MIDLIGE RICHTER, LLC
645 Martinsville Road
Basking Ridge, New Jersey 07920
(908) 626-0622
James S. Richter

Of Counsel (Pro Hac Vice Forthcoming)
William A. Rakoczy (wrakoczy@rmmslegal.com)
Tara M. Raghavan (traghavan@rmmslegal.com)
Dylan Sacenti (dsacenti@rmmslegal.com)
Wojciech Jankiewicz (wjankiewicz@rmmslegal.com)
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, Illinois 60654
(312) 527-2157

Attorneys for Defendant,
MSN Laboratories Private Ltd.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

INTRA-CELLULAR THERAPIES, INC.,	:	Honorable Michael A. Shipp, U.S.D.J.
Plaintiff.	:	Civil Action No. 24 CV 4325 (MAS)(JBD)
v.	:	
MSN LABORATORIES PRIVATE LTD.,	:	**MSN LABORATORIES PRIVATE LTD.'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO COMPLAINT FOR PATENT INFRINGEMENT**
Defendant.	:	

MSN Laboratories Private Ltd., ("Defendant" or "MSN"), hereby provides its answers and asserts the following defenses to the Complaint for Patent Infringement of Intra-Cellular Therapies, Inc. ("Plaintiff," "Intra-Cellular Therapies," or "ITCI"), as follows.

GENERAL DENIAL

Pursuant to Federal Rule of Civil Procedure 8(b)(3), Defendant denies all allegations in Plaintiff's Complaint for Patent Infringement except those specifically admitted below.

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq*., and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, 35 U.S.C. § 100 *et seq*., that arises out of MSN's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of CAPLYTA® (lumateperone) capsules, 10.5 mg, 21 mg, and 42 mg, prior to the expiration of U.S. Patent Nos. 9,956,227 ("the '227 patent"), 10,695,345 ("the '345 patent"), 10,960,009 ("the '009 patent"), 11,026,951 ("the '951 patent"), 11,052,084 ("the '084 patent"), 11,690,842 ("the '842 patent"), 11,753,419 ("the '419 patent"), 11,806,348 ("the '348 patent"), and RE48,839 ("the RE '839 patent"). These patents are referred to collectively herein as the "Patents-in-Suit."

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that the Complaint purports to state a claim for alleged patent infringement. MSN further admits that MSN submitted an Abbreviated New Drug Application ("MSN's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval for lumateperone capsules, 10.5 mg, 21 mg and 42 mg ("MSN's ANDA Product") prior to the expiration of U.S. Patent Nos. 9,956,227 ("the '227 patent"), 10,695,345 ("the '345 patent"), 10,960,009 ("the '009 patent"), 11,026,951 ("the '951 patent"), 11,052,084 ("the '084 patent"), 11,690,842 ("the '842 patent"), 11,753,419 ("the '419 patent"), 11,806,348 ("the '348 patent"), and RE48,839 ("the RE '839 patent") (collectively, "Asserted Patents"). MSN denies any and all remaining allegations of Paragraph 1.

2. MSN notified Plaintiff by letter dated February 16, 2024 ("MSN's Notice Letter") that it had submitted to the FDA ANDA No. 219248 ("MSN'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, ("MSN's ANDA Product") prior to the expiration of the Patents-in-Suit.

ANSWER: Paragraph 2 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN, by a letter dated February 16, 2024 ("MSN's Notice Letter"), properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Plaintiff Intra-Cellular Therapies, Inc. that MSN submitted ANDA No. 219248 to FDA seeking approval to market MSN's ANDA Product prior to the expiration of the Asserted Patents. MSN denies any and all remaining allegations of Paragraph 2.

The Parties

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

ANSWER: MSN restates and incorporates by reference each of its responses 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: Paragraph 4 contains legal conclusions to which no answer is required. To the extent MSN is required to answer, MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 4, and therefore denies any and all allegations of Paragraph 4.

5. Upon information and belief, Defendant MSN Laboratories Private Ltd. is a corporation organized and existing under the laws of the Republic of India and having a principal place of business at MSN House, Plot No. C 24, Sanath Nagar Industrial Estate, Sanathnagar, Hyderabad, Telangana, India, 500018.

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN Laboratories Private Ltd. is a Private Limited company organized and existing under the laws of India, with a principal place of

business at MSN House, Plot No.: C-24, Industrial Estate, Sanathnagar, Hyderabad – 500018 Telangana, India. MSN denies any and all remaining allegations of Paragraph 5.

6. Upon information and belief, MSN is in the business of, among other things, importing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, MSN knows and intends that upon approval of MSN's ANDA, MSN will manufacture MSN's ANDA Product and MSN will directly or indirectly market, sell, and distribute MSN's ANDA Product throughout the United States, including in New Jersey.

ANSWER: Paragraph 6 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, denied.

Jurisdiction

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

8. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1338(a), and [*sic*] 2201 and 2202.

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN states that for the limited purposes of this action only, it does not contest subject matter jurisdiction solely for the claims directed against MSN under 35 U.S.C. § 271(e)(2)(A) in this matter. MSN denies any and all remaining allegations of Paragraph 8.

9. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over MSN.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN does not contest personal jurisdiction solely for the limited purposes of this action only. MSN denies any and all remaining allegations of Paragraph 9.

10. Upon information and belief, MSN is in the business of, among other things, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic versions of branded pharmaceutical products throughout the United States, including in New Jersey, through its own actions and/or through the actions of its agents and subsidiaries, from which MSN derives a substantial portion of its revenue.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, denied.

11. Upon information and belief, MSN, through its own actions and/or through the actions of its agents and subsidiaries, has engaged in the research and development, and the preparation and filing, of MSN's ANDA; continues to engage in seeking FDA approval of MSN's ANDA; intends to engage in the commercial manufacture, marketing, offer for sale, sale, or importation of MSN's ANDA Product throughout the United States, including in New Jersey; and stands to benefit from the approval of MSN's ANDA.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, denied.

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

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN submitted ANDA No. 219248 to FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). MSN denies any and all remaining allegations of Paragraph 12.

13. Upon information and belief, upon FDA approval of MSN's ANDA, MSN will market, offer to sell, sell, or distribute MSN's ANDA Product throughout the United States, including in New Jersey, consistently with MSN's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, MSN 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, MSN's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. Upon information and belief, MSN's ANDA Product will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and/or used by patients in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the Patents-in-Suit in the event that MSN's ANDA Product is approved before the Patents-in-Suit expire.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, denied.

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

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, denied.

15. MSN is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, MSN develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, denied. Further answering, MSN does not contest personal jurisdiction solely for the limited purposes of this action only. MSN denies any and all remaining allegations of Paragraph 15.

16. This Court also has personal jurisdiction over MSN because, among other things, upon information and belief: (1) MSN filed MSN's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product in the United States, including in New Jersey; and (2) upon approval of MSN's ANDA, MSN will directly, or indirectly through subsidiaries, intermediaries, distributors, retailers, or others, market, distribute, offer for sale, sell, and/or import MSN's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of MSN's ANDA Product in New Jersey. Upon information and belief, upon approval of MSN's ANDA, MSN's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, denied. Further answering, MSN does not contest

personal jurisdiction solely for the limited purposes of this action only. MSN denies any and all remaining allegations of Paragraph 16.

17. This Court also has personal jurisdiction over MSN because MSN has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiff, which manufactures CAPLYTA® drug products for sale and use throughout the United States, including in New Jersey. As a result, the consequences of MSN's actions were, and will be, suffered in New Jersey. MSN knew or should have known that the consequences of its actions were, and will be, suffered in New Jersey. At the time MSN sent notice of the certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), it was reasonably foreseeable that MSN would be sued within 45 days in New Jersey. Upon information and belief, MSN's actions will injure Plaintiff by displacing at least some, if not all, of Plaintiff's sales of CAPLYTA® drug products in New Jersey, as well as resulting in price erosion and loss of goodwill with the purchasers and distributors of CAPLYTA® drug products in New Jersey.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, denied. Further answering, MSN does not contest personal jurisdiction solely for the limited purposes of this action only. MSN denies any and all remaining allegations of Paragraph 17.

18. MSN is also subject to personal jurisdiction in New Jersey because it (1) engages in patent litigation concerning MSN's generic versions of branded pharmaceutical products in this District, (2) does not contest personal jurisdiction in this District, and (3) purposefully avails itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g., Jazz Pharms. Rsch. UK Ltd. v. Teva Pharms., Inc.*, No. 23-cv-03914, ECF No. 40 (D.N.J. Sept. 21, 2023); *Jazz Pharms. Rsch. UK Ltd. v. Teva Pharms., Inc.*, No. 23-cv-00018, ECF No. 95 (D.N.J. Mar. 17, 2023).

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, denied. Further answering, MSN does not contest personal jurisdiction solely for the limited purposes of this action only. MSN denies any and all remaining allegations of Paragraph 18.

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

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, denied. Further answering, MSN does not contest

personal jurisdiction solely for the limited purposes of this action only. MSN denies any and all remaining allegations of Paragraph 19.

Venue

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN does not contest venue solely for the limited purposes of this action only. MSN denies any and all remaining allegations of Paragraph 21.

Factual Background

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 23 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that the CAPLYTA® label (Revised 06/2023) states:

----------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)

MSN denies any and all remaining allegations of Paragraph 23.

