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

Intra-Cellular Therapies, Inc., *Plaintiff,* v. Sandoz Inc., *Defendant.*	Civil Action No. 3:24-cv-04327

DEFENDANT SANDOZ INC.'S ANSWER TO
COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant Sandoz Inc. ("Sandoz") hereby answers and asserts the following defenses to the Complaint brought by Plaintiff Intra-Cellular Therapies, Inc., ("Plaintiff") on March 28, 2024.

ANSWER TO COMPLAINT

Each of the paragraphs and section titles below corresponds to the same-numbered paragraphs and section titles in Plaintiff's Complaint, respectively. Sandoz denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or specifications that arguably follow from the admitted facts. Sandoz denies that Plaintiff is entitled to the relief requested or any other relief.

With respect to the allegations made in the Complaint, Sandoz states as follows:

Nature of the Action

Complaint ¶ 1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, that arises out of Sandoz's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of CAPLYTA® (lumateperone) capsules, 10.5 mg, 21 mg, and 42 mg, prior to the expiration of U.S. Patent Nos. 8,648,077 ("the '077 patent"), 9,168,258 ("the '258 patent"), 9,199,995 ("the '995 patent"), 9,616,061 ("the '061 patent"), 9,956,227 ("the '227 patent"), 10,117,867 ("the '867 patent"), 10,464,938 ("the '938 patent"), 10,695,345 ("the '345 patent"), 10,960,009 ("the '009 patent"), 11,026,951 ("the '951 patent"), 11,052,084 ("the '084 patent"), 11,690,842 ("the '842 patent"), 11,753,419 ("the '419 patent"), 11,806,348 ("the '348 patent"), RE48,825 ("the RE '825 patent"), and RE48,839 ("the RE '839 patent"). These patents are referred to collectively herein as the "Patents-in-Suit."

Response: Paragraph 1 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the Complaint purports to state a civil action for patent infringement of United States Patent Nos. 8,648,077 ("the '077 patent"), 9,168,258 ("the '258 patent"), 9,199,995 ("the '995 patent"), 9,616,061 ("the '061 patent"), 9,956,227 ("the '227 patent"), 10,117,867 ("the '867 patent"), 10,464,938 ("the '938 patent"), 10,695,345 ("the '345 patent"), 10,960,009 ("the '009 patent"), 11,026,951 ("the '951 patent"), 11,052,084 ("the '084 patent"), 11,690,842 ("the '842 patent"), 11,753,419 ("the '419 patent"), 11,806,348 ("the '348 patent"), RE48,825 ("the RE '825 patent"), and RE48,839 ("the RE '839 patent"). These patents are referred to collectively herein as the "Patents-in-Suit." Sandoz further admits that the Complaint purports to relate to Sandoz's submission of Abbreviated New Drug Application ("ANDA") No. 218938 ("Sandoz's ANDA") to the United States Food and Drug Administration ("FDA"), seeking approval of its generic lumateperone capsules, 10.5 mg, 21 mg, and 42 mg ("Sandoz's ANDA Product"). Sandoz denies the remaining allegations of Paragraph 1.

Complaint ¶ 2. Sandoz notified Plaintiff by letter dated February 15, 2024 ("Sandoz's Notice Letter") that it had submitted to the FDA ANDA No. 218938 ("Sandoz's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offer for

sale, sale, and/or importation of generic lumateperone capsules, 10.5 mg, 21 mg, and 42 mg, ("Sandoz's ANDA Product") prior to the expiration of the Patents-in-Suit.

Response: Sandoz admits that it sent a letter, dated February 15, 2024, to Plaintiff ("Sandoz's Notice Letter") and states that Sandoz's Notice Letter speaks for itself. Sandoz further states that it submitted Sandoz's ANDA to the FDA seeking approval of Sandoz's ANDA Product. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 2.

The Parties

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

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 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.

Response: Sandoz admits that FDA's Orange Book identifies "INTRA-CELLULAR THERAPIES INC" as holder of 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. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 4 and therefore denies them.

Complaint ¶ 5. Upon information and belief, Defendant Sandoz is a corporation organized and existing under the laws of Delaware and having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

Response: Admitted.

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

Response: Sandoz admits that it submitted Sandoz's ANDA No. 218938 to the FDA seeking approval of Sandoz's ANDA Product. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 6.

Jurisdiction

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

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

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

Response: Paragraph 8 states legal conclusions to which no response is required. To the extent that a response is required, and solely for the limited purposes of this action only, Sandoz does not contest subject matter jurisdiction as to Plaintiff's infringement allegations against Sandoz under 35 U.S.C. § 271(e)(2)(A). Sandoz denies that subject matter jurisdiction is proper for any claims asserted against Sandoz under 35 U.S.C. § 271(a), (b), or (c). Sandoz denies the remaining allegations of Paragraph 8.

Complaint ¶ 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 Sandoz.

Response: Paragraph 9 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey.

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

Response: Paragraph 10 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey.

Complaint ¶ 11. Upon information and belief, Sandoz is registered to do business in New Jersey under Entity Identification Number 0100097265 and is registered with the New Jersey Department of Health as a drug manufacturer and wholesaler under Registration Number 5003732.

Response: Sandoz admits that it is registered to do business in New Jersey and is registered with the New Jersey Department of Health as a drug manufacturer and wholesaler under Registration Number 5003732. Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey.

Complaint ¶ 12. Upon information and belief, Sandoz, through its own actions and/or through the actions of its agents and subsidiaries, has engaged in the research and development, and the preparation and filing, of Sandoz's ANDA; continues to engage in seeking FDA approval of Sandoz's ANDA; intends to engage in the commercial manufacture, marketing, offer for sale, sale, or importation of Sandoz's ANDA Product throughout the United States, including in New Jersey; and stands to benefit from the approval of Sandoz's ANDA.

Response: Paragraph 12 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it prepared and submitted Sandoz's ANDA No. 218938. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey.

Complaint ¶ 13. Upon information and belief, Sandoz, through its own actions and/or through the actions of its agents and subsidiaries, prepared and submitted Sandoz's ANDA with certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Response: Paragraph 13 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it prepared and submitted Sandoz's ANDA No. 218938 to FDA with certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Sandoz further admits that solely for the limited purposes of this action only, Sandoz does not contest

personal jurisdiction in the District of New Jersey. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 13.

Complaint ¶ 14. Upon information and belief, upon FDA approval of Sandoz's ANDA, Sandoz will market, offer to sell, sell, or distribute Sandoz's ANDA Product throughout the United States, including in New Jersey, consistently with Sandoz's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Sandoz regularly does business in New Jersey, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in New Jersey. Upon information and belief, Sandoz's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. Upon information and belief, Sandoz's ANDA Product will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and/or used by patients in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the Patents-in-Suit in the event that Sandoz's ANDA Product is approved before the Patents-in-Suit expire.

Response: Paragraph 14 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted Sandoz's ANDA to FDA seeking approval of Sandoz's ANDA Product. Sandoz further admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 14.

Complaint ¶ 15. Upon information and belief, Sandoz derives substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and which are manufactured by Sandoz and/or for which Sandoz is the named applicant on approved ANDAs. Upon information and belief, various products for which Sandoz is the named applicant on approved ANDAs are available at retail pharmacies in New Jersey.

Response: Paragraph 15 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 15.

Complaint ¶ 16. Sandoz is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Sandoz is a corporation with a principal place of business in New Jersey, is registered to do business in New Jersey, and has appointed a registered agent for service of process in New Jersey.

It therefore has consented to general jurisdiction in New Jersey. In addition, upon information and belief, Sandoz develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

Response: Paragraph 16 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey.

Complaint ¶ 17. This Court also has personal jurisdiction over Sandoz because, among other things, upon information and belief: (1) Sandoz filed Sandoz's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product in the United States, including in New Jersey; and (2) upon approval of Sandoz's ANDA, Sandoz will directly, or indirectly through subsidiaries, intermediaries, distributors, retailers, or others, market, distribute, offer for sale, sell, and/or import Sandoz's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Sandoz's ANDA Product in New Jersey. Upon information and belief, upon approval of Sandoz's ANDA, Sandoz's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

Response: Paragraph 17 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted Sandoz's ANDA to FDA seeking approval of Sandoz's ANDA Product. Sandoz further admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 17.

Complaint ¶ 18. This Court also has personal jurisdiction over Sandoz because Sandoz has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiff, which manufactures CAPLYTA® drug products for sale and use throughout the United States, including in New Jersey. As a result, the consequences of Sandoz's actions were, and will be, suffered in New Jersey. Sandoz knew or should have known that the consequences of its actions were, and will be, suffered in New Jersey. At the time Sandoz sent notice of the certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), it was reasonably foreseeable that Sandoz would be sued within 45 days in New Jersey, where Sandoz is located. Upon information and belief, Sandoz's actions will injure Plaintiff by displacing at least some, if not all, of Plaintiff's sales of CAPLYTA® drug

products in New Jersey, as well as resulting in price erosion and loss of goodwill with the purchasers and distributors of CAPLYTA® drug products in New Jersey.

Response: Paragraph 18 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted Sandoz's ANDA to FDA seeking approval of Sandoz's ANDA Product. Sandoz further admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 18.

Complaint ¶ 19. Sandoz is also subject to personal jurisdiction in New Jersey because it (1) engages in patent litigation concerning Sandoz's generic versions of branded pharmaceutical products in this District, (2) does not contest personal jurisdiction in this District, and (3) purposefully avails itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Astellas Pharma Inc. v. Sandoz, Inc.*, No. 23-cv-01214, ECF No. 17 (D.N.J. May 1, 2023); *Aragon Pharms., Inc. v. Sandoz,* No. 22-cv-03044, ECF No. 23 (D.N.J. Aug. 1, 2022).

Response: Paragraph 19 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey.

Complaint ¶ 20. For the above reasons, it would not be unfair or unreasonable for Sandoz to litigate this action in this District, and the Court has personal jurisdiction over Sandoz.

Response: Paragraph 20 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 20.

Venue

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

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 22. Venue is proper in this district under 28 U.S.C. § 1391, at least because, upon information and belief, Sandoz resides in this district and a substantial part of the events and injury giving rise to Plaintiff's claims has and continues to occur in this district.

Response: Paragraph 22 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest venue in the District of New Jersey.

Complaint ¶ 23. Venue is proper in this district under 28 U.S.C. § 1400(b), at least because, upon information and belief, Sandoz has a principal place of business in New Jersey and has committed acts of infringement in New Jersey. Upon information and belief, among other things, (1) Sandoz prepared and/or submitted Sandoz's ANDA with Paragraph IV certifications in New Jersey, where Sandoz is located; and (2) upon approval of Sandoz's ANDA, Sandoz will market, distribute, offer for sale, sell, and/or import Sandoz's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Sandoz's ANDA Product in New Jersey.

Response: Paragraph 23 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest venue in the District of New Jersey. Sandoz further admits that it submitted Sandoz's ANDA to FDA seeking approval of Sandoz's ANDA Product. Sandoz further admits that it prepared and submitted Sandoz's ANDA No. 218938 to FDA with certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 23.

Complaint ¶ 24. Venue is proper in this district as to Sandoz because Sandoz (1) engages in patent litigation concerning Sandoz's generic versions of branded pharmaceutical products in this District, and (2) does not contest that venue is proper in this district. *See, e.g.*, *Astellas Pharma Inc. v. Sandoz, Inc.*, No. 23-cv-01214, ECF No. 17 (D.N.J. May 1, 2023); *Aragon Pharms., Inc. v. Sandoz*, No. 22-cv-03044, ECF No. 23 (D.N.J. Aug. 1, 2022).

Response: Paragraph 24 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest venue in the District of New Jersey.

Factual Background

Complaint ¶ 25. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 26. CAPLYTA® , lumateperone capsules, 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.

Response: Sandoz admits that pursuant to the June 2023 FDA approved label packaging insert for CAPLYTA®, "CAPLYTA is an atypical antipsychotic indicated for the treatment of: schizophrenia in adults and depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate." Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 26.

Complaint ¶ 27. In Sandoz's Notice Letter, Sandoz stated that the subject of Sandoz's ANDA is lumateperone capsules, 10.5 mg, 21 mg, and 42 mg. In Sandoz's Notice Letter, Sandoz stated that Sandoz's ANDA was submitted under 21 U.S.C. § 355(j)(1) & (2)(a) and contended that Sandoz's ANDA contains bioavailability and/or bioequivalence studies for Sandoz's ANDA Product. Upon information and belief, Sandoz's ANDA Product is a generic version of CAPLYTA®.

Response: Paragraph 27 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA with the FDA pursuant to 21 U.S.C. § 355(j) & (2)(a) seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 27.

Complaint ¶ 28. In Sandoz's Notice Letter, Sandoz 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 Sandoz is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit.

Response: Paragraph 28 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA to FDA seeking

approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 28.

Complaint ¶ 29. The purpose of Sandoz's submission of Sandoz'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 Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit.

