to 21 U.S.C. § 355(j)(5)(C), Zydus USA offered Plaintiff confidential access to ANDA No. 218652. Zydus further admits that Plaintiff requested that Zydus USA provide information and materials beyond

what is required by 21 U.S.C. § 355(j)(5)(C)(III), including the Drug Master Files referenced in ANDA No. 218652, samples, data and other documents. Zydus further admits that Zydus USA and Plaintiff did not reach agreement. Zydus denies all other allegations in paragraph 30.

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

**ANSWER**: Zydus admits that Plaintiff received Zydus USA's Notice Letter on February 14, 2024. Zydus further admits that Plaintiff filed the Complaint alleging infringement of the Patents-In-Suit on March 28, 2024. Zydus denies all other allegations in paragraph 31.

**Count I—Infringement of the '345 Patent**

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

**ANSWER**: Defendants restate and incorporate by reference their answers to each of the preceding paragraphs as if fully set forth herein.

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

**ANSWER**: The allegations in paragraph 33 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '345 patent lists June 30, 2020 as the "Date of Patent" and is titled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" on the face of the patent. Zydus further admits that, on information and belief, what purports to be a copy of the '345 patent is attached to the Complaint as Exhibit A. Zydus denies all other allegations in paragraph 33.

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

**ANSWER**: The allegations in paragraph 34 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '345 patent lists Peng Li and

Robert Davis as the "Inventors" on the face of the patent. Zydus denies all other allegations in paragraph 34.

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

**ANSWER**: The allegations in paragraph 35 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '345 patent lists "Intra-Cellular Therapies, Inc." as the "Assignee" on the face of the patent and that "Intra-Cellular Therapies, Inc." is listed as the "Assignee" according to the electronic patent assignment listings of the United States Patent and Trademark Office ("USPTO") at Reel 052462, Frame 0142. Zydus denies all other allegations in paragraph 35.

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

**ANSWER**: The allegations in paragraph 36 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that FDA's Orange Book lists the '345 patent and "CAPLYTA" as the Proprietary Name in connection with NDA No. 209500. Zydus denies all other allegations in paragraph 36.

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

**ANSWER**: Zydus admits that Zydus USA transmitted its Notice Letter dated February 12, 2024 to Intra-Cellular Therapies, Inc., notifying it that Zydus USA submitted ANDA No. 218652 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes Paragraph IV Certifications

with respect to the Patents-In-Suit, including the '345 patent. Zydus denies all other allegations in paragraph 37.

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

**ANSWER**: Zydus admits that Zydus USA transmitted its Notice Letter dated February 12, 2024 to Intra-Cellular Therapies, Inc., notifying it that Zydus USA submitted ANDA No. 218652 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes a Paragraph IV Certification with respect to the '345 patent, stating that, the patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 38.

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

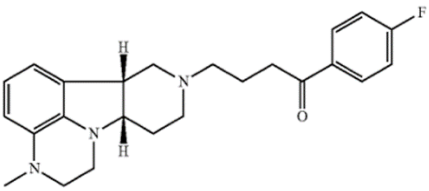
**ANSWER**: Zydus admits that Zydus USA's Notice Letter states in part that Zydus's Proposed ANDA Product is lumateperone capsules, 10.5 mg, 21 mg, and 42 mg. Zydus denies all other allegations in paragraph 39.

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

**ANSWER**: Denied.

41. As an example, claim 1 of the '345 patent recites:

A pharmaceutical capsule for oral administration, comprising lumateperone:

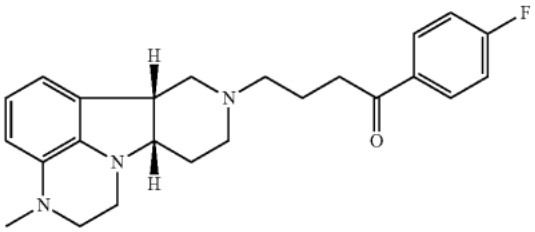


in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form; and

wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium, 0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule.

**ANSWER**: Zydus admits that claim 1 of the '345 patent states:

**1**. A pharmaceutical capsule for oral administration, comprising lumateperone:



in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form; and

wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium, 0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule.

Zydus denies that the importation, manufacture, use, sale of, or offer to sell within the United States of Zydus's Proposed ANDA Product would infringe any valid and enforceable claim of the '345 patent.

42. Upon information and belief, Zydus's ANDA Product is a pharmaceutical capsule for oral administration comprising lumateperone mono-tosylate in solid crystal form in a blend with the specific excipients in the specific amounts recited in claim 1.

**ANSWER**: The allegations in paragraph 42 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the importation, manufacture, use,

sale of, or offer to sell within the United States of Zydus's Proposed ANDA Product would infringe any valid and enforceable claim of the '345 patent. Zydus denies all other allegations in paragraph 42.

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

**ANSWER**: Denied.

44. Zydus's submission of Zydus's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product before the expiration of the '345 patent was an act of infringement of the '345 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER**: Denied.

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

**ANSWER**: Zydus admits that Zydus USA submitted ANDA No. 218652 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes Paragraph IV Certifications with respect to the Patents-In-Suit. Zydus denies all other allegations of paragraph 45.