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

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN's Notice Letter speaks for itself. MSN denies any and all remaining allegations of Paragraph 24.

25. In MSN's Notice Letter, MSN 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 MSN is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of MSN's ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN's Notice Letter speaks for itself. MSN denies any and all remaining allegations of Paragraph 25.

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

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN seeks FDA approval of MSN's ANDA prior to the expiration of the Asserted Patents. MSN denies any and all remaining allegations of Paragraph 26.

27. Upon information and belief, MSN's ANDA Product is not publicly available, nor is ANDA No. 219248 accessible to the public.

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that to MSN's knowledge MSN's ANDA is confidential and not publicly available. MSN denies any and all remaining allegations of Paragraph 27.

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

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, pursuant to 21 C.F.R. § 314.95(c)(8), MSN's Notice Letter included an Offer of Confidential Access ("OCA") to portions of MSN's ANDA that would allow Plaintiff to determine whether an action under 21 U.S.C. § 355 should be filed. MSN denies any and all remaining allegations of Paragraph 28.

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

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN's OCA fully complied with all statutory and regulatory requirements and that Plaintiff rejected the reasonable and appropriate terms and restrictions in said OCA. MSN denies any and all remaining allegations of Paragraph 29.

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

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that Plaintiff filed the Complaint on March 28, 2024. MSN denies any and all remaining allegations of Paragraph 30.

Count I—RE '839 Patent

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

32. The RE '839 patent, entitled "Methods and Compositions for Sleep Disorders and Other Disorders" (attached as Exhibit A), was duly and legally issued on December 7, 2021.

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the United States Patent and Trademark Office ("USPTO"), the RE '839 patent, titled "METHODS AND COMPOSITIONS FOR SLEEP DISORDERS AND OTHER DISORDERS," issued on or about December 7, 2021. MSN denies that the RE '839 patent was "duly and legally issued," and any suggestion or implication that the RE '839 patent is valid or enforceable. MSN also admits that a purported copy of the RE '839 patent is attached as Exhibit A to the Complaint. MSN denies any and all remaining allegations of Paragraph 32.

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

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, the face of the RE '839 patent lists the purported "Inventors" as Sharon Mates,

Allen Fienberg, and Lawrence Wennogle. MSN denies any and all remaining allegations of Paragraph 33.

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

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the RE '839 patent. MSN lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 34, and therefore denies any and all remaining allegations of Paragraph 34.

35. CAPLYTA® is covered by one or more claims of the RE '839 patent, which has been listed in connection with CAPLYTA® in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the Orange Book").

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that the electronic version of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") currently identifies the RE '839 patent in connection with NDA No. 209500 for CAPLYTA®. MSN denies any and all remaining allegations of Paragraph 35.

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

ANSWER: MSN admits that MSN, by MSN's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that MSN submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Product prior to the expiration of the Asserted Patents. MSN denies any and all remaining allegations of Paragraph 36.

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

ANSWER: Paragraph 37 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN has provided written certifications to FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the RE '839 patent are invalid and/or will not be infringed by MSN's ANDA Product. MSN denies any and all remaining allegations of Paragraph 37.

38. According to MSN's Notice Letter, MSN's ANDA Product contains lumateperone.

ANSWER: Paragraph 38 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN's Notice Letter speaks for itself. MSN further admits that MSN's Notice Letter states, among other things:

> V. Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the active ingredient in the proposed drug products is lumateperone tosylate; the strengths of the proposed drug products are 10.5 mg, 21 mg, and 42 mg equivalent base; and the dosage form of the proposed drug products is a capsule.

MSN denies any and all remaining allegations of Paragraph 38.

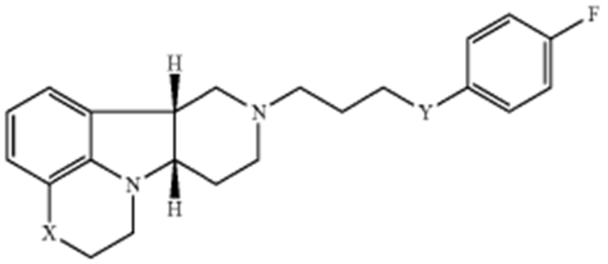
39. Upon information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed labeling for that product would infringe one or more claims of the RE '839 patent.

ANSWER: Denied.

40. As an example, claim 1 of the RE '839 patent recites:

> A method for the treatment of one or more 5-HT_{2A}-related disorders, comprising administering to a patient in need thereof a Compound of Formula I:

Formula I

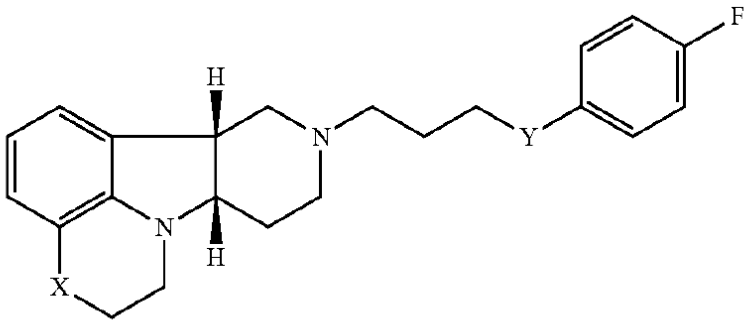


wherein X is O, —NH or —N(CH_3); and Y is —O— or —C(O) —, in free or pharmaceutically acceptable salt form, in a dose which selectively blocks the 5-HT_{2A} receptor.

ANSWER: Paragraph 40 contains legal conclusions and allegations to which no answer is required. To the extent that MSN is required to answer, MSN admits that claim 1 of the RE '839 patent reads as follows:

1. A method for the treatment of one or more 5-HT_{2A}-related disorders, comprising administering to a patient in need thereof a Compound of Formula I:

Formula I



wherein X is O, —NH or —N(CH_3); and Y is —O— or —C(O)—, in free or pharmaceutically acceptable salt form, in a dose which selectively blocks the 5-HT_{2A} receptor.

(The RE '839 patent at Claim 1). MSN denies any and all remaining allegations of Paragraph 40.

41. Upon information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed label would involve treating one or more 5-HT_{2A}-related disorders, including by administering to the patient in need thereof a free or pharmaceutically

acceptable salt form of a Formula I compound (which includes lumateperone) in a dose which selectively blocks the 5-HT$_{2A}$ receptor, as recited in claim 1.

ANSWER: Denied.

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

ANSWER: Denied.

43. MSN's submission of MSN's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product before the expiration of the RE '839 patent was an act of infringement of the RE '839 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

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

ANSWER: MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 44, and therefore denies any and all allegations of Paragraph 44.

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

ANSWER: Denied.

46. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of MSN's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the RE '839 patent.

ANSWER: Denied.

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

ANSWER: Denied.

48. Upon information and belief, MSN knows that MSN's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the RE '839 patent, that

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

ANSWER: Denied.

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

ANSWER: Denied.

50. The foregoing actions by MSN constitute and/or will constitute infringement of the RE '839 patent; active inducement of infringement of the RE '839 patent; and/or contribution to the infringement by others of the RE '839 patent.

ANSWER: Denied.

51. Upon information and belief, MSN has acted with full knowledge of the RE '839 patent and without a reasonable basis for believing that it would not be liable for infringement of the RE '839 patent; active inducement of infringement of the RE '839 patent; and/or contribution to the infringement by others of the RE '839 patent.

ANSWER: Denied.

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

ANSWER: Denied.

53. Unless MSN is enjoined from infringing the RE '839 patent, actively inducing infringement of the RE '839 patent, and contributing to the infringement by others of the RE '839 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

ANSWER: Denied.

Count II—RE '839 Patent

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

55. 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 MSN on the other regarding MSN's infringement, active inducement of infringement, contribution to the infringement by others of the RE '839 patent, and/or the validity of the RE '839 patent.

ANSWER: Denied.

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

ANSWER: Denied.

Count III—'227 Patent

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 58 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, the '227 patent, titled "METHOD FOR THE TREATMENT OF RESIDUAL SYMPTOMS OF SCHIZOPHRENIA," issued on or about May 1, 2018. MSN denies that the '227 patent was "duly and legally issued," and any suggestion or implication that the '227 patent is valid or enforceable. MSN also admits that a purported copy of the '227 patent is attached as Exhibit B to the Complaint. MSN denies any and all remaining allegations of Paragraph 58.

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

ANSWER: Paragraph 59 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, the face of the '227 patent lists the purported "Inventors" as Kimberly Vanover,

Peng Li, Sharon Mates, Robert Davis, and Lawrence P. Wennogle. MSN denies any and all remaining allegations of Paragraph 59.

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

ANSWER: Paragraph 60 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '227 patent. MSN lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 60, and therefore denies any and all remaining allegations of Paragraph 60.

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

ANSWER: Paragraph 61 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that the Orange Book currently identifies the '227 patent in connection with NDA No. 209500 for CAPLYTA®. MSN denies any and all remaining allegations of Paragraph 61.

62. In MSN's Notice Letter, MSN notified Plaintiff of the submission of MSN'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 MSN's ANDA Product prior to the expiration of the Patents-in-Suit, including the '227 patent.

ANSWER: MSN admits that MSN, by MSN's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that MSN submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Product prior to the expiration of the Asserted Patents. MSN denies any and all remaining allegations of Paragraph 62.