Response: Paragraph 29 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted Sandoz's ANDA to FDA seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 29.

Complaint ¶ 30. Upon information and belief, Sandoz's ANDA Product is not publicly available, nor is ANDA No. 218938 accessible to the public.

Response: Paragraph 30 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Sandoz has not made its ANDA Product and ANDA No. 218938 accessible to the public.

Complaint ¶ 31. In Sandoz's Notice Letter, Sandoz included an Offer of Confidential Access to a redacted version of Sandoz's ANDA, and Sandoz's offer was subject to various unreasonably restrictive conditions.

Response: Sandoz admits that Sandoz's Notice Letter included an Offer for Confidential Access ("OCA"). Except as otherwise expressly admitted, Sandoz denies the remaining allegations in Paragraph 31.

Complaint ¶ 32. In an exchange of correspondence, counsel for Plaintiff and counsel for Sandoz discussed the terms of Sandoz's Offer of Confidential Access. The parties did not agree on terms under which Plaintiff could review, among other things, Sandoz's unredacted ANDA, any Drug Master File referred to therein, or all relevant characterization data. Sandoz further refused to produce samples of Sandoz's ANDA Product and other internal documents and material relevant to infringement.

Response: Sandoz admits that there was an exchange of correspondence between counsel for Plaintiff and counsel for Sandoz discussing the terms of Sandoz's Offer of Confidential Access ("OCA"). In that exchange, Sandoz negotiated in good faith and agreed to almost all of Plaintiff's proposed modifications to the OCA, including allowing Plaintiff access to an unredacted copy of Sandoz's ANDA despite Sandoz's statutory right to provide the ANDA in redacted form to "remove any information of no relevance to any issue of patent infringement." Sandoz stated that pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), Plaintiff was not entitled to the DMF, samples, or any other characterization data outside of Sandoz's ANDA under the OCA and before litigation had commenced. Plaintiff refused to further negotiate the OCA and did not provide a legal basis for its request for information outside of the ANDA under an OCA. Except as otherwise expressly admitted, Sandoz denies the remaining allegations in Paragraph 32.

Complaint ¶ 33. This action is being commenced within 45 days from the date Plaintiff received Sandoz's Notice Letter.

Response: Sandoz admits that Plaintiff filed this action on March 28, 2024. Except as otherwise expressly admitted, Sandoz denies the remaining allegations in Paragraph 33.

Count I—Infringement of the RE '839 Patent

Complaint ¶ 34. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 35. 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.

Response: Paragraph 35 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the RE '839 Patent is titled "Methods and Compositions for Sleep Disorders and Other Disorders" and that the face of the RE '839 Patent identifies December 7, 2021 as the "Date of Reissued Patent." Sandoz admits that Exhibit A to

Plaintiff's Complaint purports to be a copy of the RE '839 Patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 35.

Complaint ¶ 36. The inventors named on the RE '839 patent are Sharon Mates, Allen Fienberg, and Lawrence Wennogle.

Response: Paragraph 36 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the RE '839 patent identifies "Sharon Mates," "Allen Fienberg," and "Lawrence Wennogle" as the inventors. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 36 and therefore denies them.

Complaint ¶ 37. Plaintiff is the owner and assignee of the RE '839 patent.

Response: Paragraph 37 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the RE '839 patent identifies "Intra-Cellular Therapies, Inc." as the assignee. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 37 and therefore denies them.

Complaint ¶ 38. 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").

Response: Paragraph 38 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that FDA's Orange Book entry for CAPLYTA® identifies the RE '839 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations in Paragraph 38.

Complaint ¶ 39. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the RE '839 patent.

Response: Paragraph 39 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it notified Plaintiff, via Sandoz's Notice Letter, of the submission of Sandoz's ANDA to the FDA. Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 39.

Complaint ¶ 40. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the RE '839 patent. Upon information and belief, Sandoz 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 Sandoz's ANDA Product.

Response: Paragraph 40 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA with the FDA pursuant to 21 U.S.C. § 355(j) seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 40.

Complaint ¶ 41. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

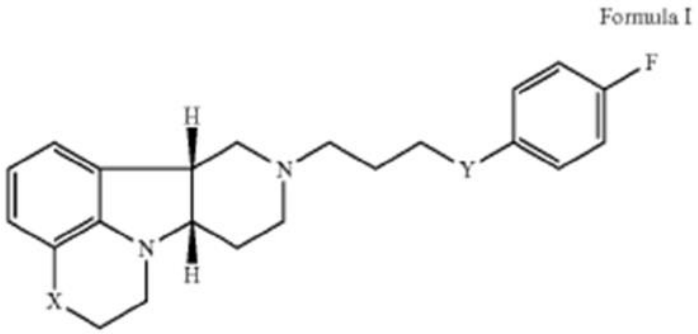
Response: Paragraph 41 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's Notice Letter says "Pursuant to 21 C.F.R. § 314.95(c)(5), the active ingredient in the proposed drug product is lumateperone; the strength of the proposed drug product is 10.5 mg lumateperone, 21 mg lumateperone, and 42 mg lumateperone." Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 41.

Complaint ¶ 42. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe one or more claims of the RE '839 patent.

Response: Paragraph 42 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 43. As an example, claim 1 of the RE '839 patent recites:

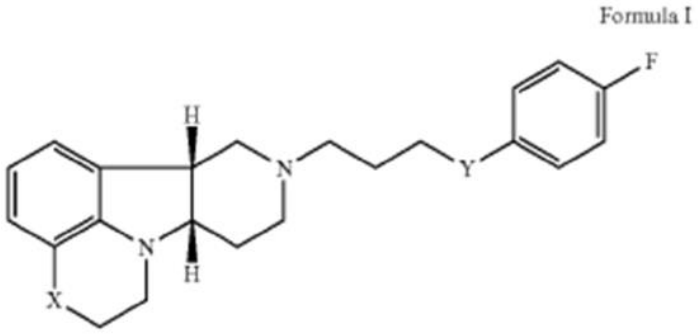
> A method for the treatment of one or more 5-HT2*A*-related disorders, comprising administering to a patient in need thereof a Compound of Formula I:



> 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-HT2*A* receptor.

Response: Paragraph 43 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the RE '839 patent recites the following for claim 1:

> A method for the treatment of one or more 5-HT2*A*-related disorders, comprising administering to a patient in need thereof a Compound of 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-HT2*A* receptor.

Complaint ¶ 44. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed label would involve treating one or more 5-HT2*A*-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-HT2*A* receptor, as recited in claim 1.

Response: Paragraph 44 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that its proposed label speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 44.

Complaint ¶ 45. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed product labeling would infringe one or more claims of the RE '839 patent, literally or under the doctrine of equivalents.

Response: Paragraph 45 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 46. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the RE '839 patent was an act of infringement of the RE '839 patent under 35 U.S.C. § 271(e)(2)(A).

Response: Paragraph 46 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 46.

Complaint ¶ 47. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of its ANDA.

Response: Paragraph 47 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 47.

Complaint ¶ 48. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the RE '839 patent.

Response: Paragraph 48 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 49. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the RE '839 patent.

Response: Paragraph 49 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 50. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the RE '839 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the RE '839 patent and specific intent to infringe that patent.

Response: Paragraph 50 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 51. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the RE '839 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the RE '839 patent immediately and imminently upon approval of Sandoz's ANDA.

Response: Paragraph 51 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 52. Notwithstanding Sandoz's knowledge of the claims of the RE '839 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the RE '839 patent.

Response: Paragraph 52 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 53. The foregoing actions by Sandoz 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.

Response: Paragraph 53 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 54. Upon information and belief, Sandoz 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.

Response: Paragraph 54 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 55. Plaintiff will be substantially and irreparably damaged by infringement of the RE '839 patent.

Response: Paragraph 55 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 56. Unless Sandoz 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.

Response: Paragraph 56 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count II—Declaratory Judgment of Infringement of the RE '839 Patent

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

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 58. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the RE '839 patent, and/or the validity of the RE '839 patent.

Response: Paragraph 58 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that because of Plaintiff's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the RE '839 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 58.

Complaint ¶ 59. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the 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.

Response: Paragraph 59 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count III—Infringement of the '258 Patent

Complaint ¶ 60. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 61. The '258 patent, entitled "Methods and Compositions for Sleep Disorders and Other Disorders" (attached as Exhibit B), was duly and legally issued on October 27, 2015.

Response: Paragraph 61 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '258 Patent is titled "Methods and Compositions for Sleep Disorders and Other Disorders" and that the face of the '258 Patent identifies October 27, 2015 as the "Date of Patent." Sandoz admits that Exhibit B to Plaintiff's Complaint purports to be a copy of the '258 Patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 61.

Complaint ¶ 62. The inventors named on the '258 patent are Sharon Mates, Allen Fienberg, and Lawrence P. Wennogle.

Response: Paragraph 62 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '258 patent identifies "Sharon Mates," "Allen Fienberg," and "Lawrence P. Wennogle" as the inventors. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 62 and therefore denies them.

Complaint ¶ 63. Plaintiff is the owner and assignee of the '258 patent.

Response: Paragraph 63 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '258 patent identifies "INTRA-CELLULAR THERAPIES, INC." as the assignee. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 63 and therefore denies them.

Complaint ¶ 64. CAPLYTA® is covered by one or more claims of the '258 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

Response: Paragraph 64 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that FDA's Orange Book entry for CAPLYTA® identifies the '258 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 64.

Complaint ¶ 65. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '258 patent.

Response: Paragraph 65 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it notified Plaintiff, via Sandoz's Notice Letter, of the submission of Sandoz's ANDA to the FDA. Sandoz states that Sandoz's Notice

Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 65.

Complaint ¶ 66. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '258 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '258 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

Response: Paragraph 66 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA with the FDA pursuant to 21 U.S.C. § 355(j) seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 66.

Complaint ¶ 67. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

Response: Paragraph 67 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 67.

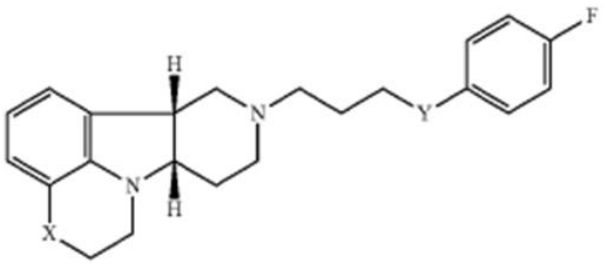
Complaint ¶ 68. Upon information and belief, Sandoz's ANDA Product and the use of Sandoz's ANDA Product are covered by one or more claims of the '258 patent, either literally or under the doctrine of equivalents.

Response: Paragraph 68 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 69. As an example, claim 1 of the '258 patent recites:

> A pharmaceutical composition in oral unit dose form comprising an amount of 10 mg or less of 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 combination or association with a pharmaceutically acceptable diluent or carrier, provided that in the case of a salt, the weight is calculated as the free base, where the amount of the Compound of Formula I:

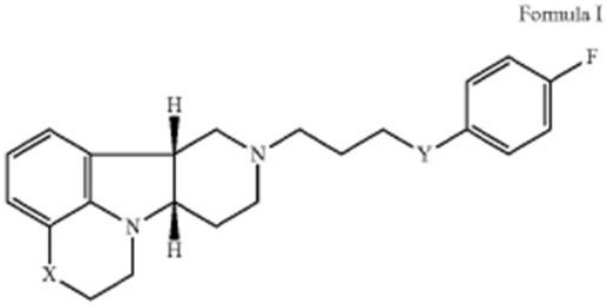
a) is sufficient to block the 5-HT*2A* receptor; and

b) either does not block, or minimally blocks the dopamine D2 receptor.

Response: Paragraph 69 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '258 patent recites the following for claim 1:

A pharmaceutical composition in oral unit dose form comprising an amount of 10 mg or less of 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 combination or association with a pharmaceutically acceptable diluent or carrier, provided that in the case of a salt, the weight is

> calculated as the free base, where the amount of the Compound of Formula I:
>
> a) is sufficient to block the 5-HT2*A* receptor; and
>
> b) either does not block, or minimally blocks the dopamine D2 receptor.

Complaint ¶ 70. Upon information and belief, Sandoz's ANDA Product contains a pharmaceutical composition in oral unit dose form containing an amount of 10 mg or less (calculated as the free base) of a Formula I compound (lumateperone) in pharmaceutically acceptable salt form in combination or association with a pharmaceutically acceptable diluent or carrier and in an amount that is sufficient to block the 5-HT2*A* receptor and that does not block, or minimally blocks, the dopamine D2 receptor, as recited in claim 1.

Response: Paragraph 70 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA, which describes its ANDA Product, speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 70.

Complaint ¶ 71. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '258 patent, literally or under the doctrine of equivalents.

Response: Paragraph 71 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 72. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '258 patent was an act of infringement of the '258 patent under 35 U.S.C. § 271(e)(2)(A).

Response: Paragraph 72 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 72.

Complaint ¶ 73. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of its ANDA.