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

**ANSWER**: Denied.

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

**ANSWER**: Denied.

48. Upon information and belief, Zydus plans and intends to, and will, actively induce infringement of the '345 patent when Zydus's ANDA is approved, and plans and intends to, and

will, do so immediately and imminently upon approval. Zydus's activities will be done with knowledge of the '345 patent and specific intent to infringe that patent.

**ANSWER**: Denied.

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

**ANSWER**: Denied.

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

**ANSWER**: Zydus admits that Zydus USA submitted ANDA No. 218652 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes Paragraph IV Certifications with respect to the Patents-In-Suit, including the '345 patent. Zydus denies all other allegations of paragraph 50.

51. The foregoing actions by Zydus constitute and/or will constitute infringement of the '345 patent; active inducement of infringement of the '345 patent; and/or contribution to the infringement by others of the '345 patent.

**ANSWER**: Denied.

52. Upon information and belief, Zydus has acted with full knowledge of the '345 patent and without a reasonable basis for believing that it would not be liable for infringement of the '345 patent; active inducement of infringement of the '345 patent; and/or contribution to the infringement by others of the '345 patent.

**ANSWER**: Denied.

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

**ANSWER**: Denied.

54. Unless Zydus is enjoined from infringing the '345 patent, actively inducing infringement of the '345 patent, and contributing to the infringement by others of the '345 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

**ANSWER**: Denied.

**Count II—Declaratory Judgment of Infringement of the '345 Patent**

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

**ANSWER**: Defendants restate and incorporate by reference their answers to each of the preceding paragraphs as if fully set forth herein.

56. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Zydus on the other regarding Zydus's infringement, active inducement of infringement, contribution to the infringement by others of the '345 patent, and/or the validity of the '345 patent.

**ANSWER**: The allegations in paragraph 56 state legal conclusions to which no answer is required, to the extent an answer is required, Zydus denies that the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus's Proposed ANDA Product would infringe any valid and enforceable claim of the '345 patent.

57. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Zydus's ANDA Product with its proposed labeling, or any other Zydus drug product that is covered by or whose use is covered by the '345 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '345 patent, and that the claims of the '345 patent are not invalid.

**ANSWER**: Denied.

**Count III—Infringement of the '084 Patent**

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

**ANSWER**: Defendants restate and incorporate by reference their answers to each of the preceding paragraphs as if fully set forth herein.

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

**ANSWER**: The allegations in paragraph 59 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '084 patent lists July 6, 2021 as the "Date of Patent" and is titled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" on the face of the patent. Zydus further admits that, on information and belief, what purports to be a copy of the '084 patent is attached to the Complaint as Exhibit B. Zydus denies all other allegations in paragraph 59.

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

**ANSWER**: The allegations in paragraph 60 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '084 patent lists Peng Li and Robert Davis as the "Inventors" on the face of the patent. Zydus denies all other allegations in paragraph 60.

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

**ANSWER**: The allegations in paragraph 61 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '084 patent lists "Intra-Cellular Therapies, Inc." as the "Assignee" on the face of the patent and that "Intra-Cellular Therapies, Inc." is listed as the "Assignee" according to the electronic patent assignment listings of the USPTO at Reel 055218, Frame 0198. Zydus denies all other allegations in paragraph 61.

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

**ANSWER**: The allegations in paragraph 62 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that FDA's Orange Book lists the '084 patent and "CAPLYTA" as the Proprietary Name in connection with NDA No. 209500. Zydus denies all other allegations in paragraph 62.

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

**ANSWER**: Zydus admits that Zydus USA transmitted its Notice Letter dated February 12, 2024 to Intra-Cellular Therapies, Inc., notifying it that Zydus USA submitted ANDA No. 218652 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes Paragraph IV Certifications with respect to the Patents-In-Suit, including the '084 patent. Zydus denies all other allegations in paragraph 63.

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

**ANSWER**: Zydus admits that Zydus USA transmitted its Notice Letter dated February 12, 2024 to Intra-Cellular Therapies, Inc., notifying it that Zydus USA submitted ANDA No. 218652 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes a Paragraph IV Certification with respect to the '084 patent, stating that, the patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 64.

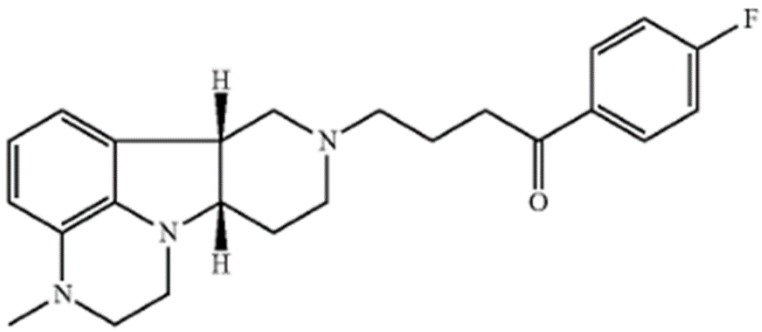
65. According to Zydus's Notice Letter, Zydus's ANDA Product contains lumateperone.

**ANSWER**: Zydus admits that Zydus USA's Notice Letter states in part that Zydus's Proposed ANDA Product is lumateperone capsules, 10.5 mg, 21 mg, and 42 mg. Zydus denies all other allegations in paragraph 65.