63. In MSN's Notice Letter, MSN also notified Plaintiff that, as part of its ANDA, MSN had filed Paragraph IV certifications with respect to the '227 patent. Upon information and belief, MSN submitted its ANDA to the FDA containing Paragraph IV certifications asserting that

the '227 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product.

ANSWER: Paragraph 63 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN has provided written certifications to FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '227 patent are invalid and/or will not be infringed by MSN's ANDA Product. MSN denies any and all remaining allegations of Paragraph 63.

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

ANSWER: Paragraph 64 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN's Notice Letter speaks for itself. MSN further admits that MSN's Notice Letter states, among other things:

> V. Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the active ingredient in the proposed drug products is lumateperone tosylate; the strengths of the proposed drug products are 10.5 mg, 21 mg, and 42 mg equivalent base; and the dosage form of the proposed drug products is a capsule.

MSN denies any and all remaining allegations of Paragraph 64.

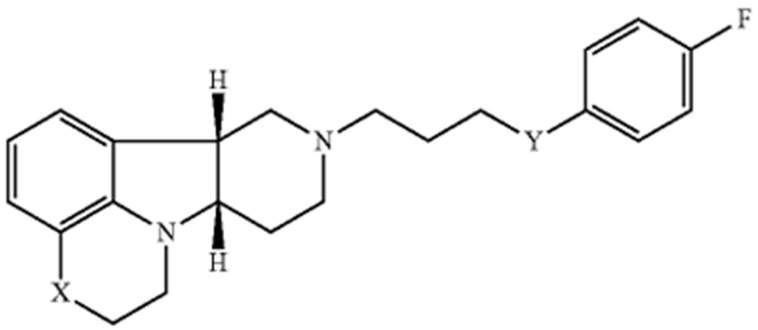
65. Upon information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed labeling for that product would infringe one or more claims of the '227 patent.

ANSWER: Denied.

66. As an example, claim 1 of the '227 patent recites:

> A method for the treatment of residual symptoms of schizophrenia as defined in the Positive and Negative Syndrome Scale (PANSS) for Schizophrenia, comprising administering to a patient in need thereof, after treatment of acute symptoms of schizophrenia with an antipsychotic agent, an effective amount of a compound of Formula I:

Formula I

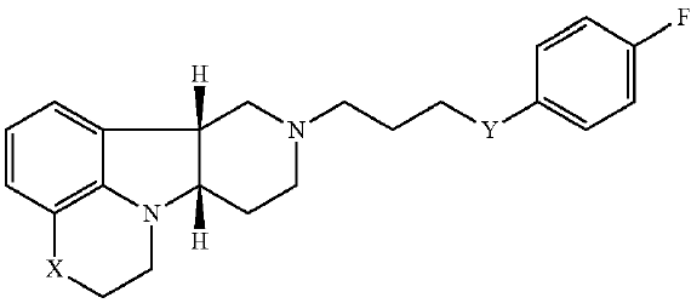


wherein:
X is —O—, —NH— or —N(CH_3)—;
Y is —O—, —C(R_2)(OH)—, —C(R_3)(OR_1) or —C(O)—; and
R_1 is —C_{1-6} alkyl or —C(O)—C_{1-21} alkyl, optionally saturated or unsaturated and optionally substituted with one or more hydroxyl or C_{1-22} alkoxy groups wherein such compound hydrolyzes to form the residue of a natural or unnatural, saturated or unsaturated fatty acid;
R_2 is H or C_{1-6} alkyl; and R_3 is H or —C_{1-6} alkyl;
in free or pharmaceutically acceptable salt form; wherein the patient significantly improves on the Prosocial PANSS Factor change from baseline.

ANSWER: Paragraph 66 contains legal conclusions and allegations to which no answer is required. To the extent that MSN is required to answer, MSN admits that claim 1 of the '227 patent reads as follows:

> 1. A method for the treatment of residual symptoms of schizophrenia as defined in the Positive and Negative Syndrome Scale (PANSS) for Schizophrenia, comprising administering to a patient in need thereof, after treatment of acute symptoms of schizophrenia with an anti-psychotic agent, an effective amount of a compound of Formula I:

Formula I



wherein:

X is —O—, —NH— or —N(CH_3)—;

Y is —O—, —C(R_2)(OH)—, —C(R_3)(OR_1) or —C(O)—; and

R_1 is —C_{1-6}alkyl or —C(O)—C_{1-21}alkyl, optionally saturated or unsaturated and optionally substituted with one or more hydroxyl or C_{1-22}alkoxy groups wherein such compound hydrolyzes to form the residue of a natural or unnatural, saturated or unsaturated fatty acid;

R_2 is H or —C_{1-6}alkyl; and

R_3 is H or —C_{1-6}alkyl;

in free or pharmaceutically acceptable salt form;

wherein the patient significantly improves on the Prosocial PANSS Factor change from baseline.

(The ’227 patent at Claim 1). MSN denies any and all remaining allegations of Paragraph 66.

67. Upon information and belief, the use of MSN’s ANDA Product in accordance with and as directed by MSN’s proposed label would involve treating residual symptoms of schizophrenia after treatment of acute symptoms of schizophrenia with an antipsychotic agent, including by administering to the patient in need thereof an effective amount of the compound recited in claim 1.

ANSWER: Denied.

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

ANSWER: Denied.

69. MSN’s submission of MSN’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN’s ANDA Product before the expiration of the ’227 patent was an act of infringement of the ’227 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

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

ANSWER: MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 70, and therefore denies any and all allegations of Paragraph 70.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

76. The foregoing actions by MSN constitute and/or will constitute infringement of the '227 patent; active inducement of infringement of the '227 patent; and/or contribution to the infringement by others of the '227 patent.

ANSWER: Denied.

77. Upon information and belief, MSN has acted with full knowledge of the '227 patent and without a reasonable basis for believing that it would not be liable for infringement of the '227 patent; active inducement of infringement of the '227 patent; and/or contribution to the infringement by others of the '227 patent.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

Count IV—'227 Patent

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

81. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and MSN on the other regarding MSN's infringement, active inducement of infringement, contribution to the infringement by others of the '227 patent, and/or the validity of the '227 patent.

ANSWER: Denied.

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

ANSWER: Denied.

Count V—'009 Patent

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 84 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, the '009 patent, titled "METHODS OF TREATING SCHIZOPHRENIA AND DEPRESSION," issued on or about March 30, 2021. MSN denies that the '009 patent was "duly and legally issued," and any suggestion or implication that the '009 patent is valid or enforceable. MSN also admits that a purported copy of the '009 patent is attached as Exhibit C to the Complaint. MSN denies any and all remaining allegations of Paragraph 84.

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

ANSWER: Paragraph 85 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, the face of the '009 patent lists the purported "Inventors" as Kimberly Vanover, Peng Li, Sharon Mates, Robert Davis, and Lawrence P. Wennogle. MSN denies any and all remaining allegations of Paragraph 85.

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

ANSWER: Paragraph 86 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '009 patent. MSN lacks knowledge or information sufficient to form a belief as to the truth of

the remaining allegations of Paragraph 86, and therefore denies any and all remaining allegations of Paragraph 86.

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

ANSWER: Paragraph 87 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that the Orange Book currently identifies the '009 patent in connection with NDA No. 209500 for CAPLYTA®. MSN denies any and all remaining allegations of Paragraph 87.

88. In MSN's Notice Letter, MSN notified Plaintiff of the submission of MSN'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 MSN's ANDA Product prior to the expiration of the Patents-in-Suit, including the '009 patent.

ANSWER: MSN admits that MSN, by MSN's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that MSN submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Product prior to the expiration of the Asserted Patents. MSN denies any and all remaining allegations of Paragraph 88.

89. In MSN's Notice Letter, MSN also notified Plaintiff that, as part of its ANDA, MSN had filed Paragraph IV certifications with respect to the '009 patent. Upon information and belief, MSN submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '009 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product.

ANSWER: Paragraph 89 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN has provided written certifications to FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '009 patent are invalid and/or will not be infringed by MSN's ANDA Product. MSN denies any and all remaining allegations of Paragraph 89.

90. According to MSN's Notice Letter, MSN's ANDA Product contains lumateperone.

ANSWER: Paragraph 90 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN's Notice Letter speaks for itself. MSN further admits that MSN's Notice Letter states, among other things:

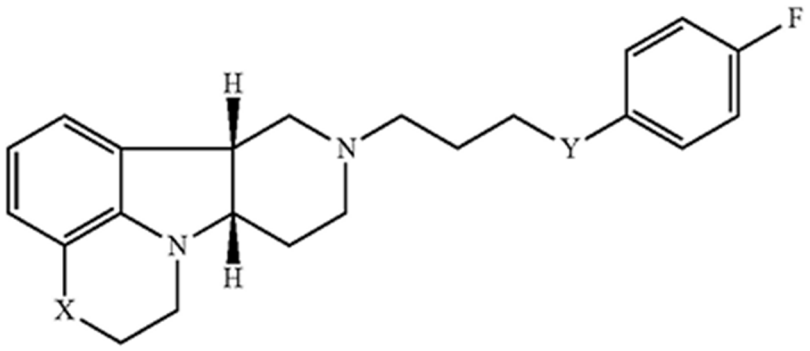
> V. Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the active ingredient in the proposed drug products is lumateperone tosylate; the strengths of the proposed drug products are 10.5 mg, 21 mg, and 42 mg equivalent base; and the dosage form of the proposed drug products is a capsule.