Response: Paragraph 73 states legal conclusions to which no response is required, to the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 73.

Complaint ¶ 74. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '258 patent.

Response: Paragraph 74 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 75. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '258 patent.

Response: Paragraph 75 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 76. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '258 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '258 patent and specific intent to infringe that patent.

Response: Paragraph 76 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 77. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '258 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '258 patent immediately and imminently upon approval of Sandoz's ANDA.

Response: Paragraph 77 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 78. Notwithstanding Sandoz's knowledge of the claims of the '258 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '258 patent.

Response: Paragraph 78 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 79. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '258 patent; active inducement of infringement of the '258 patent; and/or contribution to the infringement by others of the '258 patent.

Response: Paragraph 79 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 80. Upon information and belief, Sandoz has acted with full knowledge of the '258 patent and without a reasonable basis for believing that it would not be liable for infringement of the '258 patent; active inducement of infringement of the '258 patent; and/or contribution to the infringement by others of the '258 patent.

Response: Paragraph 80 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 81. Plaintiff will be substantially and irreparably damaged by infringement of the '258 patent.

Response: Paragraph 81 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 82. Unless Sandoz is enjoined from infringing the '258 patent, actively inducing infringement of the '258 patent, and contributing to the infringement by others of the '258 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Response: Paragraph 82 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count IV—Declaratory Judgment of Infringement of the '258 Patent

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

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 84. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active

inducement of infringement, contribution to the infringement by others of the '258 patent, and/or the validity of the '258 patent.

Response: Paragraph 84 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that because of Plaintiff's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '258 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 84.

Complaint ¶ 85. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '258 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '258 patent, and that the claims of the '258 patent are not invalid.

Response: Paragraph 85 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count V—Infringement of the '061 Patent

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

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 87. The '061 patent, entitled "Methods and Compositions for Sleep Disorders and Other Disorders" (attached as Exhibit C), was duly and legally issued on April 11, 2017.

Response: Paragraph 87 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '061 Patent is titled "Methods and Compositions for Sleep Disorders and Other Disorders" and that the face of the '061 Patent identifies April 11, 2017 as the "Date of Patent." Sandoz admits that Exhibit C to Plaintiff's Complaint purports to be a copy of the '061 Patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 87.

Complaint ¶ 88. The inventors named on the '061 patent are Sharon Mates, Allen Fienberg, and Lawrence Wennogle.

Response: Paragraph 88 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '061 patent identifies "Sharon Mates," "Allen Fienberg," and "Lawrence Wennogle" as the inventors. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 88 and therefore denies them.

Complaint ¶ 89. Plaintiff is the owner and assignee of the '061 patent.

Response: Paragraph 89 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '061 patent identifies "INTRA-CELLULAR THERAPIES, INC." as the assignee. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 89 and therefore denies them.

Complaint ¶ 90. CAPLYTA® is covered by one or more claims of the '061 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

Response: Paragraph 90 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that FDA's Orange Book entry for CAPLYTA® identifies the '061 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 90.

Complaint ¶ 91. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '061 patent.

Response: Paragraph 91 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it notified Plaintiff, via Sandoz's Notice Letter, of the submission of Sandoz's ANDA to the FDA. Sandoz states that Sandoz's Notice

Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 91.

Complaint ¶ 92. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '061 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '061 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

Response: Paragraph 92 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA with the FDA pursuant to 21 U.S.C. § 355(j) seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 92.

Complaint ¶ 93. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

Response: Paragraph 93 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 93.

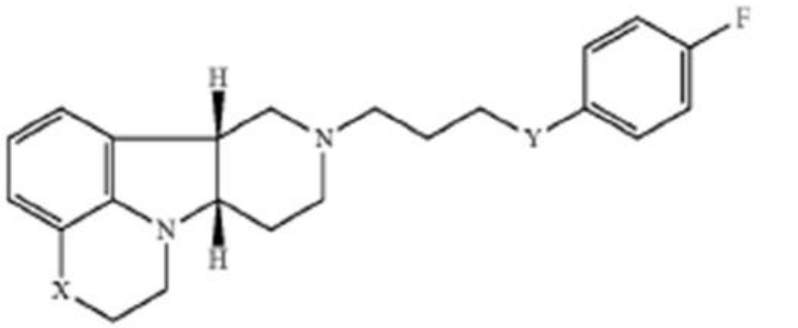
Complaint ¶ 94. Upon information and belief, Sandoz's ANDA Product and the use of Sandoz's ANDA Product are covered by one or more claims of the '061 patent, either literally or under the doctrine of equivalents.

Response: Paragraph 94 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 95. As an example, claim 1 of the '061 patent recites:

> A pharmaceutical composition in oral unit dose form comprising an amount of from 0.1-20 mg of a Compound of Formula I:

Formula I

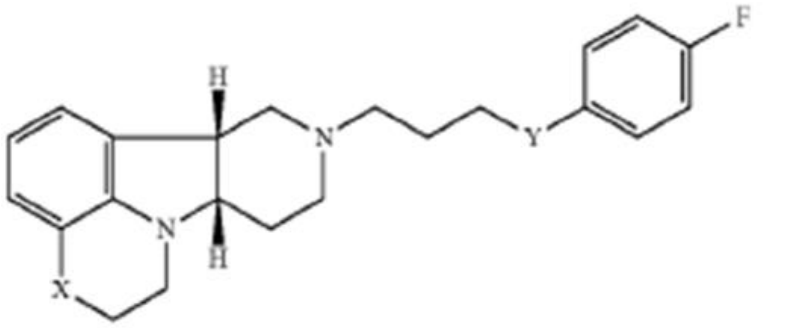


wherein X is —N(CH_3); and Y is —C(O)—, in free or pharmaceutically acceptable salt form, in combination or association with a pharmaceutically acceptable diluent or carrier, provided that in the case of a salt, the weight is calculated as the free base.

Response: Paragraph 95 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '061 patent recites the following for claim 1:

A pharmaceutical composition in oral unit dose form comprising an amount of from 0.1-20 mg 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, in combination or association with a pharmaceutically acceptable diluent or carrier, provided that in the case of a salt, the weight is calculated as the free base.

Complaint ¶ 96. Upon information and belief, Sandoz's ANDA Product contains a pharmaceutical composition in oral unit dose form containing an amount of from 0.1-20 mg

(calculated as the free base) of a Formula I compound (lumateperone) in pharmaceutically acceptable salt form in combination or association with a pharmaceutically acceptable diluent or carrier, as recited in claim 1.

Response: Paragraph 96 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA, which describes its ANDA Product, speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 96.

Complaint ¶ 97. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '061 patent, literally or under the doctrine of equivalents.

Response: Paragraph 97 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 98. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '061 patent was an act of infringement of the '061 patent under 35 U.S.C. § 271(e)(2)(A).

Response: Paragraph 98 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 98.

Complaint ¶ 99. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of its ANDA.

Response: Paragraph 99 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 99.

Complaint ¶ 100. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '061 patent.

Response: Paragraph 100 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 101. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '061 patent.

Response: Paragraph 101 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 102. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '061 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '061 patent and specific intent to infringe that patent.

Response: Paragraph 102 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 103. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '061 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '061 patent immediately and imminently upon approval of Sandoz's ANDA.

Response: Paragraph 103 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 104. Notwithstanding Sandoz's knowledge of the claims of the '061 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '061 patent.

Response: Paragraph 104 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 105. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '061 patent; active inducement of infringement of the '061 patent; and/or contribution to the infringement by others of the '061 patent.

Response: Paragraph 105 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 106. Upon information and belief, Sandoz has acted with full knowledge of the '061 patent and without a reasonable basis for believing that it would not be liable for

infringement of the '061 patent; active inducement of infringement of the '061 patent; and/or contribution to the infringement by others of the '061 patent.

Response: Paragraph 106 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 107. Plaintiff will be substantially and irreparably damaged by infringement of the '061 patent.

Response: Paragraph 107 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 108. Unless Sandoz is enjoined from infringing the '061 patent, actively inducing infringement of the '061 patent, and contributing to the infringement by others of the '061 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Response: Paragraph 108 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count VI—Declaratory Judgment of Infringement of the '061 Patent

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

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 110. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '061 patent, and/or the validity of the '061 patent.

Response: Paragraph 110 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that because of Plaintiff's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '061 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 110.

Complaint ¶ 111. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or

any other Sandoz drug product that is covered by or whose use is covered by the '061 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '061 patent, and that the claims of the '061 patent are not invalid.

Response: Paragraph 111 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count VII—Infringement of the '867 Patent

Complaint ¶ 112. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 113. The '867 patent, entitled "Methods and Compositions for Sleep Disorders and Other Disorders" (attached as Exhibit D), was duly and legally issued on November 6, 2018.

Response: Paragraph 113 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '867 Patent is titled "Methods and Compositions for Sleep Disorders and Other Disorders" and that the face of the '867 Patent identifies November 6, 2018 as the "Date of Patent." Sandoz admits that Exhibit D to Plaintiff's Complaint purports to be a copy of the '867 Patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 113.

Complaint ¶ 114. The inventors named on the '867 patent are Sharon Mates, Allen Fienberg, and Lawrence P. Wennogle.

Response: Paragraph 114 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '867 patent identifies "Sharon Mates," "Allen Fienberg," and "Lawrence P. Wennogle" as the inventors. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 114 and therefore denies them.

Complaint ¶ 115. Plaintiff is the owner and assignee of the '867 patent.

Response: Paragraph 115 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '867 patent identifies "INTRA-CELLULAR THERAPIES, INC." as the assignee. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 115 and therefore denies them.

Complaint ¶ 116. CAPLYTA® is covered by one or more claims of the '867 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

Response: Paragraph 116 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that FDA's Orange Book entry for CAPLYTA® identifies the '867 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations in Paragraph 116.

Complaint ¶ 117. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '867 patent.

Response: Paragraph 117 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it notified Plaintiff, via Sandoz's Notice Letter, of the submission of Sandoz's ANDA to the FDA. Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 117.

Complaint ¶ 118. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '867 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '867 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

Response: Paragraph 118 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA with the FDA pursuant

to 21 U.S.C. § 355(j) seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 118.

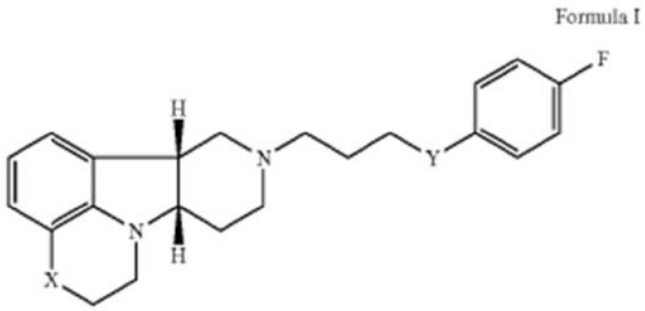
Complaint ¶ 119. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

Response: Paragraph 119 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 119.

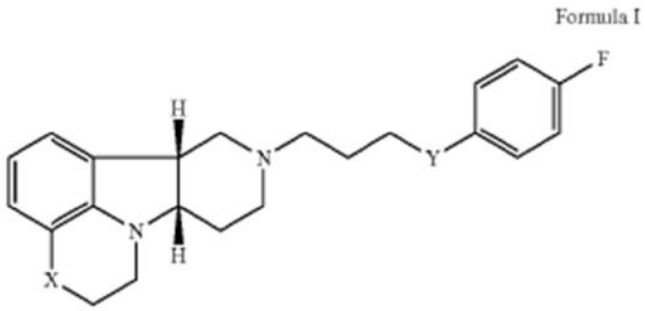
Complaint ¶ 120. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe one or more claims of the '867 patent.

Response: Paragraph 120 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 121. As an example, claim 1 of the '867 patent recites:

> A method for the treatment of bipolar depression, 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.

Response: Paragraph 121 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '867 patent recites the following for claim 1:

> A method for the treatment of bipolar depression, 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.

Complaint ¶ 122. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed label would involve treating bipolar depression, including by administering to the patient in need thereof a free or pharmaceutically acceptable salt form of a Formula I compound, as recited in claim 1.

Response: Paragraph 122 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz states that the proposed Sandoz ANDA Product label includes the following indications "[s]chizophrenia in adults [see Clinical Studies (14.1)]" and "[d]epressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate [see Clinical Studies (14.2)]." Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 122.

Complaint ¶ 123. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '867 patent, literally or under the doctrine of equivalents.

Response: Paragraph 123 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 124. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '867 patent was an act of infringement of the '867 patent under 35 U.S.C. § 271(e)(2)(A).

Response: Paragraph 124 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 124.

Complaint ¶ 125. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of its ANDA.

Response: Paragraph 125 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 125.

Complaint ¶ 126. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '867 patent.

Response: Paragraph 126 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 127. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '867 patent.

Response: Paragraph 127 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 128. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '867 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '867 patent and specific intent to infringe that patent.

Response: Paragraph 128 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 129. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '867 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '867 patent immediately and imminently upon approval of Sandoz's ANDA.