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

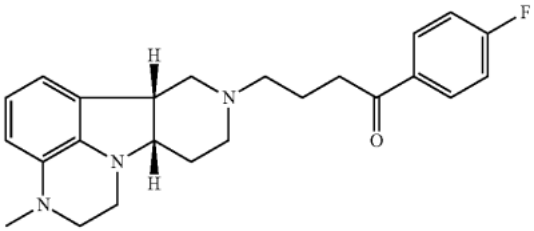
**ANSWER**: Denied.

67. As an example, claim 1 of the '084 patent recites:

> A pharmaceutical capsule for oral administration, comprising lumateperone:
>
> 
> 
>
> in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form; and wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium, 0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule, wherein the capsule comprises the lumateperone mono-tosylate in an amount equivalent to 0.01 to 30 mg of lumateperone free base.

**ANSWER**: Zydus admits that claim 1 of the '084 patent states:

1. A pharmaceutical capsule for oral administration, comprising lumateperone:




in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form; and

wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium, 0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule,

wherein the capsule comprises the lumateperone mono-tosylate in an amount equivalent to 0.01 to 30 mg of lumateperone free base.

Zydus denies that the importation, manufacture, use, sale of, or offer to sell within the United States of Zydus's Proposed ANDA Product would infringe any valid and enforceable claim of the '084 patent.

68. Upon information and belief, Zydus's ANDA Product is a pharmaceutical capsule for oral administration comprising 0.01 to 30 mg of lumateperone mono-tosylate in solid crystal form (measured as the free base) and the specific excipients in the specific amounts recited in claim 1.

**ANSWER**: The allegations in paragraph 68 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the importation, manufacture, use, sale of, or offer to sell within the United States of Zydus's Proposed ANDA Product would infringe any valid and enforceable claim of the '084 patent. Zydus denies all other allegations in paragraph 68.

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

**ANSWER**: Denied.

70. Zydus's submission of Zydus's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product before the expiration of the '084 patent was an act of infringement of the '084 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER**: Denied.

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

**ANSWER**: Zydus admits that Zydus USA submitted ANDA No. 218652 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes Paragraph IV Certifications with respect to the Patents-In-Suit. Zydus denies all other allegations of paragraph 71.

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

**ANSWER**: Denied.

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

**ANSWER**: Denied.

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

**ANSWER**: Denied.

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

**ANSWER**: Denied.

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

**ANSWER**: Zydus admits that Zydus USA submitted ANDA No. 218652 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes Paragraph IV Certifications with respect to the Patents-In-Suit, including the '084 patent. Zydus denies all other allegations of paragraph 76.

77. The foregoing actions by Zydus constitute and/or will constitute infringement of the '084 patent; active inducement of infringement of the '084 patent; and/or contribution to the infringement by others of the '084 patent.

**ANSWER**: Denied.

78. Upon information and belief, Zydus has acted with full knowledge of the '084 patent and without a reasonable basis for believing that it would not be liable for infringement of the '084 patent; active inducement of infringement of the '084 patent; and/or contribution to the infringement by others of the '084 patent.

**ANSWER**: Denied.

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

**ANSWER**: Denied.

80. Unless Zydus is enjoined from infringing the '084 patent, actively inducing infringement of the '084 patent, and contributing to the infringement by others of the '084 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

**ANSWER**: Denied.

**Count IV—Declaratory Judgment of Infringement of the '084 Patent**

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

**ANSWER**: Defendants restate and incorporate by reference their answers to each of the preceding paragraphs as if fully set forth herein.

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

**ANSWER**: The allegations in paragraph 82 state legal conclusions to which no answer is required, to the extent an answer is required, Zydus denies that the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus's Proposed ANDA Product would infringe any valid and enforceable claim of the '084 patent.

83. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Zydus's ANDA Product with its proposed labeling, or any other Zydus drug product that is covered by or whose use is covered by the '084 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '084 patent, and that the claims of the '084 patent are not invalid.

**ANSWER**: Denied.

**Count V—Infringement of the '842 Patent**

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

**ANSWER**: Defendants restate and incorporate by reference their answers to each of the preceding paragraphs as if fully set forth herein.

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

**ANSWER**: The allegations in paragraph 85 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '842 patent lists July 4, 2023 as the "Date of Patent" and is titled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" on the face of the patent. Zydus further admits that, on information

and belief, what purports to be a copy of the '842 patent is attached to the Complaint as Exhibit C. Zydus denies all other allegations in paragraph 85.

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

**ANSWER**: The allegations in paragraph 86 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '842 patent lists Peng Li and Robert Davis as the "Inventors" on the face of the patent. Zydus denies all other allegations in paragraph 86.

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

**ANSWER**: The allegations in paragraph 87 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '842 patent lists "Intra-Cellular Therapies, Inc." as the "Assignee" on the face of the patent and that "Intra-Cellular Therapies, Inc." is listed as the "Assignee" according to the electronic patent assignment listings of the USPTO at Reel 058016, Frame 0364. Zydus denies all other allegations in paragraph 87.

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

**ANSWER**: The allegations in paragraph 88 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that FDA's Orange Book lists the '842 patent and "CAPLYTA" as the Proprietary Name in connection with NDA No. 209500. Zydus denies all other allegations in paragraph 88.

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

**ANSWER**: Zydus admits that Zydus USA transmitted its Notice Letter dated February 12, 2024 to Intra-Cellular Therapies, Inc., notifying it that Zydus USA submitted ANDA No.

218652 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes Paragraph IV Certifications with respect to the Patents-In-Suit, including the '842 patent. Zydus denies all other allegations in paragraph 89.