MSN denies any and all remaining allegations of Paragraph 90.

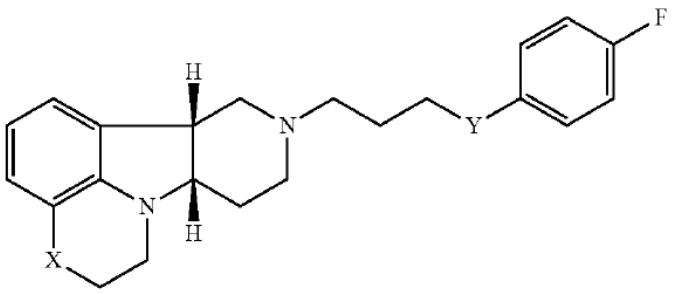
91. Upon information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed labeling for that product would infringe one or more claims of the '009 patent.

ANSWER: Denied.

92. As an example, claim 1 of the '009 patent recites:

> A method for the treatment of the negative symptoms of schizophrenia comprising administering to a schizophrenic patient in need thereof an effective amount of a Compound of Formula I:
>
> Formula I
>
> 
>
>
> wherein:
> X is —N(CH_3)— and Y is —C(O)—;
> in free or pharmaceutically acceptable salt form,
> wherein the effective amount of the Compound of Formula I is 40 mg to 60 mg per day, measured as the weight of the corresponding free base form of the Compound.

ANSWER: Paragraph 92 contains legal conclusions and allegations to which no answer is required. To the extent that MSN is required to answer, denied. MSN further responds that claim 1 of the '009 patent reads as follows:

> **1**. A method for the treatment of the negative symptoms of schizophrenia comprising administering to a schizophrenic patient in need thereof an effective amount
>
> Formula I
>
> 
>
>
> of a Compound of Formula
> wherein:
> X is —N(CH_3)— and Y is —C(O)—;
> in free or pharmaceutically acceptable salt form,
> wherein the effective amount of the Compound of Formula I is 40 mg to 60 mg per day, measured as the weight of the corresponding free base form of the Compound.

(The '009 patent at Claim 1). MSN denies any and all remaining allegations of Paragraph 92.

93. Upon information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed label would involve treating negative symptoms of schizophrenia, including by administering to the patient in need thereof 40 mg to 60 mg (measured as the free base) per day of a Formula I compound in free or pharmaceutically acceptable salt form, as recited in claim 1.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANDA Product before the expiration of the '009 patent was an act of infringement of the '009 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

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

ANSWER: MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 96, and therefore denies any and all allegations of Paragraph 96.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

102. The foregoing actions by MSN constitute and/or will constitute infringement of the '009 patent; active inducement of infringement of the '009 patent; and/or contribution to the infringement by others of the '009 patent.

ANSWER: Denied.

103. Upon information and belief, MSN has acted with full knowledge of the '009 patent and without a reasonable basis for believing that it would not be liable for infringement of the '009 patent; active inducement of infringement of the '009 patent; and/or contribution to the infringement by others of the '009 patent.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

Count VI—'009 Patent

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

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

ANSWER: Denied.

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

ANSWER: Denied.

Count VII—'951 Patent

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 110 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, the '951 patent, titled "METHODS OF TREATING BIPOLAR DISORDER," issued on or about June 8, 2021. MSN denies that the '951 patent was "duly and legally issued," and any suggestion or implication that the '951 patent is valid or enforceable. MSN also admits that a purported copy of the '951 patent is attached as Exhibit D to the Complaint. MSN denies any and all remaining allegations of Paragraph 110.

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

ANSWER: Paragraph 111 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, the face of the '951 patent lists the purported "Inventors" as Kimberly Vanover, Peng Li, Sharon Mates, Robert Davis, and Lawrence P. Wennogle. MSN denies any and all remaining allegations of Paragraph 111.

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

ANSWER: Paragraph 112 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '295 patent. MSN lacks knowledge or information sufficient to form a belief as to the truth of

the remaining allegations of Paragraph 112, and therefore denies any and all remaining allegations of Paragraph 112.

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

ANSWER: Paragraph 113 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that the Orange Book currently identifies the '951 patent in connection with NDA No. 209500 for CAPLYTA®. MSN denies any and all remaining allegations of Paragraph 113.

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

ANSWER: MSN admits that MSN, by MSN's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that MSN submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Product prior to the expiration of the Asserted Patents. MSN denies any and all remaining allegations of Paragraph 114.

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

ANSWER: Paragraph 115 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN has provided written certifications to FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '951 patent are invalid and/or will not be infringed by MSN's ANDA Product. MSN denies any and all remaining allegations of Paragraph 115.

116. According to MSN's Notice Letter, MSN's ANDA Product contains lumateperone.

ANSWER: Paragraph 116 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN's Notice Letter speaks for itself. MSN further admits that MSN's Notice Letter states, among other things:

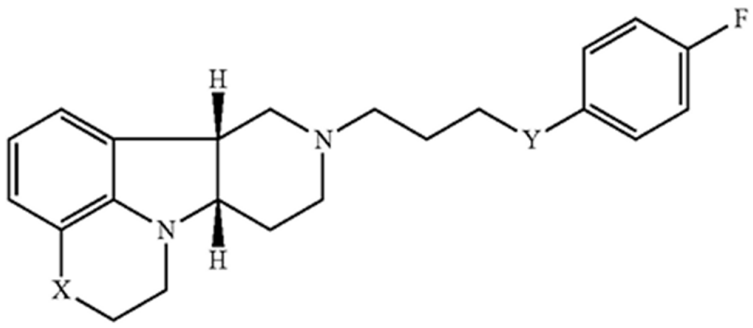
> V. Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the active ingredient in the proposed drug products is lumateperone tosylate; the strengths of the proposed drug products are 10.5 mg, 21 mg, and 42 mg equivalent base; and the dosage form of the proposed drug products is a capsule.

MSN denies any and all remaining allegations of Paragraph 116.

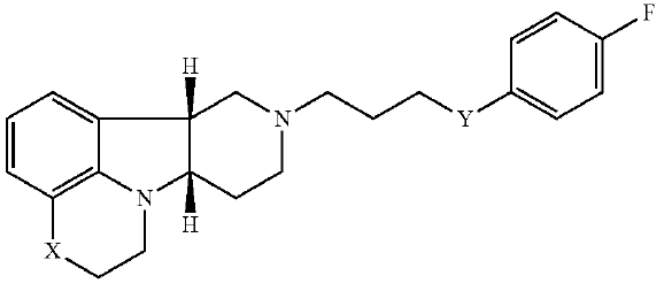
117. Upon information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed labeling for that product would infringe one or more claims of the '951 patent.

ANSWER: Denied.

118. As an example, claim 1 of the '951 patent recites:

> A method for the treatment of bipolar disorder I and/or bipolar II disorder comprising administering to a patient in need thereof an effective amount of a Compound of Formula I:
>
> Formula I
>
> 
>
>
> wherein:
> X is —N(CH_3)— and Y is —C(O)—;
> in free or pharmaceutically acceptable salt form, wherein said Compound is not used in combination with another antipsychotic agent.

ANSWER: Paragraph 118 contains legal conclusions and allegations to which no answer is required. To the extent that MSN is required to answer, MSN admits that claim 1 of the '951 patent reads as follows:

> **1**. A method for the treatment of bipolar disorder I and/or bipolar II disorder comprising administering to a patient in need thereof an effective amount of a Compound of Formula I:
>
> Formula I
>
> 
>
>
> wherein:
> X is —N(CH_3)— and Y is —C(O)—;
> in free or pharmaceutically acceptable salt form, wherein said Compound is not used in combination with another antipsychotic agent.

(The '951 patent at Claim 1). MSN denies any and all remaining allegations of Paragraph 118.

119. Upon information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed label would involve treating bipolar disorder I and/or bipolar II disorder, including by administering to the patient in need thereof an effective amount of a Formula I compound in free or pharmaceutically acceptable salt form and not in combination with another antipsychotic agent.

ANSWER: Denied.

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

ANSWER: Denied.

121. MSN's submission of MSN's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's ANDA Product before the expiration of the '951 patent was an act of infringement of the '951 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

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

ANSWER: MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 122, and therefore denies any and all allegations of Paragraph 122.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

127. Notwithstanding MSN's knowledge of the claims of the '951 patent, MSN has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import MSN's ANDA Product with its product labeling following FDA approval of MSN's ANDA prior to the expiration of the '951 patent.

ANSWER: Denied.

128. The foregoing actions by MSN constitute and/or will constitute infringement of the '951 patent; active inducement of infringement of the '951 patent; and/or contribution to the infringement by others of the '951 patent.

ANSWER: Denied.

129. Upon information and belief, MSN has acted with full knowledge of the '951 patent and without a reasonable basis for believing that it would not be liable for infringement of the '951 patent; active inducement of infringement of the '951 patent; and/or contribution to the infringement by others of the '951 patent.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

Count VIII—'951 Patent

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

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

ANSWER: Denied.

134. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of MSN's ANDA Product with its proposed labeling, or any other MSN drug product that is covered by or whose use is covered by the '951 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '951 patent, and that the claims of the '951 patent are not invalid.

ANSWER: Denied.