Response: Paragraph 129 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 130. Notwithstanding Sandoz's knowledge of the claims of the '867 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '867 patent.

Response: Paragraph 130 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 131. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '867 patent; active inducement of infringement of the '867 patent; and/or contribution to the infringement by others of the '867 patent.

Response: Paragraph 131 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 132. Upon information and belief, Sandoz has acted with full knowledge of the '867 patent and without a reasonable basis for believing that it would not be liable for infringement of the '867 patent; active inducement of infringement of the '867 patent; and/or contribution to the infringement by others of the '867 patent.

Response: Paragraph 132 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 133. Plaintiff will be substantially and irreparably damaged by infringement of the '867 patent.

Response: Paragraph 133 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 134. Unless Sandoz is enjoined from infringing the '867 patent, actively inducing infringement of the '867 patent, and contributing to the infringement by others of the '867 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Response: Paragraph 134 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count VIII—Declaratory Judgment of Infringement of the '867 Patent

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

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 136. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '867 patent, and/or the validity of the '867 patent.

Response: Paragraph 136 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that because of Plaintiff's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '867 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 136.

Complaint ¶ 137. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '867 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '867 patent, and that the claims of the '867 patent are not invalid.

Response: Paragraph 137 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count IX—Infringement of the '077 Patent

Complaint ¶ 138. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 139. The ’077 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-fluorophenyl)-1-butanone Toluenesulfonic Acid Addition Salt and Salt Crystals” (attached as Exhibit E), was duly and legally issued on February 11, 2014.

Response: Paragraph 139 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the ’077 Patent is titled “4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone Toluenesulfonic Acid Addition Salt and Salt Crystals” and that the face of the ’077 Patent identifies February 11, 2014 as the “Date of Patent.” Sandoz admits that Exhibit E to Plaintiff’s Complaint purports to be a copy of the ’077 Patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 139.

Complaint ¶ 140. The inventors named on the ’077 patent are John Tomesch and Lawrence P. Wennogle.

Response: Paragraph 140 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the ’077 patent identifies “John Tomesch” and “Lawrence P. Wennogle” as the inventors. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 140 and therefore denies them.

Complaint ¶ 141. Plaintiff is the owner and assignee of the ’077 patent.

Response: Paragraph 141 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the ’077 patent identifies “Intra-Cellular Therapies, Inc.” as the assignee. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 141 and therefore denies them.

Complaint ¶ 142. CAPLYTA® is covered by one or more claims of the ’077 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

Response: Paragraph 142 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that FDA's Orange Book entry for CAPLYTA® identifies the '077 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations in Paragraph 142.

Complaint ¶ 143. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '077 patent.

Response: Paragraph 143 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it notified Plaintiff, via Sandoz's Notice Letter, of the submission of Sandoz's ANDA to the FDA. Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 143.

Complaint ¶ 144. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '077 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '077 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

Response: Paragraph 144 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA with the FDA pursuant to 21 U.S.C. § 355(j) seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 144.

Complaint ¶ 145. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

Response: Paragraph 145 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's Notice Letter speaks for itself.

Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 145.

Complaint ¶ 146. Upon information and belief, Sandoz's ANDA Product and the use of Sandoz's ANDA Product are covered by one or more claims of the '077 patent, either literally or under the doctrine of equivalents.

Response: Paragraph 146 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 147. As an example, claim 1 of the '077 patent recites:

> A toluenesulfonic acid addition salt crystal of 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-fluorophenyl)-1-butanone, wherein said salt crystal exhibits an X-ray powder diffraction pattern comprising at least two peaks having 2-theta values selected from the group consisting of 5.68°, 12.11°, 16.04°, 17.03°, 18.16°, 19.00°, 21.67°, 22.55°, 23.48° and 24.30°, wherein the X-ray powder diffraction data is collected on a diffractometer operating with a copper anode with a nickel filter.

Response: Paragraph 147 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '077 patent recites the following for claim 1:

> A toluenesulfonic acid addition salt crystal of 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-fluorophenyl)-1-butanone, wherein said salt crystal exhibits an X-ray powder diffraction pattern comprising at least two peaks having 2-theta values selected from the group consisting of 5.68°, 12.11°, 16.04°, 17.03°, 18.16°, 19.00°, 21.67°, 22.55°, 23.48° and 24.30°, wherein the X-ray powder diffraction data is collected on a diffractometer operating with a copper anode with a nickel filter.

Complaint ¶ 148. Upon information and belief, Sandoz's ANDA Product contains a crystalline form of the compound recited in claim 1.

Response: Paragraph 148 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA, which describes its ANDA

Product, speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 148.

Complaint ¶ 149. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '077 patent, literally or under the doctrine of equivalents.

Response: Paragraph 149 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 150. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '077 patent was an act of infringement of the '077 patent under 35 U.S.C. § 271(e)(2)(A).

Response: Paragraph 150 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 150.

Complaint ¶ 151. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of its ANDA.

Response: Paragraph 151 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 151.

Complaint ¶ 152. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '077 patent.

Response: Paragraph 152 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 153. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '077 patent.

Response: Paragraph 153 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 154. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '077 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '077 patent and specific intent to infringe that patent.

Response: Paragraph 154 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 155. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '077 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '077 patent immediately and imminently upon approval of Sandoz's ANDA.

Response: Paragraph 155 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 156. Notwithstanding Sandoz's knowledge of the claims of the '077 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '077 patent.

Response: Paragraph 156 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 157. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '077 patent; active inducement of infringement of the '077 patent; and/or contribution to the infringement by others of the '077 patent.

Response: Paragraph 157 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 158. Upon information and belief, Sandoz has acted with full knowledge of the '077 patent and without a reasonable basis for believing that it would not be liable for infringement of the '077 patent; active inducement of infringement of the '077 patent; and/or contribution to the infringement by others of the '077 patent.

Response: Paragraph 158 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 159. Plaintiff will be substantially and irreparably damaged by infringement of the '077 patent.

Response: Paragraph 159 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 160. Unless Sandoz is enjoined from infringing the '077 patent, actively inducing infringement of the '077 patent, and contributing to the infringement by others of the '077 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Response: Paragraph 160 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count X—Declaratory Judgment of Infringement of the '077 Patent

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

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 162. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '077 patent, and/or the validity of the '077 patent.

Response: Paragraph 162 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that because of Plaintiff's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '077 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 162.

Complaint ¶ 163. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '077 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '077 patent, and that the claims of the '077 patent are not invalid.

Response: Paragraph 163 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XI—Infringement of the '995 Patent

Complaint ¶ 164. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 165. The '995 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-fluorophenyl)-1-butanone Toluenesulfonic Acid Addition Salt and Salt Crystals" (attached as Exhibit F), was duly and legally issued on December 1, 2015.

Response: Paragraph 165 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '995 Patent is titled "4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone Toluenesulfonic Acid Addition Salt and Salt Crystals" and that the face of the '995 Patent identifies December 1, 2015 as the "Date of Patent." Sandoz admits that Exhibit F to Plaintiff's Complaint purports to be a copy of the '995 Patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 165.

Complaint ¶ 166. The inventors named on the '995 patent are John Tomesch and Lawrence P. Wennogle.

Response: Paragraph 166 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '995 patent identifies "John Tomesch" and "Lawrence P. Wennogle" as the inventors. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 166 and therefore denies them.

Complaint ¶ 167. Plaintiff is the owner and assignee of the '995 patent.

Response: Paragraph 167 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '995 patent identifies "INTRA-CELLULAR THERAPIES, INC." as the assignee. Sandoz lacks knowledge or information

sufficient to form a belief as to the truth of the remaining allegations in Paragraph 167 and therefore denies them.

Complaint ¶ 168. CAPLYTA® is covered by one or more claims of the '995 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

Response: Paragraph 168 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that FDA's Orange Book entry for CAPLYTA® identifies the '995 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations in Paragraph 168.

Complaint ¶ 169. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '995 patent.

Response: Paragraph 169 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it notified Plaintiff, via Sandoz's Notice Letter, of the submission of Sandoz's ANDA to the FDA. Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 169.

Complaint ¶ 170. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '995 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '995 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

Response: Paragraph 170 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA with the FDA pursuant to 21 U.S.C. § 355(j) seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 170.

Complaint ¶ 171. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

Response: Paragraph 171 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 171.

Complaint ¶ 172. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe one or more claims of the '995 patent.

Response: Paragraph 172 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 173. As an example, claim 2 of the '995 patent recites:

> A method for modulating 5-hydroxytryptamine 2A receptor activity in a patient, comprising administering to a patient in need thereof an effective amount of 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-fluorophenyl)-1-butanone toluene sulfonic acid salt crystal, wherein said salt crystal exhibits an X-ray powder diffraction pattern comprising at least two peaks having 2-theta values selected from the group consisting of 5.68°, 12.11°, 16.04°, 17.03°, 18.16°, 19.00°, 21.67°, 22.55°, 23.48° and 24.30°, wherein the X-ray powder diffraction data is collected on a diffractometer operating with a copper anode with a nickel filter.

Response: Paragraph 173 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '995 patent recites the following for claim 2:

> A method for modulating 5-hydroxytryptamine 2A receptor activity in a patient, comprising administering to a patient in need thereof an effective amount of 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-fluorophenyl)-1-butanone toluene sulfonic acid salt crystal, wherein said salt crystal exhibits an X-ray powder diffraction pattern comprising at least two peaks having 2-theta values selected from the group consisting of 5.68°, 12.11°, 16.04°,

> 17.03°, 18.16°, 19.00°, 21.67°, 22.55°, 23.48° and 24.30°, wherein the X-ray powder diffraction data is collected on a diffractometer operating with a copper anode with a nickel filter.

Complaint ¶ 174. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed label would involve modulating 5-hydroxytryptamine 2A receptor activity in a patient, including by administering to the patient in need thereof an effective amount of the salt crystal recited in claim 2.

Response: Paragraph 174 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 175. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '995 patent, literally or under the doctrine of equivalents.

Response: Paragraph 175 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 176. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '995 patent was an act of infringement of the '995 patent under 35 U.S.C. § 271(e)(2)(A).

Response: Paragraph 176 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 176.

Complaint ¶ 177. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of its ANDA.

Response: Paragraph 177 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 177.

Complaint ¶ 178. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '995 patent.

Response: Paragraph 178 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 179. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '995 patent.

Response: Paragraph 179 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 180. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '995 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '995 patent and specific intent to infringe that patent.

Response: Paragraph 180 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 181. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '995 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '995 patent immediately and imminently upon approval of Sandoz's ANDA.

Response: Paragraph 181 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 182. Notwithstanding Sandoz's knowledge of the claims of the '995 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '995 patent.

Response: Paragraph 182 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 183. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '995 patent; active inducement of infringement of the '995 patent; and/or contribution to the infringement by others of the '995 patent.

Response: Paragraph 183 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 184. Upon information and belief, Sandoz has acted with full knowledge of the '995 patent and without a reasonable basis for believing that it would not be liable for infringement of the '995 patent; active inducement of infringement of the '995 patent; and/or contribution to the infringement by others of the '995 patent.

Response: Paragraph 184 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 185. Plaintiff will be substantially and irreparably damaged by infringement of the '995 patent.

Response: Paragraph 185 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 186. Unless Sandoz is enjoined from infringing the '995 patent, actively inducing infringement of the '995 patent, and contributing to the infringement by others of the '995 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Response: Paragraph 186 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XII—Declaratory Judgment of Infringement of the '995 Patent

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

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 188. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '995 patent, and/or the validity of the '995 patent.

Response: Paragraph 188 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that because of Plaintiff's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the

infringement, validity, and enforceability of the '995 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 188.

Complaint ¶ 189. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '995 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '995 patent, and that the claims of the '995 patent are not invalid.

Response: Paragraph 189 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XIII—Infringement of the RE '825 Patent

Complaint ¶ 190. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 191. The RE '825 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-fluorophenyl)-1-butanone Toluenesulfonic Acid Salt Crystal Forms" (attached as Exhibit G), was duly and legally issued on November 23, 2021.

Response: Paragraph 191 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the RE '825 Patent is titled "4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone Toluenesulfonic Acid Salt and Salt Crystal Forms" and that the face of the RE '825 Patent identifies November 23, 2021 as the "Date of Reissued Patent." Sandoz admits that Exhibit G to Plaintiff's Complaint purports to be a copy of the RE '825 Patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 191.

Complaint ¶ 192. The inventors named on the RE '825 patent are John Tomesch and Lawrence P. Wennogle.

Response: Paragraph 192 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the RE '825 patent identifies "John

Tomesch" and "Lawrence P. Wennogle" as the inventors. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 192 and therefore denies them.

Complaint ¶ 193. Plaintiff is the owner and assignee of the RE '825 patent.

Response: Paragraph 193 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the RE '825 patent identifies "INTRA-CELLULAR THERAPIES, INC." as the assignee. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 193 and therefore denies them.