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

**ANSWER**: Zydus admits that Zydus USA transmitted its Notice Letter dated February 12, 2024 to Intra-Cellular Therapies, Inc., notifying it that Zydus USA submitted ANDA No. 218652 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes a Paragraph IV Certification with respect to the '842 patent, stating that, the patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 90.

91. According to Zydus's Notice Letter, Zydus's ANDA Product contains lumateperone.

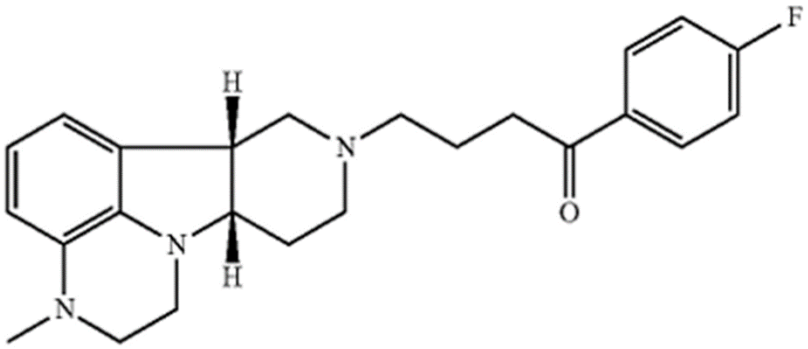
**ANSWER**: Zydus admits that Zydus USA's Notice Letter states in part that Zydus's Proposed ANDA Product is lumateperone capsules, 10.5 mg, 21 mg, and 42 mg. Zydus denies all other allegations in paragraph 91.

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

**ANSWER**: Denied.

93. As an example, claim 1 of the ’842 patent recites:

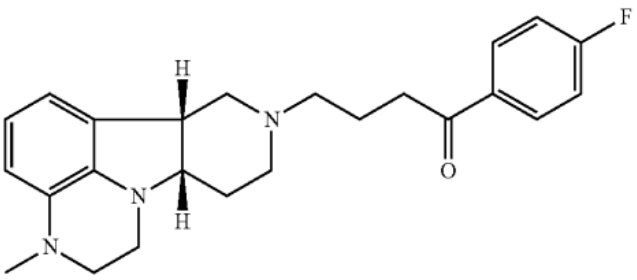
A pharmaceutical capsule for oral administration, comprising lumateperone:




in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form; and wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium, 0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule, and wherein a single capsule dissolves in 500 mL of 0.1N aqueous hydrochloric acid to the extent of at least 85% after 15 minutes, and/or to the extent of at least 92% after 30 minutes, and/or to the extent of at least 94% after 45 minutes.

**ANSWER**: Zydus admits that claim 1 of the ’842 patent states:

1. A pharmaceutical capsule for oral administration, comprising lumateperone:




in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form; and

wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium, 0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule, and

wherein a single capsule dissolves in 500 mL of 0.1N aqueous hydrochloric acid to the extent of at least 85% after 15 minutes, and/or to the extent of at least 92% after 30 minutes, and/or to the extent of at least 94% after 45 minutes.

Zydus denies that the importation, manufacture, use, sale of, or offer to sell within the United States of Zydus's Proposed ANDA Product would infringe any valid and enforceable claim of the '842 patent.

94. Upon information and belief, Zydus's ANDA Product is a pharmaceutical capsule for oral administration comprising lumateperone mono-tosylate in solid crystal form and the specific excipients in the specific amounts recited in claim 1 and possessing the specific dissolution profile recited in claim 1.

**ANSWER**: The allegations in paragraph 94 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the importation, manufacture, use, sale of, or offer to sell within the United States of Zydus's Proposed ANDA Product would infringe any valid and enforceable claim of the '842 patent. Zydus denies all other allegations in paragraph 94.

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

**ANSWER**: Denied.

96. Zydus's submission of Zydus's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product before the expiration of the '842 patent was an act of infringement of the '842 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER**: Denied.

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

**ANSWER**: Zydus admits that Zydus USA submitted ANDA No. 218652 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes Paragraph IV Certifications with respect to the Patents-In-Suit. Zydus denies all other allegations of paragraph 97.

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

**ANSWER**: Denied.

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

**ANSWER**: Denied.

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

**ANSWER**: Denied.

101. Upon information and belief, Zydus knows that Zydus's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '842 patent, that Zydus's

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

**ANSWER**: Denied.

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

**ANSWER**: Zydus admits that Zydus USA submitted ANDA No. 218652 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes Paragraph IV Certifications with respect to the Patents-In-Suit, including the '842 patent. Zydus denies all other allegations of paragraph 102.

103. The foregoing actions by Zydus constitute and/or will constitute infringement of the '842 patent; active inducement of infringement of the '842 patent; and/or contribution to the infringement by others of the '842 patent.

**ANSWER**: Denied.

104. Upon information and belief, Zydus has acted with full knowledge of the '842 patent and without a reasonable basis for believing that it would not be liable for infringement of the '842 patent; active inducement of infringement of the '842 patent; and/or contribution to the infringement by others of the '842 patent.

**ANSWER**: Denied.

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

**ANSWER**: Denied.

106. Unless Zydus is enjoined from infringing the '842 patent, actively inducing infringement of the '842 patent, and contributing to the infringement by others of the '842 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

**ANSWER**: Denied.

**Count VI—Declaratory Judgment of Infringement of the '842 Patent**

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

**ANSWER**: Defendants restate and incorporate by reference their answers to each of the preceding paragraphs as if fully set forth herein.