Count IX—'345 Patent

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 136 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, the '345 patent, titled "PHARMACEUTICAL CAPSULE COMPOSITIONS COMPRISING LUMATEPERONE MONO-TOSYLATE," issued on or about June 30, 2020. MSN denies that the '345 patent was "duly and legally issued," and any suggestion or implication that the '345 patent is valid or enforceable. MSN also admits that a purported copy of the '345 patent is attached as Exhibit E to the Complaint. MSN denies any and all remaining allegations of Paragraph 136.

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

ANSWER: Paragraph 137 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, the face of the '345 patent lists the purported "Inventors" as Peng Li and Robert Davis. MSN denies any and all remaining allegations of Paragraph 137.

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

ANSWER: Paragraph 138 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '345 patent. MSN lacks knowledge or information sufficient to form a belief as to the truth of

the remaining allegations of Paragraph 138, and therefore denies any and all remaining allegations of Paragraph 138.

139. 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: Paragraph 139 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that the Orange Book currently identifies the '345 patent in connection with NDA No. 209500 for CAPLYTA®. MSN denies any and all remaining allegations of Paragraph 139.

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

ANSWER: MSN admits that MSN, by MSN's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that MSN submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Product prior to the expiration of the Asserted Patents. MSN denies any and all remaining allegations of Paragraph 140.

141. In MSN's Notice Letter, MSN also notified Plaintiff that, as part of its ANDA, MSN had filed Paragraph IV certifications with respect to the '345 patent. Upon information and belief, MSN 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 MSN's ANDA Product.

ANSWER: Paragraph 141 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN has provided written certifications to FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '345 patent are invalid and/or will not be infringed by MSN's ANDA Product. MSN denies any and all remaining allegations of Paragraph 141.

142. According to MSN's Notice Letter, MSN's ANDA Product contains lumateperone.

ANSWER: Paragraph 142 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN's Notice Letter speaks for itself. MSN further admits that MSN's Notice Letter states, among other things:

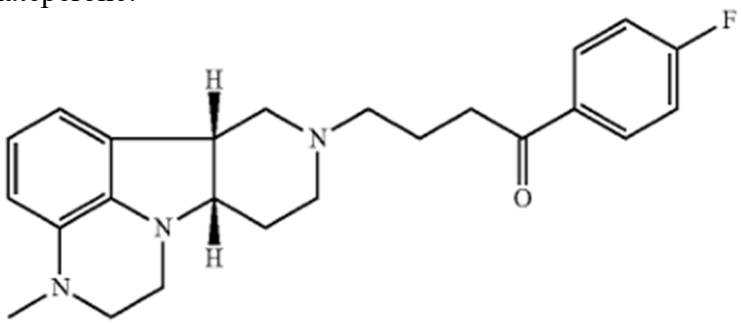
> V. Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the active ingredient in the proposed drug products is lumateperone tosylate; the strengths of the proposed drug products are 10.5 mg, 21 mg, and 42 mg equivalent base; and the dosage form of the proposed drug products is a capsule.

MSN denies any and all remaining allegations of Paragraph 142.

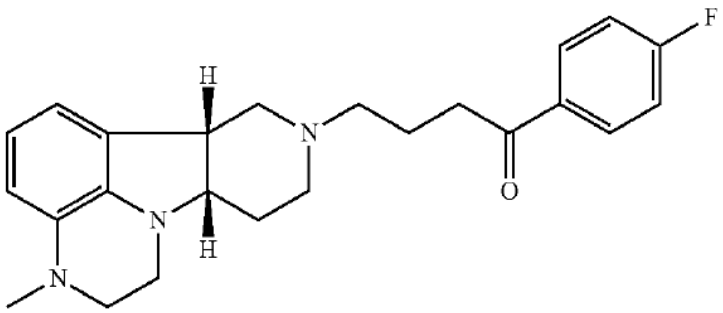
143. Upon information and belief, MSN's ANDA Product and the use of MSN's ANDA Product are covered by one or more claims of the '345 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

144. 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: Paragraph 144 contains legal conclusions and allegations to which no answer is required. To the extent that MSN is required to answer, MSN admits that claim 1 of the '345 patent reads as follows:

> **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.

(The '345 patent at Claim 1). MSN denies any and all remaining allegations of Paragraph 144.

145. Upon information and belief, MSN'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: Denied.

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

ANSWER: Denied.

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

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

ANSWER: MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 148, and therefore denies any and all allegations of Paragraph 148.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

154. The foregoing actions by MSN 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.

155. Upon information and belief, MSN 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.

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

ANSWER: Denied.

157. Unless MSN 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 X—'345 Patent

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

159. 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 MSN on the other regarding MSN'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: Denied.

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

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 162 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, the '084 patent, titled "PHARMACEUTICAL CAPSULE COMPOSITIONS COMPRISING LUMATEPERONE MONO-TOSYLATE," issued on or about July 6, 2021. MSN denies that the '084 patent was "duly and legally issued," and any suggestion or implication that the '084 patent is valid or enforceable. MSN also admits that a purported copy of the '084 patent is attached as Exhibit F to the Complaint. MSN denies any and all remaining allegations of Paragraph 162.

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

ANSWER: Paragraph 163 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, the face of the '084 patent lists the purported "Inventors" as Peng Li and Robert Davis. MSN denies any and all remaining allegations of Paragraph 163.

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

ANSWER: Paragraph 164 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '084 patent. MSN lacks knowledge or information sufficient to form a belief as to the truth of

the remaining allegations of Paragraph 164, and therefore denies any and all remaining allegations of Paragraph 164.

165. 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: Paragraph 165 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that the Orange Book currently identifies the '084 patent in connection with NDA No. 209500 for CAPLYTA®. MSN denies any and all remaining allegations of Paragraph 165.

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

ANSWER: MSN admits that MSN, by MSN's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that MSN submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Product prior to the expiration of the Asserted Patents. MSN denies any and all remaining allegations of Paragraph 166.

167. In MSN's Notice Letter, MSN also notified Plaintiff that, as part of its ANDA, MSN had filed Paragraph IV certifications with respect to the '084 patent. Upon information and belief, MSN 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 MSN's ANDA Product.

ANSWER: Paragraph 167 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN has provided written certifications to FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '084 patent are invalid and/or will not be infringed by MSN's ANDA Product. MSN denies any and all remaining allegations of Paragraph 167.

168. According to MSN's Notice Letter, MSN's ANDA Product contains lumateperone.

ANSWER: Paragraph 168 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN's Notice Letter speaks for itself. MSN further admits that MSN's Notice Letter states, among other things:

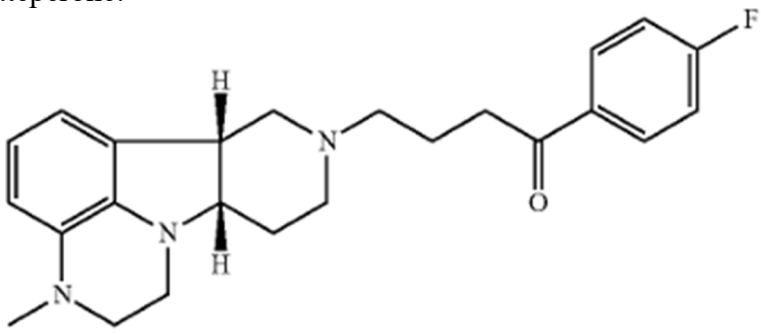
> V. Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the active ingredient in the proposed drug products is lumateperone tosylate; the strengths of the proposed drug products are 10.5 mg, 21 mg, and 42 mg equivalent base; and the dosage form of the proposed drug products is a capsule.

MSN denies any and all remaining allegations of Paragraph 168.

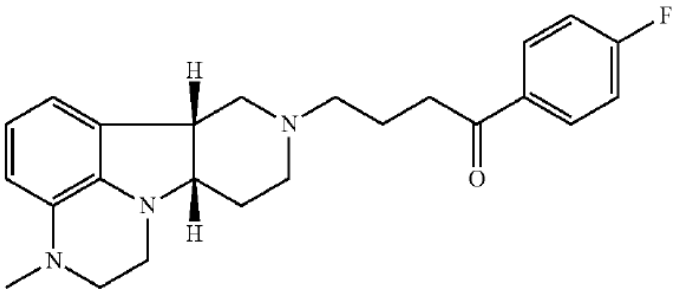
169. Upon information and belief, MSN's ANDA Product and the use of MSN's ANDA Product are covered by one or more claims of the '084 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

170. 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: Paragraph 170 contains legal conclusions and allegations to which no answer is required. To the extent that MSN is required to answer, MSN admits that claim 1 of the '084 patent reads as follows:

> **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.

(The '084 patent at Claim 1). MSN denies any and all remaining allegations of Paragraph 170.

171. Upon information and belief, MSN'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: Denied.

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

ANSWER: Denied.

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

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

ANSWER: MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 174, and therefore denies any and all allegations of Paragraph 174.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

180. The foregoing actions by MSN 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.

181. Upon information and belief, MSN 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.

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

ANSWER: Denied.

183. Unless MSN 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 XII—'084 Patent

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

185. 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 MSN on the other regarding MSN'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: Denied.

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

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 188 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, the '842 patent, titled "PHARMACEUTICAL CAPSULE COMPOSITIONS COMPRISING LUMATEPERONE MONO-TOSYLATE," issued on or about July 4, 2023. MSN denies that the '842 patent was "duly and legally issued," and any suggestion or implication that the '842 patent is valid or enforceable. MSN also admits that a purported copy of the '842 patent is attached as Exhibit G to the Complaint. MSN denies any and all remaining allegations of Paragraph 188.