Complaint ¶ 194. CAPLYTA® is covered by one or more claims of the RE '825 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

Response: Paragraph 194 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that FDA's Orange Book entry for CAPLYTA® identifies the RE '825 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations in Paragraph 194.

Complaint ¶ 195. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the RE '825 patent.

Response: Paragraph 195 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it notified Plaintiff, via Sandoz's Notice Letter, of the submission of Sandoz's ANDA to the FDA. Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 195.

Complaint ¶ 196. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the RE '825 patent.

Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the RE '825 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

Response: Paragraph 196 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA with the FDA pursuant to 21 U.S.C. § 355(j) seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 196.

Complaint ¶ 197. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

Response: Paragraph 197 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 197.

Complaint ¶ 198. Upon information and belief, Sandoz's ANDA Product and the use of Sandoz's ANDA Product are covered by one or more claims of the RE '825 patent, either literally or under the doctrine of equivalents.

Response: Paragraph 198 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 199. As an example, claim 1 of the RE '825 patent recites:

> A 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-fluorophenyl)-1-butanone toluenesulfonic acid addition salt crystal form, wherein said salt crystal form exhibits an X-ray powder diffraction pattern comprising at least two peaks selected from the group consisting of 5.68°, 12.11°, 16.04°, 17.03°, 18.16°, 19.00°, 21.67°, 22.55°, 23.48° and 24.30°±0.2° 2θ.

Response: Paragraph 199 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the RE '825 patent recites the following for claim 1:

> A 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-fluorophenyl)-1-butanone toluenesulfonic acid addition salt crystal form, wherein said salt crystal form exhibits an X-ray powder diffraction pattern comprising at least two peaks selected from the group consisting of 5.68°, 12.11°, 16.04°, 17.03°, 18.16°, 19.00°, 21.67°, 22.55°, 23.48° and 24.30°±0.2° 2θ.

Complaint ¶ 200. Upon information and belief, Sandoz's ANDA Product contains a crystalline form of the compound recited in claim 1.

Response: Paragraph 200 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA, which describes its ANDA Product, speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 200.

Complaint ¶ 201. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the RE '825 patent, literally or under the doctrine of equivalents.

Response: Paragraph 201 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 202. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the RE '825 patent was an act of infringement of the RE '825 patent under 35 U.S.C. § 271(e)(2)(A).

Response: Paragraph 202 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 202.

Complaint ¶ 203. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of its ANDA.

Response: Paragraph 203 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 203.

Complaint ¶ 204. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the RE '825 patent.

Response: Paragraph 204 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 205. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the RE '825 patent.

Response: Paragraph 205 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 206. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the RE '825 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the RE '825 patent and specific intent to infringe that patent.

Response: Paragraph 206 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 207. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the RE '825 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the RE '825 patent immediately and imminently upon approval of Sandoz's ANDA.

Response: Paragraph 207 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 208. Notwithstanding Sandoz's knowledge of the claims of the RE '825 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the RE '825 patent.

Response: Paragraph 208 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 209. The foregoing actions by Sandoz constitute and/or will constitute infringement of the RE '825 patent; active inducement of infringement of the RE '825 patent; and/or contribution to the infringement by others of the RE '825 patent.

Response: Paragraph 209 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 210. Upon information and belief, Sandoz has acted with full knowledge of the RE '825 patent and without a reasonable basis for believing that it would not be liable for infringement of the RE '825 patent; active inducement of infringement of the RE '825 patent; and/or contribution to the infringement by others of the RE '825 patent.

Response: Paragraph 210 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 211. Plaintiff will be substantially and irreparably damaged by infringement of the RE '825 patent.

Response: Paragraph 211 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 212. Unless Sandoz is enjoined from infringing the RE '825 patent, actively inducing infringement of the RE '825 patent, and contributing to the infringement by others of the RE '825 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Response: Paragraph 212 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XIV—Declaratory Judgment of Infringement of the RE '825 Patent

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

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 214. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active

inducement of infringement, contribution to the infringement by others of the RE ’825 patent, and/or the validity of the RE ’825 patent.

Response: Paragraph 214 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that because of Plaintiff’s Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the RE ’825 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 214.

Complaint ¶ 215. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz’s ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the RE ’825 patent, will infringe, induce infringement of, and contribute to the infringement by others of the RE ’825 patent, and that the claims of the RE ’825 patent are not invalid.

Response: Paragraph 215 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XV—Infringement of the ’938 Patent

Complaint ¶ 216. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 217. The ’938 patent, entitled “Pharmaceutical Compositions Comprising ((6bR,10aS)-1-(4-fluorophenyl)-4-(3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)butan-1-one or Pharmaceutically Acceptable Salts Thereof” (attached as Exhibit H), was duly and legally issued on November 5, 2019.

Response: Paragraph 217 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the ’938 Patent is titled “Pharmaceutical Compositions Comprising ((6bR,10aS)-1-(4-fluorophenyl)-4-(3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)butan-1-one or Pharmaceutically Acceptable Salts Thereof” and that the face of the ’938 Patent identifies November 5, 2019 as the “Date of Patent.” Sandoz admits that Exhibit H to Plaintiff’s Complaint

purports to be a copy of the '938 Patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 217.

Complaint ¶ 218. The inventors named on the '938 patent are John Charles Tomesch, Peng Li, Wei Yao, Qiang Zhang, James David Beard, Andrew S. Thompson, Hua Cheng, and Lawrence P. Wennogle.

Response: Paragraph 218 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '938 patent identifies "John Charles Tomesch," "Peng Li," "Wei Yao," "Qiang Zhang," "James David Beard," "Andrew S. Thompson," "Hua Cheng," and "Lawrence P. Wennogle" as the inventors. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 218 and therefore denies them.

Complaint ¶ 219. Plaintiff is the owner and assignee of the '938 patent.

Response: Paragraph 219 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '938 patent identifies "INTRA-CELLULAR THERAPIES, INC." as the assignee. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 219 and therefore denies them.

Complaint ¶ 220. CAPLYTA® is covered by one or more claims of the '938 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

Response: Paragraph 220 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that FDA's Orange Book entry for CAPLYTA® identifies the '938 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations in Paragraph 220.

Complaint ¶ 221. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for

sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '938 patent.

Response: Paragraph 221 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it notified Plaintiff, via Sandoz's Notice Letter, of the submission of Sandoz's ANDA to the FDA. Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 221.

Complaint ¶ 222. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '938 patent. Upon information and belief, Sandoz submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the '938 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product.

Response: Paragraph 222 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA with the FDA pursuant to 21 U.S.C. § 355(j) seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 222.

Complaint ¶ 223. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

Response: Paragraph 223 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 223.

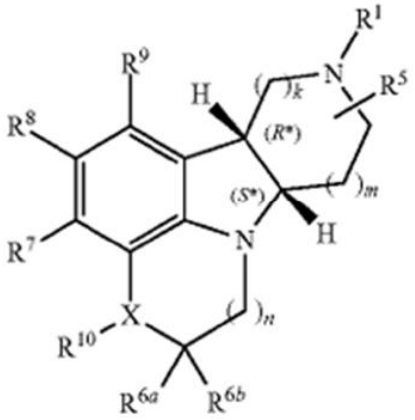
Complaint ¶ 224. Upon information and belief, Sandoz's ANDA Product and the use of Sandoz's ANDA Product are covered by one or more claims of the '938 patent, either literally or under the doctrine of equivalents.

Response: Paragraph 224 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 225. As an example, claim 1 of the '938 patent recites:

> A pharmaceutical composition comprising toluenesulfonic acid and the compound of Formula 2J:

Formula 2J

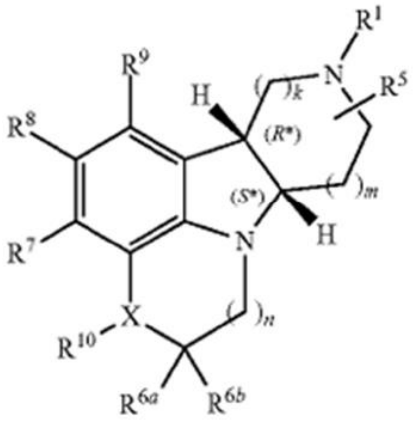


> or a pharmaceutically acceptable salt thereof, wherein:
>
> k is 1;
>
> m is 1;
>
> n is 1;
>
> R^1 is 4-(4-fluorophenyl)-4-oxobutyl;
>
> R^5 is H;
>
> R^{6a} and R^{6b} are independently H;
>
> R^7, R^8 and R^9 are independently H;
>
> R^{10} is CH_3; and
>
> X is —N—.

Response: Paragraph 225 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '938 patent recites the following for claim 1:

> A pharmaceutical composition comprising toluenesulfonic acid and the compound of Formula 2J:

Formula 2J



or a pharmaceutically acceptable salt thereof, wherein:

k is 1;

m is 1;

n is 1;

R^1 is 4-(4-fluorophenyl)-4-oxobutyl;

R^5 is H;

R^{6a} and R^{6b} are independently H;

R^7, R^8 and R^9 are independently H;

R^{10} is CH_3; and

X is —N—.

Complaint ¶ 226. Upon information and belief, Sandoz's ANDA Product is a pharmaceutical composition comprising toluenesulfonic acid and the Formula 2J compound recited in claim 1.

Response: Paragraph 226 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA, which describes its ANDA Product, speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 226.

Complaint ¶ 227. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '938 patent, literally or under the doctrine of equivalents.

Response: Paragraph 227 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 228. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '938 patent was an act of infringement of the '938 patent under 35 U.S.C. § 271(e)(2)(A).

Response: Paragraph 228 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 228.

Complaint ¶ 229. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of its ANDA.

Response: Paragraph 229 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 229.

Complaint ¶ 230. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '938 patent.

Response: Paragraph 230 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 231. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '938 patent.

Response: Paragraph 231 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 232. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '938 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '938 patent and specific intent to infringe that patent.

Response: Paragraph 232 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 233. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '938 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '938 patent immediately and imminently upon approval of Sandoz's ANDA.

Response: Paragraph 233 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 234. Notwithstanding Sandoz's knowledge of the claims of the '938 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '938 patent.

Response: Paragraph 234 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 235. The foregoing actions by Sandoz constitute and/or will constitute infringement of the '938 patent; active inducement of infringement of the '938 patent; and/or contribution to the infringement by others of the '938 patent.

Response: Paragraph 235 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 236. Upon information and belief, Sandoz has acted with full knowledge of the '938 patent and without a reasonable basis for believing that it would not be liable for infringement of the '938 patent; active inducement of infringement of the '938 patent; and/or contribution to the infringement by others of the '938 patent.

Response: Paragraph 236 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 237. Plaintiff will be substantially and irreparably damaged by infringement of the '938 patent.

Response: Paragraph 237 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 238. Unless Sandoz is enjoined from infringing the '938 patent, actively inducing infringement of the '938 patent, and contributing to the infringement by others of the '938 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Response: Paragraph 238 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XVI—Declaratory Judgment of Infringement of the '938 Patent

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

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 240. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '938 patent, and/or the validity of the '938 patent.

Response: Paragraph 240 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that because of Plaintiff's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '938 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 240.

Complaint ¶ 241. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '938 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '938 patent, and that the claims of the '938 patent are not invalid.

Response: Paragraph 241 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XVII—Infringement of the '227 Patent

Complaint ¶ 242. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 243. The '227 patent, entitled "Method for the Treatment of Residual Symptoms of Schizophrenia" (attached as Exhibit I), was duly and legally issued on May 1, 2018.

Response: Paragraph 243 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '227 Patent is titled "Method for the Treatment of Residual Symptoms of Schizophrenia" and that the face of the '227 Patent identifies May 1, 2018 as the "Date of Patent." Sandoz admits that Exhibit I to Plaintiff's Complaint purports to be a copy of the '227 Patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 243.

Complaint ¶ 244. The inventors named on the '227 patent are Kimberly Vanover, Peng Li, Sharon Mates, Robert Davis, and Lawrence P. Wennogle.

Response: Paragraph 244 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '227 patent identifies "Kimberly Vanover," "Peng Li," "Sharon Mates," "Robert Davis," and "Lawrence P. Wennogle" as the inventors. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 244 and therefore denies them.

Complaint ¶ 245. Plaintiff is the owner and assignee of the '227 patent.

Response: Paragraph 245 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '227 patent identifies "INTRA-CELLULAR THERAPIES, INC." as the assignee. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 245 and therefore denies them.

Complaint ¶ 246. CAPLYTA® is covered by one or more claims of the '227 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

Response: Paragraph 246 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that FDA's Orange Book entry for CAPLYTA®

identifies the '227 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations in Paragraph 246.

Complaint ¶ 247. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '227 patent.

Response: Paragraph 247 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it notified Plaintiff, via Sandoz's Notice Letter, of the submission of Sandoz's ANDA to the FDA. Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 247.

Complaint ¶ 248. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '227 patent. Upon information and belief, Sandoz 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 Sandoz's ANDA Product.

Response: Paragraph 248 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA with the FDA pursuant to 21 U.S.C. § 355(j) seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 248.