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

**ANSWER**: The allegations in paragraph 108 state legal conclusions to which no answer is required, to the extent an answer is required, Zydus denies that the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus's Proposed ANDA Product would infringe any valid and enforceable claim of the '842 patent.

109. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Zydus's ANDA Product with its proposed labeling, or any other Zydus drug product that is covered by or whose use is covered by the '842 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '842 patent, and that the claims of the '842 patent are not invalid.

**ANSWER**: Denied.

**Count VII—Infringement of the '348 Patent**

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

**ANSWER**: Defendants restate and incorporate by reference their answers to each of the preceding paragraphs as if fully set forth herein.

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

**ANSWER**: The allegations in paragraph 111 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '348 patent lists November 7, 2023 as the "Date of Patent" and is titled "Methods of Treatment Using Pharmaceutical Capsule

Compositions Comprising Lumateperone Mono-Tosylate" on the face of the patent. Zydus further admits that, on information and belief, what purports to be a copy of the '348 patent is attached to the Complaint as Exhibit D. Zydus denies all other allegations in paragraph 111.

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

**ANSWER**: The allegations in paragraph 112 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '348 patent lists Peng Li and Robert Davis as the "Inventors" on the face of the patent. Zydus denies all other allegations in paragraph 112.

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

**ANSWER**: The allegations in paragraph 113 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '348 patent lists "Intra-Cellular Therapies, Inc." as the "Assignee" on the face of the patent and that "Intra-Cellular Therapies, Inc." is listed as the "Assignee" according to the electronic patent assignment listings of the USPTO at Reel 059336, Frame 0500. Zydus denies all other allegations in paragraph 113.

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

**ANSWER**: The allegations in paragraph 114 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that FDA's Orange Book lists the '348 patent and "CAPLYTA" as the Proprietary Name in connection with NDA No. 209500. Zydus denies all other allegations in paragraph 114.

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

**ANSWER**: Zydus admits that Zydus USA transmitted its Notice Letter dated February 12, 2024 to Intra-Cellular Therapies, Inc., notifying it that Zydus USA submitted ANDA No. 218652 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes Paragraph IV Certifications with respect to the Patents-In-Suit, including the '348 patent. Zydus denies all other allegations in paragraph 115.

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

**ANSWER**: Zydus admits that Zydus USA transmitted its Notice Letter dated February 12, 2024 to Intra-Cellular Therapies, Inc., notifying it that Zydus USA submitted ANDA No. 218652 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes Paragraph IV Certifications with respect to the '348 patent, stating that, the patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 116.

117. According to Zydus's Notice Letter, Zydus's ANDA Product contains lumateperone.

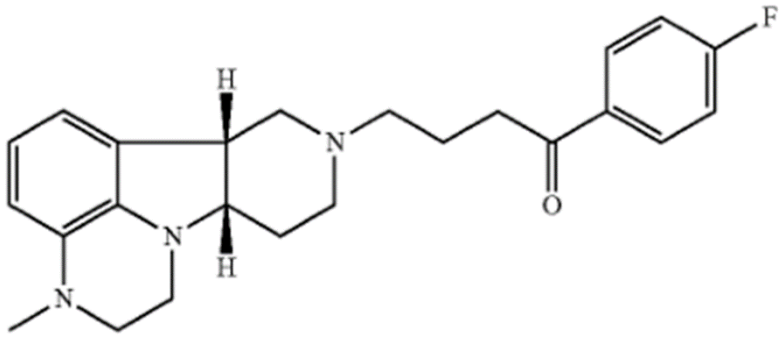
**ANSWER**: Zydus admits that Zydus USA's Notice Letter states in part that Zydus's Proposed ANDA Product is lumateperone capsules, 10.5 mg, 21 mg, and 42 mg. Zydus denies all other allegations in paragraph 117.

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

**ANSWER**: Denied.

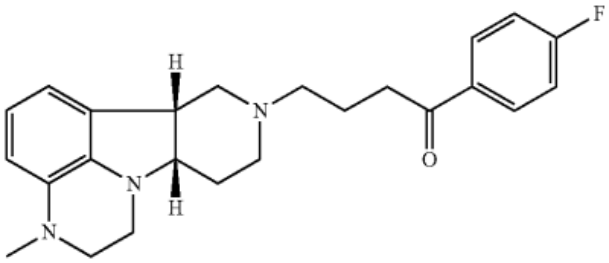
119. As an example, claim 1 of the '348 patent recites:

> A method for the treatment of a disease or disorder involving or mediated by the 5-HT2A receptor, serotonin transporter (SERT), and/or dopamine D1/D2 receptor signaling pathways, comprising administering to a patient in need thereof a pharmaceutical capsule for oral administration, comprising lumateperone:




> in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form; and wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium, 0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule, wherein the capsule comprises the lumateperone mono-tosylate in an amount equivalent to 0.01 to 30 mg or 35 to 45 mg of lumateperone free base.