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

ANSWER: Paragraph 189 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, the face of the '842 patent lists the purported "Inventors" as Peng Li and Robert Davis. MSN denies any and all remaining allegations of Paragraph 189.

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

ANSWER: Paragraph 190 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '842 patent. MSN lacks knowledge or information sufficient to form a belief as to the truth of

the remaining allegations of Paragraph 190, and therefore denies any and all remaining allegations of Paragraph 190.

191. 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: Paragraph 191 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that the Orange Book currently identifies the '842 patent in connection with NDA No. 209500 for CAPLYTA®. MSN denies any and all remaining allegations of Paragraph 191.

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

ANSWER: MSN admits that MSN, by MSN's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that MSN submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Product prior to the expiration of the Asserted Patents. MSN denies any and all remaining allegations of Paragraph 192.

193. In MSN's Notice Letter, MSN also notified Plaintiff that, as part of its ANDA, MSN had filed Paragraph IV certifications with respect to the '842 patent. Upon information and belief, MSN 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 MSN's ANDA Product.

ANSWER: Paragraph 193 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN has provided written certifications to FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '842 patent are invalid and/or will not be infringed by MSN's ANDA Product. MSN denies any and all remaining allegations of Paragraph 193.

194. According to MSN's Notice Letter, MSN's ANDA Product contains lumateperone.

ANSWER: Paragraph 194 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN's Notice Letter speaks for itself. MSN further admits that MSN's Notice Letter states, among other things:

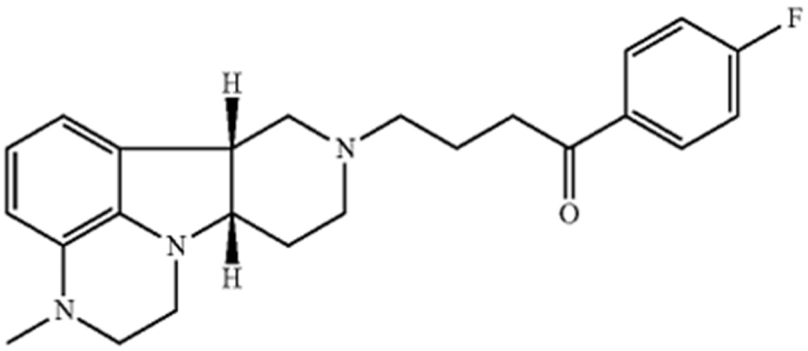
> V. Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the active ingredient in the proposed drug products is lumateperone tosylate; the strengths of the proposed drug products are 10.5 mg, 21 mg, and 42 mg equivalent base; and the dosage form of the proposed drug products is a capsule.

MSN denies any and all remaining allegations of Paragraph 194.

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

ANSWER: Denied.

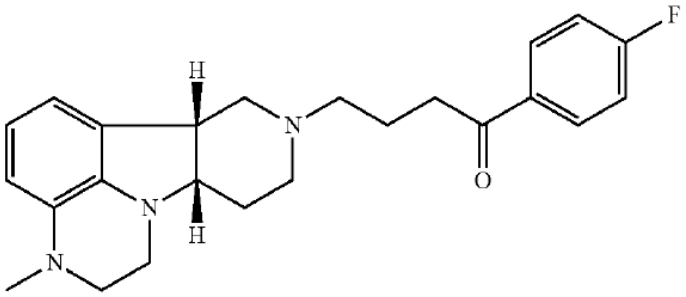
196. As an example, claim 1 of the '842 patent recites:

> 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: Paragraph 196 contains legal conclusions and allegations to which no answer is required. To the extent that MSN is required to answer, MSN admits that claim 1 of the '842 patent reads as follows:

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.

(The '842 patent at Claim 1). MSN denies any and all remaining allegations of Paragraph 196.

197. Upon information and belief, MSN'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: Denied.

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

ANSWER: Denied.

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

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

ANSWER: MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 200, and therefore denies any and all allegations of Paragraph 200.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

206. The foregoing actions by MSN 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.

207. Upon information and belief, MSN 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.

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

ANSWER: Denied.

209. Unless MSN 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 XIV—'842 Patent

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

211. 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 MSN on the other regarding MSN'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: Denied.

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

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 214 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, the '348 patent, titled "METHODS OF TREATMENT USING PHARMACEUTICAL CAPSULE COMPOSITIONS COMPRISING LUMATEPERONE MONO-TOSYLATE," issued on or about November 7, 2023. MSN denies that the '348 patent was "duly and legally issued," and any suggestion or implication that the '348 patent is valid or enforceable. MSN also admits that a purported copy of the '348 patent is attached as Exhibit H to the Complaint. MSN denies any and all remaining allegations of Paragraph 214.

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

ANSWER: Paragraph 215 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, the face of the '348 patent lists the purported "Inventors" as Peng Li and Robert Davis. MSN denies any and all remaining allegations of Paragraph 215.

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

ANSWER: Paragraph 216 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '348 patent. MSN lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 216, and therefore denies any and all remaining allegations of Paragraph 216.

217. 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: Paragraph 217 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that the Orange Book currently identifies the '348 patent in connection with NDA No. 209500 for CAPLYTA®. MSN denies any and all remaining allegations of Paragraph 217.

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

ANSWER: MSN admits that MSN, by MSN's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that MSN submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Product prior to the expiration of the Asserted Patents. MSN denies any and all remaining allegations of Paragraph 218.

219. In MSN's Notice Letter, MSN also notified Plaintiff that, as part of its ANDA, MSN had filed Paragraph IV certifications with respect to the '348 patent. Upon information and belief, MSN 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 MSN's ANDA Product.

ANSWER: Paragraph 219 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN has provided written

certifications to FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '348 patent are invalid and/or will not be infringed by MSN's ANDA Product. MSN denies any and all remaining allegations of Paragraph 219.

220. According to MSN's Notice Letter, MSN's ANDA Product contains lumateperone.

ANSWER: Paragraph 220 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN's Notice Letter speaks for itself. MSN further admits that MSN's Notice Letter states, among other things:

> V. Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the active ingredient in the proposed drug products is lumateperone tosylate; the strengths of the proposed drug products are 10.5 mg, 21 mg, and 42 mg equivalent base; and the dosage form of the proposed drug products is a capsule.

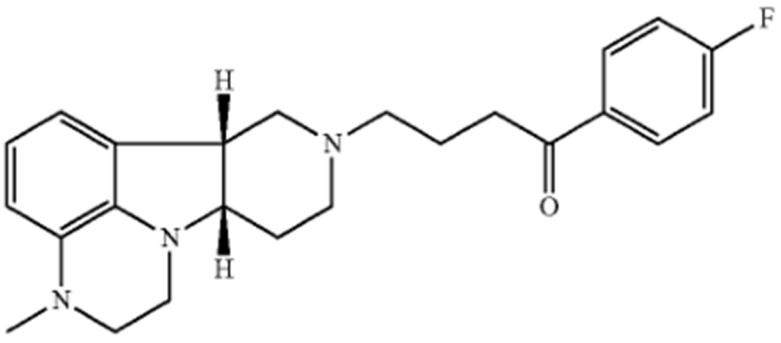
MSN denies any and all remaining allegations of Paragraph 220.

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

ANSWER: Denied.

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

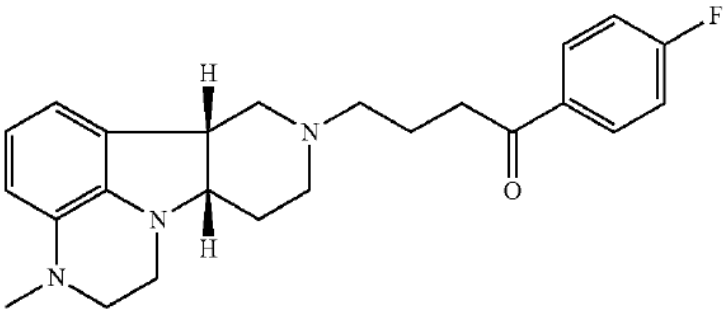
> A method for the treatment of a disease or disorder involving or mediated by the 5-HT$_{2A}$ receptor, serotonin transporter (SERT), and/or dopamine D1/D2 receptor signaling pathways, comprising administering to a patient in need thereof a pharmaceutical capsule for oral administration, comprising lumateperone:



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

ANSWER: Paragraph 222 contains legal conclusions and allegations to which no answer is required. To the extent that MSN is required to answer, MSN admits that claim 1 of the '348 patent reads as follows:

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.

(The '348 patent at Claim 1). MSN denies any and all remaining allegations of Paragraph 222.

223. Upon information and belief, the use of MSN's ANDA Product in accordance with and as directed by MSN's proposed label would involve treating a disease or disorder involving or mediated by the 5-HT_{2A} receptor, serotonin transporter (SERT), and/or dopamine D1/D2 receptor signaling pathways, including by administering to the patient in need thereof a pharmaceutical capsule for oral administration comprising 0.01 to 30 mg or 35 to 45 mg of lumateperone mono-tosylate in solid crystal form (measured as the free base) and the specific excipients in the specific amounts recited in claim 1.