Complaint ¶ 249. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

Response: Paragraph 249 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 249.

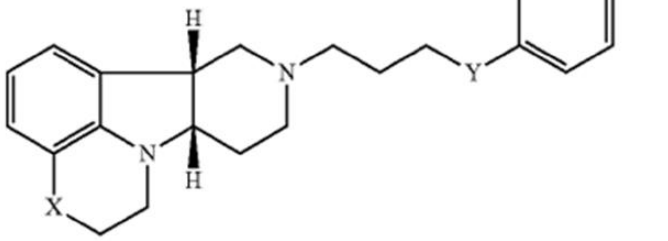
Complaint ¶ 250. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe one or more claims of the '227 patent.

Response: Paragraph 250 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 251. 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

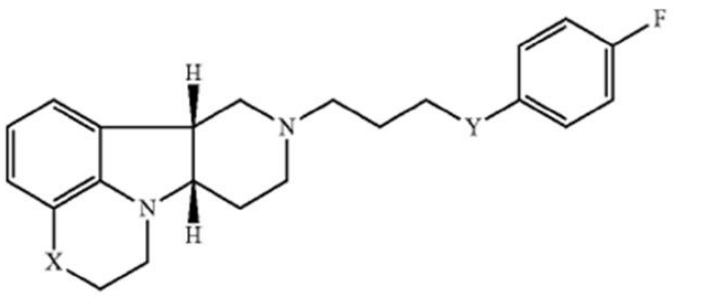


> X is —O—, —NH— or —N(CH_3)—;
>
> Y is —O—, —C(R_2)(OH)—, —C(R_3)(OR_1) or —C(O)—; and
>
> R_1 is —C_{1-6} alkyl or —C(O)—C_{1-21} alkyl, optionally saturated or unsaturated and optionally substituted with one or more hydroxyl or C_{1-22} alkoxy groups wherein such compound hydrolyzes to form the residue 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.

Response: Paragraph 251 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits the '227 patent recites the following for claim 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 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.

Complaint ¶ 252. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed label would involve treating 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.

Response: Paragraph 252 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that the proposed Sandoz ANDA Product label

speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 252.

Complaint ¶ 253. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '227 patent, literally or under the doctrine of equivalents.

Response: Paragraph 253 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 254. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '227 patent was an act of infringement of the '227 patent under 35 U.S.C. § 271(e)(2)(A).

Response: Paragraph 254 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 254.

Complaint ¶ 255. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of its ANDA.

Response: Paragraph 255 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 255.

Complaint ¶ 256. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '227 patent.

Response: Paragraph 256 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 257. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '227 patent.

Response: Paragraph 257 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 258. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '227 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '227 patent and specific intent to infringe that patent.

Response: Paragraph 258 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 259. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '227 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '227 patent immediately and imminently upon approval of Sandoz's ANDA.

Response: Paragraph 259 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 260. Notwithstanding Sandoz's knowledge of the claims of the '227 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '227 patent.

Response: Paragraph 260 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 261. The foregoing actions by Sandoz 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.

Response: Paragraph 261 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 262. Upon information and belief, Sandoz 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.

Response: Paragraph 262 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 263. Plaintiff will be substantially and irreparably damaged by infringement of the '227 patent.

Response: Paragraph 263 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 264. Unless Sandoz 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.

Response: Paragraph 264 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XVIII—Declaratory Judgment of Infringement of the '227 Patent

Complaint ¶ 265. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 266. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '227 patent, and/or the validity of the '227 patent.

Response: Paragraph 266 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that because of Plaintiff's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '227 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 266.

Complaint ¶ 267. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '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.

Response: Paragraph 267 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XIX—Infringement of the '009 Patent

Complaint ¶ 268. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 269. The '009 patent, entitled "Methods of Treating Schizophrenia and Depression" (attached as Exhibit J), was duly and legally issued on March 30, 2021.

Response: Paragraph 269 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '009 Patent is titled "Methods of Treating Schizophrenia and Depression" and that the face of the '009 Patent identifies March 30, 2021 as the "Date of Patent." Sandoz admits that Exhibit J to Plaintiff's Complaint purports to be a copy of the '009 Patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 269.

Complaint ¶ 270. The inventors named on the '009 patent are Kimberly Vanover, Peng Li, Sharon Mates, Robert Davis, and Lawrence P. Wennogle.

Response: Paragraph 270 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '009 patent identifies "Kimberly Vanover," "Peng Li," "Sharon Mates," "Robert Davis," and "Lawrence P. Wennogle" as the inventors. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 270 and therefore denies them.

Complaint ¶ 271. Plaintiff is the owner and assignee of the '009 patent.

Response: Paragraph 271 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '009 patent identifies "INTRA-CELLULAR THERAPIES, INC." as the assignee. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 271 and therefore denies them.

Complaint ¶ 272. CAPLYTA® is covered by one or more claims of the '009 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

Response: Paragraph 272 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that FDA's Orange Book entry for CAPLYTA® identifies the '009 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations in Paragraph 272.

Complaint ¶ 273. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '009 patent.

Response: Paragraph 273 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it notified Plaintiff, via Sandoz's Notice Letter, of the submission of Sandoz's ANDA to the FDA. Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 273.

Complaint ¶ 274. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '009 patent. Upon information and belief, Sandoz 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 Sandoz's ANDA Product.

Response: Paragraph 274 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA with the FDA pursuant to 21 U.S.C. § 355(j) seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 274.

Complaint ¶ 275. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

Response: Paragraph 275 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 275.

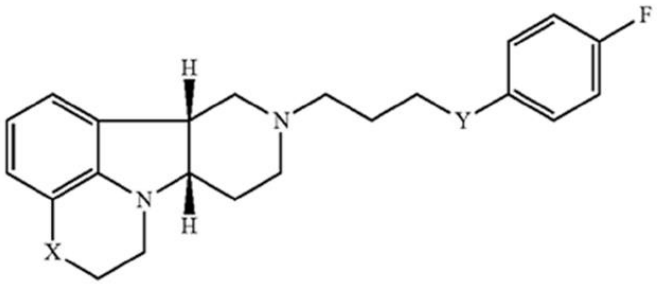
Complaint ¶ 276. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe one or more claims of the '009 patent.

Response: Paragraph 276 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 277. 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

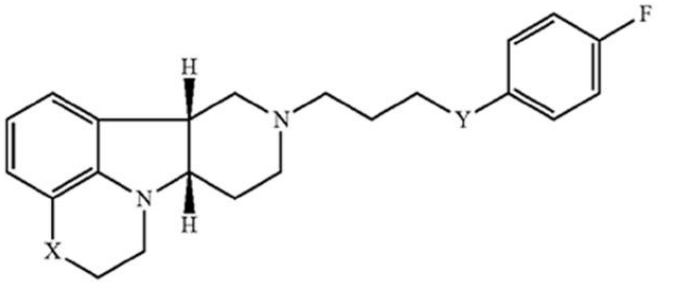


> wherein:
>
> X is —N(CH_3)— and Y is —C(O)—;
>
> in free or pharmaceutically acceptable salt form,
>
> wherein the effective amount of the Compound of Formula I is 40 mg to 60 mg per day, measured as the weight of the corresponding free base form of the Compound.

Response: Paragraph 277 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '009 patent recites the following for claim 1:

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.

Complaint ¶ 278. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed label would involve treating 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.

Response: Paragraph 278 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz states that the proposed Sandoz ANDA Product label speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 278..

Complaint ¶ 279. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '009 patent, literally or under the doctrine of equivalents.

Response: Paragraph 279 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 280. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or

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

Response: Paragraph 280 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 280.

Complaint ¶ 281. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of its ANDA.

Response: Paragraph 281 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 281.

Complaint ¶ 282. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '009 patent.

Response: Paragraph 282 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 283. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '009 patent.

Response: Paragraph 283 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 284. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '009 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '009 patent and specific intent to infringe that patent.

Response: Paragraph 284 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 285. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '009 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that

Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '009 patent immediately and imminently upon approval of Sandoz's ANDA.

Response: Paragraph 285 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 286. Notwithstanding Sandoz's knowledge of the claims of the '009 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '009 patent.

Response: Paragraph 286 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 287. The foregoing actions by Sandoz 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.

Response: Paragraph 287 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 288. Upon information and belief, Sandoz 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.

Response: Paragraph 288 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 289. Plaintiff will be substantially and irreparably damaged by infringement of the '009 patent.

Response: Paragraph 289 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 290. Unless Sandoz 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.

Response: Paragraph 290 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XX—Declaratory Judgment of Infringement of the '009 Patent

Complaint ¶ 291. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 292. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '009 patent, and/or the validity of the '009 patent.

Response: Paragraph 292 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that because of Plaintiff's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '009 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 292.

Complaint ¶ 293. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '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.

Response: Paragraph 293 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XXI—Infringement of the '951 Patent

Complaint ¶ 294. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 295. The '951 patent, entitled "Methods of Treating Bipolar Disorder" (attached as Exhibit K), was duly and legally issued on June 8, 2021.

Response: Paragraph 295 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '951 Patent is titled "Methods of Treating Bipolar Disorder" and that the face of the '951 Patent identifies June 8, 2021 as the "Date of Patent." Sandoz admits that Exhibit K to Plaintiff's Complaint purports to be a copy of the '951 Patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 295.

Complaint ¶ 296. The inventors named on the '951 patent are Kimberly Vanover, Peng Li, Sharon Mates, Robert Davis, and Lawrence P. Wennogle.

Response: Paragraph 296 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '951 patent identifies "Kimberly Vanover," "Peng Li," "Sharon Mates," "Robert Davis," and "Lawrence P. Wennogle" as the inventors. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 296 and therefore denies them.

Complaint ¶ 297. Plaintiff is the owner and assignee of the '951 patent.

Response: Paragraph 297 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '951 patent identifies "INTRA-CELLULAR THERAPIES, INC." as the assignee. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 297 and therefore denies them.

Complaint ¶ 298. CAPLYTA® is covered by one or more claims of the '951 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

Response: Paragraph 298 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that FDA's Orange Book entry for CAPLYTA® identifies the '951 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations in Paragraph 298.

Complaint ¶ 299. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '951 patent.

Response: Paragraph 299 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it notified Plaintiff, via Sandoz's Notice Letter, of the submission of Sandoz's ANDA to the FDA. Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 299.

Complaint ¶ 300. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '951 patent. Upon information and belief, Sandoz 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 Sandoz's ANDA Product.

Response: Paragraph 300 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA with the FDA pursuant to 21 U.S.C. § 355(j) seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 300.

Complaint ¶ 301. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

Response: Paragraph 301 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 301.

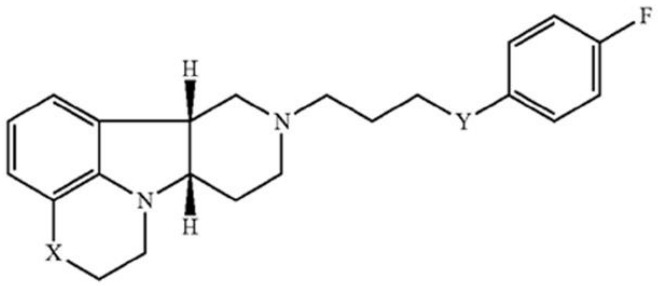
Complaint ¶ 302. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe one or more claims of the '951 patent.

Response: Paragraph 302 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 303. 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

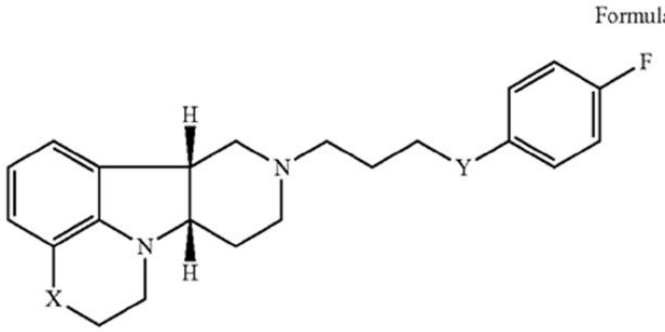


> wherein:
>
> X is —N(CH_3)— and Y is —C(O)—;
>
> in free or pharmaceutically acceptable salt form, wherein said Compound is not used in combination with another antipsychotic agent.

Response: Paragraph 303 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '951 patent recites the following for claim 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.

Complaint ¶ 304. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed label would involve treating 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, as recited in claim 1.

Response: Paragraph 304 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz states that the proposed Sandoz ANDA Product label speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 304.

Complaint ¶ 305. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '951 patent, literally or under the doctrine of equivalents.

Response: Paragraph 305 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 306. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '951 patent was an act of infringement of the '951 patent under 35 U.S.C. § 271(e)(2)(A).

Response: Paragraph 306 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 306.

Complaint ¶ 307. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of its ANDA.

Response: Paragraph 307 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 307.

Complaint ¶ 308. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '951 patent.