**ANSWER**: Zydus admits that claim 1 of the '348 patent states:

> **1**. A method for the treatment of a disease or disorder involving or mediated by the 5-$HT_{2A}$ receptor, serotonin transporter (SERT), and/or dopamine D1/D2 receptor signaling pathways, comprising administering to a patient in need thereof a pharmaceutical capsule for oral administration, comprising lumateperone:
>
> 
>
> in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form; and
>
> wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium, 0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule,
>
> wherein the capsule comprises the lumateperone mono-tosylate in an amount equivalent to 0.01 to 30 mg or 35 to 45 mg of lumateperone free base.

Zydus denies that the importation, manufacture, use, sale of, or offer to sell within the United States of Zydus's Proposed ANDA Product would infringe any valid and enforceable claim of the '348 patent.

120. Upon information and belief, the use of Zydus's ANDA Product in accordance with and as directed by Zydus's proposed label would involve treating a disease or disorder involving or mediated by the 5-HT2A receptor, serotonin transporter (SERT), and/or dopamine D1/D2 receptor signaling pathways, including by administering to the patient in need thereof a pharmaceutical capsule for oral administration comprising 0.01 to 30 mg or 35 to 45 mg of lumateperone mono-tosylate in solid crystal form (measured as the free base) and the specific excipients in the specific amounts recited in claim 1.

**ANSWER**: The allegations in paragraph 120 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the importation, manufacture, use, sale of, or offer to sell within the United States of Zydus's Proposed ANDA Product would infringe

any valid and enforceable claim of the '348 patent. Zydus denies all other allegations in paragraph 120.

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

**ANSWER**: Denied.

122. Zydus's submission of Zydus's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product before the expiration of the '348 patent was an act of infringement of the '348 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER**: Denied.

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

**ANSWER**: Zydus admits that Zydus USA submitted ANDA No. 218652 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes Paragraph IV Certifications with respect to the Patents-In-Suit. Zydus denies all other allegations of paragraph 123.

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

**ANSWER**: Denied.

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

**ANSWER**: Denied.

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

**ANSWER**: Denied.

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

**ANSWER**: Denied.

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

**ANSWER**: Zydus admits that Zydus USA submitted ANDA No. 218652 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes Paragraph IV Certifications with respect to the Patents-In-Suit, including the '384 patent. Zydus denies all other allegations of paragraph 128.

129. The foregoing actions by Zydus constitute and/or will constitute infringement of the '348 patent; active inducement of infringement of the '348 patent; and/or contribution to the infringement by others of the '348 patent.

**ANSWER**: Denied.

130. Upon information and belief, Zydus has acted with full knowledge of the '348 patent and without a reasonable basis for believing that it would not be liable for infringement of the '348 patent; active inducement of infringement of the '348 patent; and/or contribution to the infringement by others of the '348 patent.

**ANSWER**: Denied.

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

**ANSWER**: Denied.

132. Unless Zydus is enjoined from infringing the '348 patent, actively inducing infringement of the '348 patent, and contributing to the infringement by others of the '348 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

**ANSWER**: Denied.

**Count VIII—Declaratory Judgment of Infringement of the '348 Patent**

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

**ANSWER**: Defendants restate and incorporate by reference their answers to each of the preceding paragraphs as if fully set forth herein.

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

**ANSWER**: The allegations in paragraph 134 state legal conclusions to which no answer is required, to the extent an answer is required, Zydus denies that the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus's Proposed ANDA Product would infringe any valid and enforceable claim of the '348 patent.

135. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Zydus's ANDA Product with its proposed labeling, or any other Zydus drug product that is covered by or whose use is covered by the '348 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '348 patent, and that the claims of the '348 patent are not invalid.

**ANSWER**: Denied.

**Count IX—Infringement of the '419 Patent**

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

**ANSWER**: Defendants restate and incorporate by reference their answers to each of the preceding paragraphs as if fully set forth herein.

137. The '419 patent, entitled "4-((6br,10as)-3-methyl-2,3,6b,9,10,10a-hexahydro-1h-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7h)-yl)-1-(4-((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 E), was duly and legally issued on September 12, 2023.

**ANSWER**: The allegations in paragraph 137 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '419 patent lists September 12, 2023 as the "Date of Patent" and is titled "4-((6br,10as)-3-methyl-2,3,6b,9,10,10a-hexahydro-1h-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7h)-yl)-1-(4-((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" on the face of the patent. Zydus further admits that, on information and belief, what purports to be a copy of the '419 patent is attached to the Complaint as Exhibit E. Zydus denies all other allegations in paragraph 137.

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

**ANSWER**: The allegations in paragraph 138 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '419 patent lists Peng Li, Robert E. Davis, and Kimberly Vanover as the "Inventors" on the face of the patent. Zydus denies all other allegations in paragraph 138.

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

**ANSWER**: The allegations in paragraph 139 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the '419 patent lists "Intra-Cellular Therapies, Inc." as the "Assignee" on the face of the patent and that "Intra-Cellular Therapies, Inc." is listed as the "Assignee" according to the electronic patent assignment listings of the USPTO at Reel 060172, Frame 0551. Zydus denies all other allegations in paragraph 139.

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

**ANSWER**: The allegations in paragraph 140 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that FDA's Orange Book lists the '419

patent and "CAPLYTA" as the Proprietary Name in connection with NDA No. 209500. Zydus denies all other allegations in paragraph 140.

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

**ANSWER**: Zydus admits that Zydus USA transmitted its Notice Letter dated February 12, 2024 to Intra-Cellular Therapies, Inc., notifying it that Zydus USA submitted ANDA No. 218652 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes Paragraph IV Certifications with respect to the Patents-In-Suit, including the '419 patent. Zydus denies all other allegations in paragraph 141.