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 226, and therefore denies any and all allegations of Paragraph 226.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

232. The foregoing actions by MSN 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.

233. Upon information and belief, MSN 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.

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

ANSWER: Denied.

235. Unless MSN 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 XVI—'348 Patent

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

237. 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 MSN on the other regarding MSN'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: Denied.

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

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

240. 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 I), was duly and legally issued on September 12, 2023.

ANSWER: Paragraph 240 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, the '419 patent, 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," issued on or about September 12, 2023. MSN denies that the '419 patent was "duly and legally issued," and any suggestion or implication that the '419 patent is valid or enforceable. MSN also admits that a purported copy of the '419 patent is attached as Exhibit I to the Complaint. MSN denies any and all remaining allegations of Paragraph 240.

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

ANSWER: Paragraph 241 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records

of the USPTO, the face of the '419 patent lists the purported "Inventors" as Peng Li, Robert E. Davis, and Kimberly Vanover. MSN denies any and all remaining allegations of Paragraph 241.

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

ANSWER: Paragraph 242 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '419 patent. MSN lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 242, and therefore denies any and all remaining allegations of Paragraph 242.

243. 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: Paragraph 243 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that the Orange Book currently identifies the '419 patent in connection with NDA No. 209500 for CAPLYTA®. MSN denies any and all remaining allegations of Paragraph 243.

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

ANSWER: MSN admits that MSN, by MSN's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that MSN submitted MSN's ANDA to FDA seeking approval to market MSN's ANDA Product prior to the expiration of the Asserted Patents. MSN denies any and all remaining allegations of Paragraph 244.

245. In MSN's Notice Letter, MSN also notified Plaintiff that, as part of its ANDA, MSN had filed Paragraph IV certifications with respect to the '419 patent. Upon information and belief, MSN 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 MSN's ANDA Product.

ANSWER: Paragraph 245 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN has provided written certifications to FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '419 patent are invalid and/or will not be infringed by MSN's ANDA Product. MSN denies any and all remaining allegations of Paragraph 245.

246. According to MSN's Notice Letter, MSN's ANDA Product contains lumateperone.

ANSWER: Paragraph 246 contains legal conclusions to which no answer is required. To the extent that MSN is required to answer, MSN admits that MSN's Notice Letter speaks for itself. MSN further admits that MSN's Notice Letter states, among other things:

> V. Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the active ingredient in the proposed drug products is lumateperone tosylate; the strengths of the proposed drug products are 10.5 mg, 21 mg, and 42 mg equivalent base; and the dosage form of the proposed drug products is a capsule.

MSN denies any and all remaining allegations of Paragraph 246.

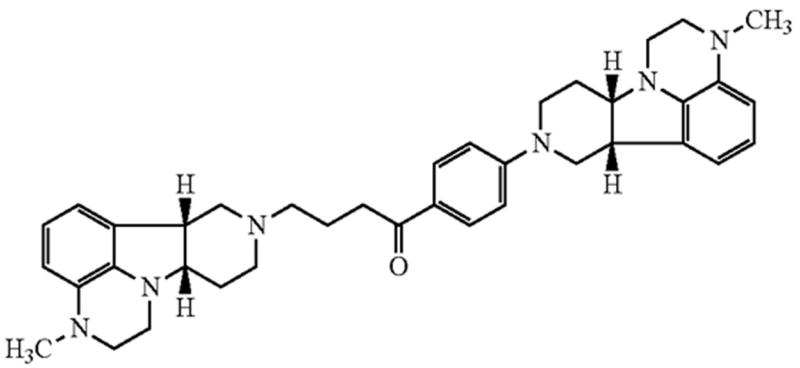
247. Upon information and belief, MSN's ANDA Product and the use of MSN's ANDA Product are covered by one or more claims of the '419 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

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

A compound of Formula I:

Formula I

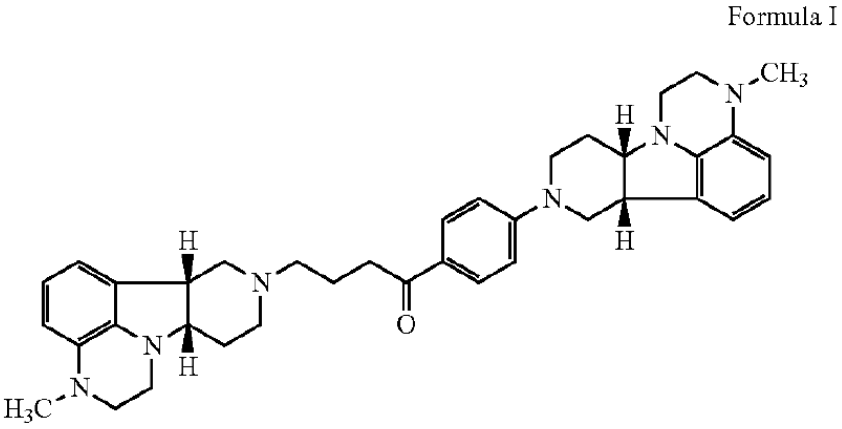


in free base or pharmaceutically acceptable salt form.

ANSWER: Paragraph 248 contains legal conclusions and allegations to which no answer is required. To the extent that MSN is required to answer, MSN admits that claim 1 of the '419 patent reads as follows:

1. A compound of Formula I:

Formula I



in free base or pharmaceutically acceptable salt form.

(The '419 patent at Claim 1). MSN denies any and all remaining allegations of Paragraph 248.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: MSN lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 252, and therefore denies any and all allegations of Paragraph 252.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

258. The foregoing actions by MSN 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.

259. Upon information and belief, MSN 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.

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

ANSWER: Denied.

261. Unless MSN 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 XVIII—'419 Patent

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

ANSWER: MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

263. 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 MSN on the other regarding MSN'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: Denied.

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

PLAINTIFF'S PRAYER FOR RELIEF

MSN denies that Plaintiff is entitled to any of the relief requested in its Prayer for Relief, or to any relief whatsoever, and further request that judgment be entered in favor of MSN, dismissing Plaintiff's Complaint with prejudice, awarding MSN attorneys' fees and costs incurred defending this action under 35 U.S.C. § 285, and granting such further relief as this Court may deem just and proper.

SEPARATE DEFENSES

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

FIRST DEFENSE
(Invalidity)

The claims of U.S. Patent Nos. 9,956,227 ("the '227 patent"), 10,695,345 ("the '345 patent"), 10,960,009 ("the '009 patent"), 11,026,951 ("the '951 patent"), 11,052,084 ("the '084 patent"), 11,690,842 ("the '842 patent"), 11,753,419 ("the '419 patent"), 11,806,348 ("the '348 patent"), and RE48,839 ("the RE '839 patent") (collectively, "Asserted Patents") are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including without limitation §§ 101, 102, 103 and/or 112, and/or any judicially-created basis for invalidation or unenforceability.

SECOND DEFENSE
(Non-Infringement)

The manufacture, use, sale, offer for sale or importation of the proposed lumateperone capsules, 10.5 mg, 21 mg, and 42 mg, that are the subject of MSN's ANDA No. 219248, does not and would not infringe, either directly or indirectly, any valid and/or enforceable claim of the Asserted Patents, either literally or under the doctrine of equivalents.

THIRD DEFENSE
(No Inducement)

MSN has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the Asserted Patents.

FOURTH DEFENSE
(No Contributory Infringement)

MSN has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the Asserted Patents.

FIFTH DEFENSE
(No Subject Matter Jurisdiction)

The Court lacks subject matter jurisdiction over this action solely for the claims against MSN including for any and all claims asserted under 35 U.S.C. § 271 (a), (b) or (c).

SIXTH DEFENSE
(Safe Harbor)

MSN is exempt from liability under the safe harbor provision of 35 U.S.C. § 271(e)(1).

SEVENTH DEFENSE
(No Exceptional Case)

The Complaint fails to state a claim for exceptional case.

EIGHTH DEFENSE
(Failure to State a Claim)

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

NINTH DEFENSE
(Additional Defenses)

Any additional defenses or counterclaims that discovery may reveal, including unenforceability.

COUNTERCLAIMS

Defendant/Counterclaim-Plaintiff MSN Laboratories Private Ltd. ("MSN") ("Defendant" or "MSN"), for MSN's Counterclaims against Plaintiff/Counterclaim-Defendant Intra-Cellular Therapies, Inc. ("Plaintiff/Counterclaim-Defendant," "Intra-Cellular Therapies," or "ITCI"), alleges as follows:

The Parties

1. MSN Laboratories is a Private Limited company organized and existing under the laws of India, having a principal place of business at MSN House Plot No. C-24, Industrial Estate, Sanathnagar, Hyderabad - 18, Telangana, India.

2. On information and belief and according to the Complaint (D.I. 1 ¶ 4), Intra-Cellular Therapies, Inc. 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.

Jurisdiction and Venue

3. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

4. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a) and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court has personal jurisdiction over Plaintiff/Counterclaim-Defendant because it has availed itself of the rights and privileges, and subjected itself to the jurisdiction of this forum by suing MSN in this District, and, on information and belief, because Plaintiff/Counterclaim-Defendant conducts substantial business in, and has regular systemic contact with, this District.

6. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

Background

7. On or about December 7, 2021, the U.S. Patent and Trademark Office (the "USPTO"), issued U.S. Patent No. RE48,839 ("the RE '839 patent").