Response: Paragraph 308 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 309. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '951 patent.

Response: Paragraph 309 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 310. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '951 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '951 patent and specific intent to infringe that patent.

Response: Paragraph 310 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 311. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '951 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '951 patent immediately and imminently upon approval of Sandoz's ANDA.

Response: Paragraph 311 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 312. Notwithstanding Sandoz's knowledge of the claims of the '951 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '951 patent.

Response: Paragraph 312 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 313. The foregoing actions by Sandoz 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.

Response: Paragraph 313 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 314. Upon information and belief, Sandoz 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.

Response: Paragraph 314 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 315. Plaintiff will be substantially and irreparably damaged by infringement of the '951 patent.

Response: Paragraph 315 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 316. Unless Sandoz 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.

Response: Paragraph 316 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XXII—Declaratory Judgment of Infringement of the '951 Patent

Complaint ¶ 317. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 318. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active

inducement of infringement, contribution to the infringement by others of the '951 patent, and/or the validity of the '951 patent.

Response: Paragraph 318 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that because of Plaintiff's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '951 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 318.

Complaint ¶ 319. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '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.

Response: Paragraph 319 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XXIII—Infringement of the '345 Patent

Complaint ¶ 320. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 321. The '345 patent, entitled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" (attached as Exhibit L), was duly and legally issued on June 30, 2020.

Response: Paragraph 321 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '345 Patent is titled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" and that the face of the '345 Patent identifies June 30, 2020 as the "Date of Patent." Sandoz admits that Exhibit L to Plaintiff's Complaint purports to be a copy of the '345 Patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 321.

Complaint ¶ 322. The inventors named on the '345 patent are Peng Li and Robert Davis.

Response: Paragraph 322 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '345 patent identifies "Peng Li," and "Robert Davis" as the inventors. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 322 and therefore denies them.

Complaint ¶ 323. Plaintiff is the owner and assignee of the '345 patent.

Response: Paragraph 323 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '345 patent identifies "INTRA-CELLULAR THERAPIES, INC." as the assignee. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 323 and therefore denies them.

Complaint ¶ 324. CAPLYTA® is covered by one or more claims of the '345 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

Response: Paragraph 324 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that FDA's Orange Book entry for CAPLYTA® identifies the '345 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations in Paragraph 324.

Complaint ¶ 325. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '345 patent.

Response: Paragraph 325 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it notified Plaintiff, via Sandoz's Notice Letter, of the submission of Sandoz's ANDA to the FDA. Sandoz states that Sandoz's Notice

Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 325.

Complaint ¶ 326. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '345 patent. Upon information and belief, Sandoz 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 Sandoz's ANDA Product.

Response: Paragraph 326 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA with the FDA pursuant to 21 U.S.C. § 355(j) seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 326.

Complaint ¶ 327. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

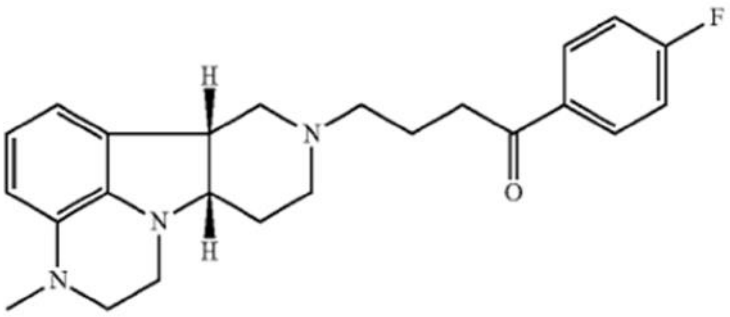
Response: Paragraph 327 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 327.

Complaint ¶ 328. Upon information and belief, Sandoz's ANDA Product and the use of Sandoz's ANDA Product are covered by one or more claims of the '345 patent, either literally or under the doctrine of equivalents.

Response: Paragraph 328 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 329. As an example, claim 1 of the '345 patent recites:

> A pharmaceutical capsule for oral administration, comprising lumateperone:

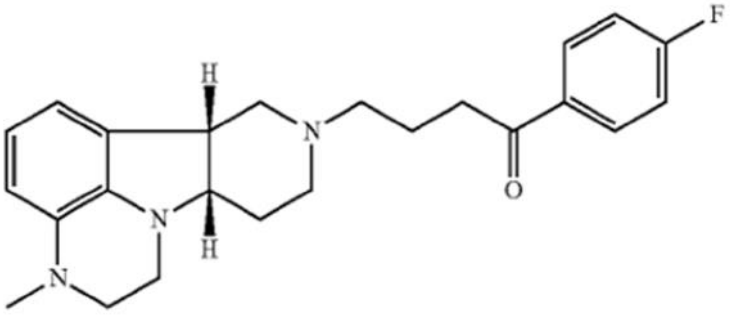


in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form; and

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.

Response: Paragraph 329 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '345 patent recites the following for claim 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.

Complaint ¶ 330. Upon information and belief, Sandoz's ANDA Product is a pharmaceutical capsule for oral administration comprising lumateperone mono-tosylate in solid crystal form in a blend with the specific excipients in the specific amounts recited in claim 1.

Response: Paragraph 330 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA, which describes its ANDA Product, speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 330.

Complaint ¶ 331. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '345 patent, literally or under the doctrine of equivalents.

Response: Paragraph 331 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 332. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '345 patent was an act of infringement of the '345 patent under 35 U.S.C. § 271(e)(2)(A).

Response: Paragraph 332 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 332.

Complaint ¶ 333. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of its ANDA.

Response: Paragraph 333 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 333.

Complaint ¶ 334. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '345 patent.

Response: Paragraph 334 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 335. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '345 patent.

Response: Paragraph 335 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 336. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '345 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '345 patent and specific intent to infringe that patent.

Response: Paragraph 336 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 337. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '345 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '345 patent immediately and imminently upon approval of Sandoz's ANDA.

Response: Paragraph 337 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 338. Notwithstanding Sandoz's knowledge of the claims of the '345 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '345 patent.

Response: Paragraph 338 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 339. The foregoing actions by Sandoz 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.

Response: Paragraph 339 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 340. Upon information and belief, Sandoz 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.

Response: Paragraph 340 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 341. Plaintiff will be substantially and irreparably damaged by infringement of the '345 patent.

Response: Paragraph 341 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 342. Unless Sandoz 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.

Response: Paragraph 342 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XXIV—Declaratory Judgment of Infringement of the '345 Patent

Complaint ¶ 343. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 344. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '345 patent, and/or the validity of the '345 patent.

Response: Paragraph 344 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that because of Plaintiff's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '345 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 344.

Complaint ¶ 345. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or

any other Sandoz drug product that is covered by or whose use is covered by the '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.

Response: Paragraph 345 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XXV—Infringement of the '084 Patent

Complaint ¶ 346. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 347. The '084 patent, entitled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" (attached as Exhibit M), was duly and legally issued on July 6, 2021.

Response: Paragraph 347 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '084 Patent is titled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" and that the face of the '084 Patent identifies July 6, 2021 as the "Date of Patent." Sandoz admits that Exhibit M to Plaintiff's Complaint purports to be a copy of the '084 Patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 347.

Complaint ¶ 348. The inventors named on the '084 patent are Peng Li and Robert Davis.

Response: Paragraph 348 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '084 patent identifies "Peng Li" and "Robert Davis" as the inventors. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 348 and therefore denies them.

Complaint ¶ 349. Plaintiff is the owner and assignee of the '084 patent.

Response: Paragraph 349 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '084 patent identifies "INTRA-CELLULAR THERAPIES, INC." as the assignee. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 349 and therefore denies them.

Complaint ¶ 350. CAPLYTA® is covered by one or more claims of the '084 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

Response: Paragraph 350 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that FDA's Orange Book entry for CAPLYTA® identifies the '084 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations in Paragraph 350.

Complaint ¶ 351. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '084 patent.

Response: Paragraph 351 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it notified Plaintiff, via Sandoz's Notice Letter, of the submission of Sandoz's ANDA to the FDA. Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 351.

Complaint ¶ 352. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '084 patent. Upon information and belief, Sandoz 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 Sandoz's ANDA Product.

Response: Paragraph 352 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA with the FDA pursuant

to 21 U.S.C. § 355(j) seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 352.

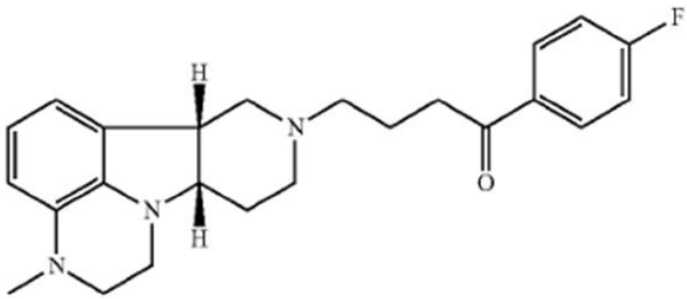
Complaint ¶ 353. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

Response: Paragraph 353 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 353.

Complaint ¶ 354. Upon information and belief, Sandoz's ANDA Product and the use of Sandoz's ANDA Product are covered by one or more claims of the '084 patent, either literally or under the doctrine of equivalents.

Response: Paragraph 354 states legal conclusions to which no response is required. To the extent a response is required, denied.

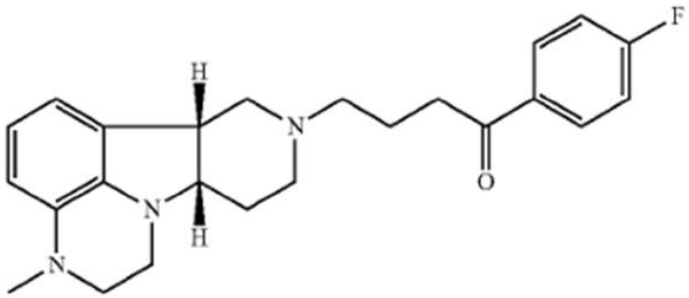
Complaint ¶ 355. As an example, claim 1 of the '084 patent recites:

> 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.

Response: Paragraph 355 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '084 patent recites the following for claim 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.

Complaint ¶ 356. Upon information and belief, Sandoz'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.

Response: Paragraph 356 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA, which describes its ANDA Product, speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 356.

Complaint ¶ 357. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '084 patent, literally or under the doctrine of equivalents.

Response: Paragraph 357 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA, which describes its ANDA Product, speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 357.

Complaint ¶ 358. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '084 patent was an act of infringement of the '084 patent under 35 U.S.C. § 271(e)(2)(A).

Response: Paragraph 358 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 358.

Complaint ¶ 359. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of its ANDA.

Response: Paragraph 359 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 359.

Complaint ¶ 360. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '084 patent.

Response: Paragraph 360 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 361. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '084 patent.

Response: Paragraph 361 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 362. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '084 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '084 patent and specific intent to infringe that patent.

Response: Paragraph 362 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 363. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '084 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '084 patent immediately and imminently upon approval of Sandoz's ANDA.

Response: Paragraph 363 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 364. Notwithstanding Sandoz's knowledge of the claims of the '084 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '084 patent.

Response: Paragraph 364 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 365. The foregoing actions by Sandoz 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.

Response: Paragraph 365 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 366. Upon information and belief, Sandoz 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.

Response: Paragraph 366 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 367. Plaintiff will be substantially and irreparably damaged by infringement of the '084 patent.

Response: Paragraph 367 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 368. Unless Sandoz 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.

Response: Paragraph 368 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XXVI—Declaratory Judgment of Infringement of the '084 Patent

Complaint ¶ 369. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 370. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '084 patent, and/or the validity of the '084 patent.

Response: Paragraph 370 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that because of Plaintiff's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '084 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 370.

Complaint ¶ 371. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '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.

Response: Paragraph 371 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XXVII—Infringement of the '842 Patent

Complaint ¶ 372. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 373. The '842 patent, entitled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" (attached as Exhibit N), was duly and legally issued on July 4, 2023.

Response: Paragraph 373 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '842 Patent is titled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" and that the face of the '842 Patent identifies July 4, 2023 as the "Date of Patent." Sandoz admits that Exhibit N to Plaintiff's Complaint purports to be a copy of the '842 Patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 373.

Complaint ¶ 374. The inventors named on the '842 patent are Peng Li and Robert Davis.

Response: Paragraph 374 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '842 patent identifies "Peng Li" and "Robert Davis" as the inventors. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 374 and therefore denies them.

Complaint ¶ 375. Plaintiff is the owner and assignee of the '842 patent.

Response: Paragraph 375 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '842 patent identifies "INTRA-CELLULAR THERAPIES, INC." as the assignee. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 375 and therefore denies them.

Complaint ¶ 376. CAPLYTA® is covered by one or more claims of the '842 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

Response: Paragraph 376 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that FDA's Orange Book entry for CAPLYTA® identifies the '842 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations in Paragraph 376.

Complaint ¶ 377. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '842 patent.