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

**ANSWER**: Zydus admits that Zydus USA transmitted its Notice Letter dated February 12, 2024 to Intra-Cellular Therapies, Inc., notifying it that ANDA No. 218652 includes Paragraph IV Certifications with respect to the '419 patent, stating that, the patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Zydus's Proposed ANDA Product. Zydus denies all other allegations in paragraph 142.

143. According to Zydus's Notice Letter, Zydus's ANDA Product contains lumateperone.

**ANSWER**: Zydus admits that Zydus USA's Notice Letter states in part that Zydus's Proposed ANDA Product is lumateperone capsules, 10.5 mg, 21 mg, and 42 mg. Zydus denies all other allegations in paragraph 143.

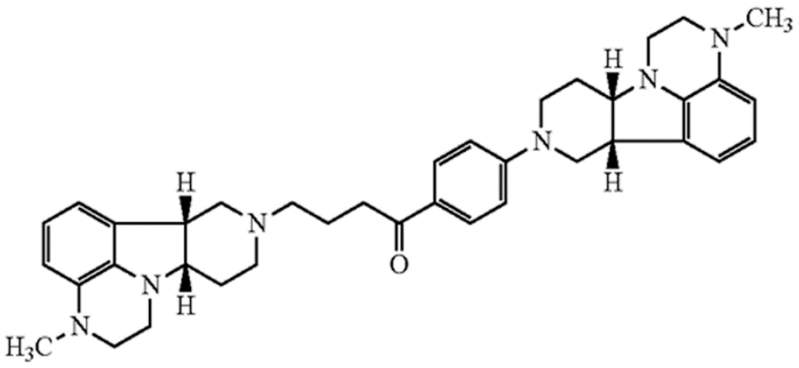
144. Upon information and belief, Zydus's ANDA Product and the use of Zydus's ANDA Product are covered by one or more claims of the '419 patent, either literally or under the doctrine of equivalents.

**ANSWER**: Denied.

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

A compound of Formula I:

Formula I

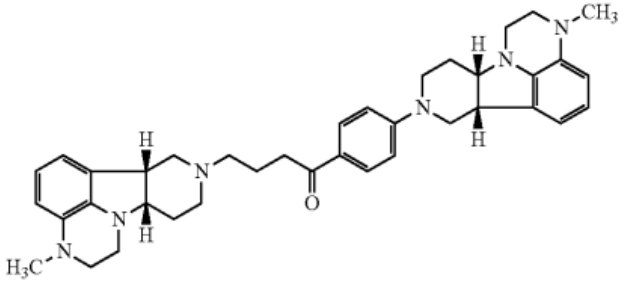


in free base or pharmaceutically acceptable salt form.

**ANSWER**: Zydus admits that claim 1 of the '419 patent states:

**1**. A compound of Formula I:

Formula I



in free base or pharmaceutically acceptable salt form.

Zydus denies that the importation, manufacture, use, sale of, or offer to sell within the United States of Zydus's Proposed ANDA Product would infringe any valid and enforceable claim of the '419 patent.

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

**ANSWER**: The allegations in paragraph 146 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus denies that the importation, manufacture, use, sale of, or offer to sell within the United States of Zydus's Proposed ANDA Product would infringe any valid and enforceable claim of the '419 patent. Zydus denies all other allegations in paragraph 146.

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

**ANSWER**: Denied.

148. Zydus's submission of Zydus's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Product before the expiration of the '419 patent was an act of infringement of the '419 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER**: Denied.

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

**ANSWER**: Zydus admits that Zydus USA submitted ANDA No. 218652 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes Paragraph IV Certifications with respect to the Patents-In-Suit. Zydus denies all other allegations of paragraph 149.

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

**ANSWER**: Denied.

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

**ANSWER**: Denied.

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

**ANSWER**: Denied.

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

**ANSWER**: Denied.

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

**ANSWER**: Zydus admits that Zydus USA submitted ANDA No. 218652 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the manufacture, use, sale, or offer to sell within, and/or importation of Zydus's Proposed ANDA Product in or into the United States. Zydus further admits that ANDA No. 218652 includes Paragraph IV Certifications with respect to the Patents-In-Suit, including the '419 patent. Zydus denies all other allegations of paragraph 154.

155. The foregoing actions by Zydus constitute and/or will constitute infringement of the '419 patent; active inducement of infringement of the '419 patent; and/or contribution to the infringement by others of the '419 patent.

**ANSWER**: Denied.

156. Upon information and belief, Zydus has acted with full knowledge of the '419 patent and without a reasonable basis for believing that it would not be liable for infringement of the '419 patent; active inducement of infringement of the '419 patent; and/or contribution to the infringement by others of the '419 patent.

**ANSWER**: Denied.

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

**ANSWER**: Denied.

158. Unless Zydus is enjoined from infringing the '419 patent, actively inducing infringement of the '419 patent, and contributing to the infringement by others of the '419 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

**ANSWER**: Denied.

**Count X—Declaratory Judgment of Infringement of the '419 Patent**

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

**ANSWER**: Defendants restate and incorporate by reference their answers to each of the preceding paragraphs as if fully set forth herein.