8. On or about May 1, 2018, the USPTO issued U.S. Patent No. 9,956,227 ("the '227 patent").

9. On or about March 30, 2021, the USPTO issued U.S. Patent No. 10,960,009 ("the '009 patent").

10. On or about June 8, 2021, the USPTO issued U.S. Patent No. 11,026,951 ("the '951 patent").

11. On or about June 30, 2020, the USPTO issued U.S. Patent No. 10,695,345 ("the '345 patent").

12. On or about July 6, 2021, the USPTO issued U.S. Patent No. 11,052,084 ("the '084 patent").

13. On or about July 4, 2023, the USPTO issued U.S. Patent No. 11,690,842 ("the '842 patent").

14. On or about November 7, 2023, the USPTO issued U.S. Patent No. 11,806,348 ("the '348 patent").

15. On or about September 12, 2023, the USPTO issued U.S. Patent No. 11,753,419 ("the '419 patent").

16. Plaintiff/Counterclaim-Defendant purports and claims to own the RE '839 patent, the '227 patent, the '009 patent, the '951 patent, the '345 patent, the '084 patent, the '842 patent,

the ’348 patent, and the ’419 patent (collectively, “Asserted Patents”) (D.I. 1 ¶¶ 34, 60, 86, 112, 138, 164, 190, 216, 242).

17. On or about March 28, 2024, Plaintiff/Counterclaim-Defendant sued MSN in this District alleging that the proposed lumateperone capsules, 10.5 mg, 21 mg, and 42 mg, that are the subject of MSN’s Abbreviated New Drug Application No. 219248 (“MSN’s ANDA Product”), will infringe the Asserted Patents under 35 U.S.C. § 271(e)(2).

18. There is an actual and justiciable controversy between the parties as to the alleged infringement and/or invalidity of the Asserted Patents.

COUNT I
(Declaratory Judgment of Non-Infringement of the RE ’839 Patent)

19. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

20. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of MSN’s ANDA Product would infringe any valid and/or enforceable claim of the RE ’839 patent.

21. MSN’s ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the RE ’839 patent.

22. MSN is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of MSN’s ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the RE ’839 patent.

COUNT II
(Declaratory Judgment of Invalidity of the RE ’839 Patent)

23. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

24. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the RE '839 patent.

25. One or more claims of the RE '839 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

26. MSN is entitled to a judicial declaration that the claims of the RE '839 patent are invalid.

COUNT III
(Declaratory Judgment of Non-Infringement of the '227 Patent)

27. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

28. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of MSN's ANDA Product would infringe any valid and/or enforceable claim of the '227 patent.

29. MSN's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '227 patent.

30. MSN is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of MSN's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '227 patent.

COUNT IV
(Declaratory Judgment of Invalidity of the '227 Patent)

31. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

32. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '227 patent.

33. One or more claims of the '227 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

34. MSN is entitled to a judicial declaration that the claims of the '227 patent are invalid.

COUNT V
(Declaratory Judgment of Non-Infringement of the '009 Patent)

35. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

36. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of MSN's ANDA Product would infringe any valid and/or enforceable claim of the '009 patent.

37. MSN's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '009 patent.

38. MSN is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of MSN's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '009 patent.

COUNT VI
(Declaratory Judgment of Invalidity of the '009 Patent)

39. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

40. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the ’009 patent.

41. One or more claims of the ’009 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

42. MSN is entitled to a judicial declaration that the claims of the ’009 patent are invalid.

COUNT VII
(Declaratory Judgment of Non-Infringement of the ’951 Patent)

43. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

44. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of MSN’s ANDA Product would infringe any valid and/or enforceable claim of the ’951 patent.

45. MSN’s ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’951 patent.

46. MSN is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of MSN’s ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’951 patent.

COUNT VIII
(Declaratory Judgment of Invalidity of the ’951 Patent)

47. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

48. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '951 patent.

49. One or more claims of the '951 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

50. MSN is entitled to a judicial declaration that the claims of the '951 patent are invalid.

COUNT IX
(Declaratory Judgment of Non-Infringement of the '345 Patent)

51. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

52. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of MSN's ANDA Product would infringe any valid and/or enforceable claim of the '345 patent.

53. MSN's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '345 patent.

54. MSN is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of MSN's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '345 patent.

COUNT X
(Declaratory Judgment of Invalidity of the '345 Patent)

55. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

56. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the ’345 patent.

57. One or more claims of the ’345 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

58. MSN is entitled to a judicial declaration that the claims of the ’345 patent are invalid.

COUNT XI
(Declaratory Judgment of Non-Infringement of the ’084 Patent)

59. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

60. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of MSN’s ANDA Product would infringe any valid and/or enforceable claim of the ’084 patent.

61. MSN’s ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’084 patent.

62. MSN is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of MSN’s ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’084 patent.

COUNT XII
(Declaratory Judgment of Invalidity of the ’084 Patent)

63. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

64. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the ’084 patent.

65. One or more claims of the ’084 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

66. MSN is entitled to a judicial declaration that the claims of the ’084 patent are invalid.

COUNT XIII
(Declaratory Judgment of Non-Infringement of the ’842 Patent)

67. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

68. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of MSN’s ANDA Product would infringe any valid and/or enforceable claim of the ’842 patent.

69. MSN’s ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’842 patent.

70. MSN is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of MSN’s ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’842 patent.

COUNT XIV
(Declaratory Judgment of Invalidity of the ’842 Patent)

71. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

72. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '842 patent.

73. One or more claims of the '842 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

74. MSN is entitled to a judicial declaration that the claims of the '842 patent are invalid.

COUNT XV
(Declaratory Judgment of Non-Infringement of the '348 Patent)

75. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

76. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of MSN's ANDA Product would infringe any valid and/or enforceable claim of the '348 patent.

77. MSN's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '348 patent.

78. MSN is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of MSN's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '348 patent.

COUNT XVI
(Declaratory Judgment of Invalidity of the '348 Patent)

79. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

80. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the ’348 patent.

81. One or more claims of the ’348 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

82. MSN is entitled to a judicial declaration that the claims of the ’348 patent are invalid.

COUNT XVII
(Declaratory Judgment of Non-Infringement of the ’419 Patent)

83. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

84. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of MSN’s ANDA Product would infringe any valid and/or enforceable claim of the ’419 patent.

85. MSN’s ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’419 patent.

86. MSN is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of MSN’s ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ’419 patent.

COUNT XVIII
(Declaratory Judgment of Invalidity of the ’419 Patent)

87. MSN restates and incorporates by reference each of its responses to each of the preceding paragraphs as if fully set forth herein.

88. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '419 patent.

89. One or more claims of the '419 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

90. MSN is entitled to a judicial declaration that the claims of the '419 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, MSN respectfully prays for judgment in its favor and against Plaintiff/Counterclaim-Defendant:

(a) Declaring that the manufacture, use, sale, offer for sale or importation of MSN's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any and/or enforceable claim of the Asserted Patents;

(b) Declaring that the claims of the Asserted Patents are invalid;

(c) Ordering that Plaintiff/Counterclaim-Defendant's Complaint be dismissed with prejudice and judgment entered in favor of Defendant/Counterclaim-Plaintiff MSN;

(d) Declaring this case exceptional and awarding MSN its reasonable attorneys' fees and costs of these Counterclaims under 35 U.S.C. § 285; and

(e) Awarding MSN such other and further relief as the Court may deem just and proper.

MIDLIGE RICHTER LLC
Attorneys for Defendant,
MSN Laboratories Private Ltd.

By: s/ James S. Richter
James S. Richter
jrichter@midlige-richter.com

Dated: June 3, 2024

OF COUNSEL *(Pro Hac Vice Forthcoming)*

William A. Rakoczy (wrakoczy@rmmslegal.com)
Tara M. Raghavan (traghavan@rmmslegal.com)
Dylan Sacenti (dsacenti@rmmslegal.com)
Wojciech Jankiewicz (wjankiewicz@rmmslegal.com)
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, Illinois 60654
(312) 527-2157

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, Defendant/Counterclaim-Plaintiff MSN Laboratories Private Ltd., by its undersigned counsel, hereby certifies that the matter in controversy is not subject to any other action pending in any court, or any pending arbitration or administrative proceeding, but it appears, at the time of this certification, that the Asserted Patents in this matter are also the subject of the following actions:

- *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-cv-04312 (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. Dr. Reddy's Laby*'s *Inc.*, C.A. No. 3:24-cv-04314 (D.N.J.)
- *Intra-Cellular Therapies, Inc. v. Sandoz Inc.*, C.A. No. 3:24-cv-04327 (D.N.J.)
- *Intra-Cellular Therapies, Inc. v. Zydus Pharms. (USA) Inc.*, C.A. No. 3:24-cv-04330 (D.N.J.)

s/ James S. Richter
James S. Richter

Dated: June 3, 2024

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendant/Counterclaim Plaintiff MSN Laboratories Private Ltd., by its undersigned counsel, hereby certifies that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

s/ James S. Richter
James S. Richter

Dated: June 3, 2024

CERTIFICATION OF SERVICE

The undersigned attorney certifies that a copy of the foregoing Answer, Affirmative Defenses, and Counterclaims to Plaintiffs' Complaint for Patent Infringement was filed via ECF and served on all counsel of record by electronic mail on June 3, 2024.

s/ James S. Richter
James S. Richter

Dated: June 3, 2024