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

**ANSWER**: The allegations in paragraph 160 state legal conclusions to which no answer is required, to the extent an answer is required, Zydus denies that the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus's Proposed ANDA Product would infringe any valid and enforceable claim of the '419 patent.

161. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Zydus's ANDA Product with its proposed labeling, or any other Zydus drug product that is covered by or whose use is covered by the '419 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '419 patent, and that the claims of the '419 patent are not invalid.

**ANSWER**: Denied.

**PRAYER FOR RELIEF**

Defendants specifically deny that Plaintiff are entitled to the general or specific relief requested against Defendants, or to any relief whatsoever, and pray for judgment in favor of Defendants dismissing this action with prejudice, and awarding Defendants their reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

**AFFIRMATIVE DEFENSES**

Without prejudice to the denials set forth in their Answer and without admitting any allegations of the Complaint not otherwise admitted, Defendants aver and assert the following Affirmative Defenses to Plaintiff's Complaint.

**FIRST AFFIRMATIVE DEFENSE**
**(Noninfringement of U.S. Patent No. 10,695,345)**

Plaintiff will not and cannot meet the burden of proof required to show that the submission of ANDA No. 218652 and/or the manufacture, use, sale, or offer to sell within, and/or importation in or into the United States of Zydus's Proposed ANDA Product that is the subject of ANDA No. 218652 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '345 patent.

**SECOND AFFIRMATIVE DEFENSE**
**(Invalidity of U.S. Patent No. 10,695,345)**

Upon information and belief, the claims of the '345 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

**THIRD AFFIRMATIVE DEFENSE**
**(Noninfringement of U.S. Patent No. 11,052,084)**

Plaintiff will not and cannot meet the burden of proof required to show that the submission of ANDA No. 218652 and/or the manufacture, use, sale, or offer to sell within, and/or importation in or into the United States of Zydus's Proposed ANDA Product that is the subject of ANDA No. 218652 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '084 patent.

**FOURTH AFFIRMATIVE DEFENSE**
**(Invalidity of U.S. Patent No. 11,052,084)**

Upon information and belief, the claims of the '084 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

**FIFTH AFFIRMATIVE DEFENSE**
**(Noninfringement of U.S. Patent No. 11,690,842)**

Plaintiffs will not and cannot meet the burden of proof required to show that the submission of ANDA No. 218652 and/or the manufacture, use, sale, or offer to sell within, and/or importation in or into the United States of Zydus's Proposed ANDA Product that is the subject of ANDA No. 218652 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '842 patent.

**SIXTH AFFIRMATIVE DEFENSE**
**(Invalidity of U.S. Patent No. 11,690,842)**

Upon information and belief, the claims of the '842 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

**SEVENTH AFFIRMATIVE DEFENSE**
**(Noninfringement of U.S. Patent No. 11,753,419)**

Plaintiff will not and cannot meet the burden of proof required to show that the submission of ANDA No. 218652 and/or the manufacture, use, sale, or offer to sell within, and/or importation in or into the United States of Zydus's Proposed ANDA Product that is the subject of ANDA No. 218652 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '419 patent.

**EIGTH AFFIRMATIVE DEFENSE**
**(Invalidity of U.S. Patent No. 11,753,419)**

Upon information and belief, the claims of the '419 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

**NINTH AFFIRMATIVE DEFENSE**
**(Noninfringement of U.S. Patent No. 11,806,348)**

Plaintiff will not and cannot meet the burden of proof required to show that the submission of ANDA No. 218652 and/or the manufacture, use, sale, or offer to sell within, and/or importation in or into the United States of Zydus's Proposed ANDA Product that is the subject of ANDA No. 218652 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '348 patent.

**TENTH AFFIRMATIVE DEFENSE**
**(Invalidity of U.S. Patent No. 11,806,348)**

Upon information and belief, the claims of the '348 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

Dated: July 1, 2024

Respectfully submitted,

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**LOCAL CIVIL RULE 11.2 CERTIFICATION**

Pursuant to Local Civil Rule 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, except that the same plaintiff has asserted the patent in this case in the following pending matters in this Judicial District: *Intra-Cellular Therapies, Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 3:24-cv-04264 (D.N.J.), *Intra-Cellular Therapies, Inc. v. Alkem Lab'ys Ltd.*, C.A. No. 3:24-04312 (D.N.J.); *Intra-Cellular Therapies, Inc. v. Dr. Reddy's Lab'ys Inc.*, C.A. No. 3:24-cv-04314 (D.N.J.); *Intra-Cellular Therapies, Inc. v. Hetero USA Inc.*, C.A. No. 3:24-cv-04317 (D.N.J.); *Intra-Cellular Therapies, Inc. v. MSN Lab'ys Pvt. Ltd.*, C.A. No. 3:24-cv-04325 (D.N.J.); *Intra-Cellular Therapies, Inc. v. Sandoz Inc.*, C.A. No. 3:24-cv-04327 (D.N.J.). Defendants are not aware of any other action pending in any court or any pending arbitration or administrative proceeding related to this matter.

Theodora McCormick

Dated: July 1, 2024

**LOCAL CIVIL RULE 201.1 CERTIFICATION**

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Theodora McCormick

Dated: July 1, 2024

**CERTIFICATE OF SERVICE**

The undersigned attorney certifies that a copy of Defendants' Answer and Affirmative Defenses was filed via ECF and served on all counsel of record by electronic mail on July 1, 2024.

Theodora McCormick

Dated: July 1, 2024