Response: Paragraph 377 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it notified Plaintiff, via Sandoz's Notice Letter, of the submission of Sandoz's ANDA to the FDA. Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 377.

Complaint ¶ 378. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '842 patent. Upon information and belief, Sandoz 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 Sandoz's ANDA Product.

Response: Paragraph 378 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA with the FDA pursuant to 21 U.S.C. § 355(j) seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 378.

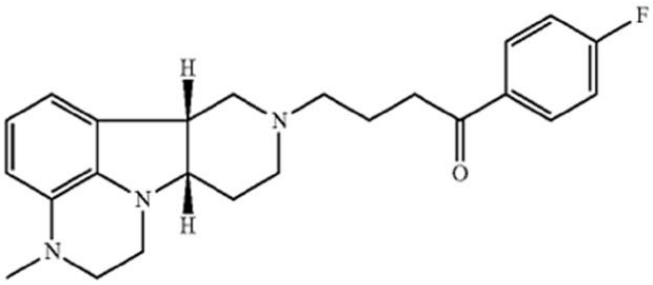
Complaint ¶ 379. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

Response: Paragraph 379 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 379.

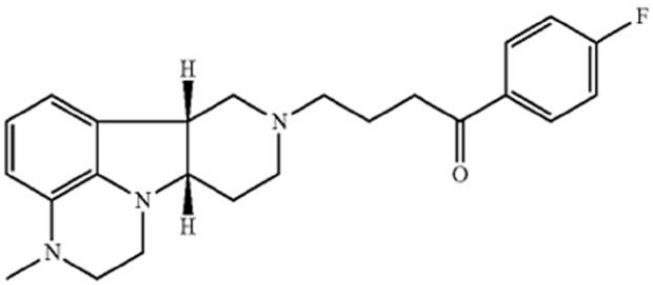
Complaint ¶ 380. Upon information and belief, Sandoz's ANDA Product and the use of Sandoz's ANDA Product are covered by one or more claims of the '842 patent, either literally or under the doctrine of equivalents.

Response: Paragraph 380 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 381. 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.

Response: Paragraph 381 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '842 patent recites the following for claim 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.

Complaint ¶ 382. Upon information and belief, Sandoz'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.

Response: Paragraph 382 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 383. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '842 patent, literally or under the doctrine of equivalents.

Response: Paragraph 383 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 384. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '842 patent was an act of infringement of the '842 patent under 35 U.S.C. § 271(e)(2)(A).

Response: Paragraph 384 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 384.

Complaint ¶ 385. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of its ANDA.

Response: Paragraph 385 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 385.

Complaint ¶ 386. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '842 patent.

Response: Paragraph 386 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 387. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '842 patent.

Response: Paragraph 387 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 388. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '842 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '842 patent and specific intent to infringe that patent.

Response: Paragraph 388 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 389. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '842 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '842 patent immediately and imminently upon approval of Sandoz's ANDA.

Response: Paragraph 389 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 390. Notwithstanding Sandoz's knowledge of the claims of the '842 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '842 patent.

Response: Paragraph 390 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 391. The foregoing actions by Sandoz 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.

Response: Paragraph 391 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 392. Upon information and belief, Sandoz 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.

Response: Paragraph 392 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 393. Plaintiff will be substantially and irreparably damaged by infringement of the '842 patent.

Response: Paragraph 393 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 394. Unless Sandoz 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.

Response: Paragraph 394 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XXVIII—Declaratory Judgment of Infringement of the '842 Patent

Complaint ¶ 395. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 396. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '842 patent, and/or the validity of the '842 patent.

Response: Paragraph 396 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that because of Plaintiff's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '842 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 396.

Complaint ¶ 397. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '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.

Response: Paragraph 397 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XXIX—Infringement of the '348 Patent

Complaint ¶ 398. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 399. The '348 patent, entitled "Methods of Treatment Using Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" (attached as Exhibit O), was duly and legally issued on November 7, 2023.

Response: Paragraph 399 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '348 Patent is titled "Methods of Treatment Using Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" and that the face of the '348 Patent identifies November 7, 2023 as the "Date of Patent." Sandoz admits that Exhibit O to Plaintiff's Complaint purports to be a copy of the '348 Patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 399.

Complaint ¶ 400. The inventors named on the '348 patent are Peng Li and Robert Davis.

Response: Paragraph 400 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '348 patent identifies "Peng Li" and "Robert Davis" as the inventors. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 400 and therefore denies them.

Complaint ¶ 401. Plaintiff is the owner and assignee of the '348 patent.

Response: Paragraph 401 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '348 patent identifies "INTRA-CELLULAR THERAPIES, INC." as the assignee. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 401 and therefore denies them.

Complaint ¶ 402. CAPLYTA® is covered by one or more claims of the '348 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

Response: Paragraph 402 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that FDA's Orange Book entry for CAPLYTA®

identifies the '348 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations in Paragraph 402.

Complaint ¶ 403. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '348 patent.

Response: Paragraph 403 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it notified Plaintiff, via Sandoz's Notice Letter, of the submission of Sandoz's ANDA to the FDA. Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 403.

Complaint ¶ 404. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '348 patent. Upon information and belief, Sandoz 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 Sandoz's ANDA Product.

Response: Paragraph 404 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA with the FDA pursuant to 21 U.S.C. § 355(j) seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 404.

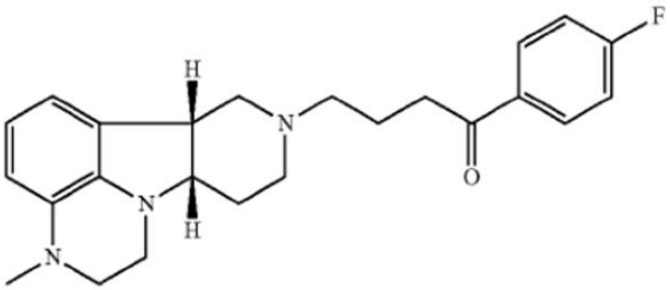
Complaint ¶ 405. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

Response: Paragraph 405 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 405.

Complaint ¶ 406. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe one or more claims of the '348 patent.

Response: Paragraph 406 states legal conclusions to which no response is required. To the extent a response is required, denied.

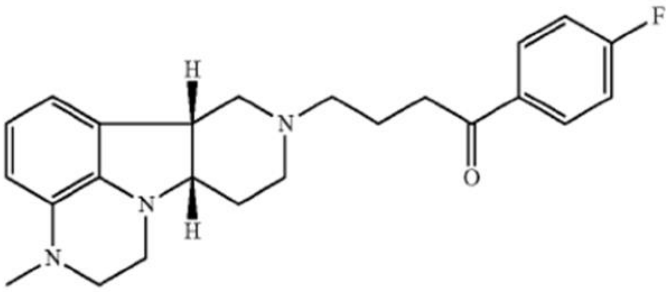
Complaint ¶ 407. As an example, claim 1 of the '348 patent recites:

> A method for the treatment of a disease or disorder involving or mediated by the 5-HT2*A* 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.

Response: Paragraph 407 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '348 patent recites the following for claim 1:

> A method for the treatment of a disease or disorder involving or mediated by the 5-HT2*A* 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.

Complaint ¶ 408. Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed label would involve treating a disease or disorder involving or mediated by the 5-HT2*A* 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.

Response: Paragraph 408 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that the proposed Sandoz ANDA Product label speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 408.

Complaint ¶ 409. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '348 patent, literally or under the doctrine of equivalents.

Response: Paragraph 409 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 410. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '348 patent was an act of infringement of the '348 patent under 35 U.S.C. § 271(e)(2)(A).

Response: Paragraph 410 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 410.

Complaint ¶ 411. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of its ANDA.

Response: Paragraph 411 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 411.

Complaint ¶ 412. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '348 patent.

Response: Paragraph 412 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 413. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '348 patent.

Response: Paragraph 413 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 414. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '348 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '348 patent and specific intent to infringe that patent.

Response: Paragraph 414 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 415. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '348 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '348 patent immediately and imminently upon approval of Sandoz's ANDA.

Response: Paragraph 415 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 416. Notwithstanding Sandoz's knowledge of the claims of the '348 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '348 patent.

Response: Paragraph 416 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 417. The foregoing actions by Sandoz 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.

Response: Paragraph 417 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 418. Upon information and belief, Sandoz 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.

Response: Paragraph 418 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 419. Plaintiff will be substantially and irreparably damaged by infringement of the '348 patent.

Response: Paragraph 419 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 420. Unless Sandoz 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.

Response: Paragraph 420 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XXX—Declaratory Judgment of Infringement of the '348 Patent

Complaint ¶ 421. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 422. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '348 patent, and/or the validity of the '348 patent.

Response: Paragraph 422 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that because of Plaintiff's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '348 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 422.

Complaint ¶ 423. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '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.

Response: Paragraph 423 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XXXI—Infringement of the '419 Patent

Complaint ¶ 424. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 425. 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 P), was duly and legally issued on September 12, 2023.

Response: Paragraph 425 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '419 Patent is titled "4-((6br,10as)-3-methyl-2,3,6b,9,10,10a-hexahydro-1h-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7h)-yl)-1-(4-((6br,10as)-3-methyl-2,3,6b,9,10,10a-hexahydro-1h-pyrido[3′4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7h)-yl)phenyl)butan-1-one for Treating Conditions of the Central Nervous System and Cardiac Disorders" and that the face of the '419 Patent identifies September 12, 2023 as the "Date of Patent." Sandoz admits that Exhibit P to Plaintiff's Complaint purports to be a copy of the '419 Patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 425.

Complaint ¶ 426. The inventors named on the '419 patent are Peng Li, Robert E. Davis, and Kimberly Vanover.

Response: Paragraph 426 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '419 patent identifies "Peng Li," "Robert E. Davis," and "Kimberly Vanover" as the inventors. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 426 and therefore denies them.

Complaint ¶ 427. Plaintiff is the owner and assignee of the '419 patent.

Response: Paragraph 427 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '419 patent identifies "INTRA-CELLULAR THERAPIES, INC." as the assignee. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 401 and therefore denies them.

Complaint ¶ 428. CAPLYTA® is covered by one or more claims of the '419 patent, which has been listed in connection with CAPLYTA® in the Orange Book.

Response: Paragraph 428 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that FDA's Orange Book entry for CAPLYTA® identifies the '419 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations in Paragraph 428.

Complaint ¶ 429. In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit, including the '419 patent.

Response: Paragraph 429 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it notified Plaintiff, via Sandoz's Notice Letter, of the submission of Sandoz's ANDA to the FDA. Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 429.

Complaint ¶ 430. In Sandoz's Notice Letter, Sandoz also notified Plaintiff that, as part of its ANDA, Sandoz had filed Paragraph IV certifications with respect to the '419 patent. Upon information and belief, Sandoz 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 Sandoz's ANDA Product.

Response: Paragraph 430 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA with the FDA pursuant to 21 U.S.C. § 355(j) seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 430.

Complaint ¶ 431. According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

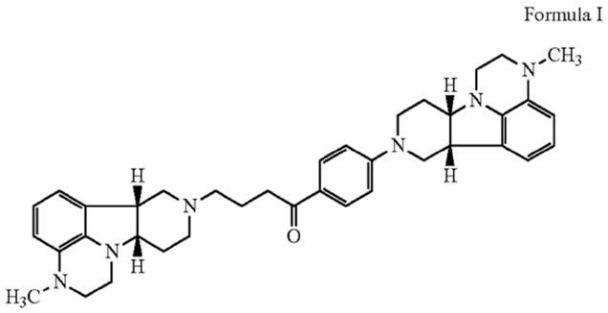
Response: Paragraph 431 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 431.

Complaint ¶ 432. Upon information and belief, Sandoz's ANDA Product and the use of Sandoz's ANDA Product are covered by one or more claims of the '419 patent, either literally or under the doctrine of equivalents.

Response: Paragraph 432 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 433. As an example, claim 1 of the '419 patent recites:

A compound of Formula I:

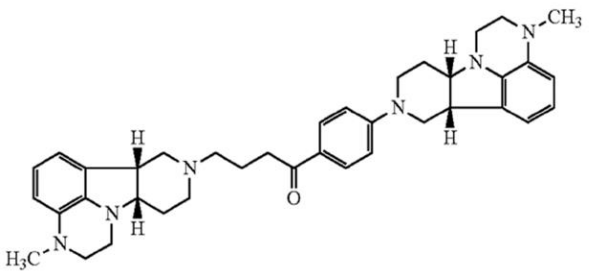


in free base or pharmaceutically acceptable salt form.

Response: Paragraph 433 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '419 patent recites the following for claim 1:

A compound of Formula I:

Formula I



in free base or pharmaceutically acceptable salt form.

Complaint ¶ 434. Upon information and belief, Sandoz's ANDA Product contains a Formula I compound in free or pharmaceutically acceptable salt form, as recited in claim 1.

Response: Paragraph 434 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA, which describes its ANDA Product, speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 434.

Complaint ¶ 435. Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '419 patent, literally or under the doctrine of equivalents.

Response: Paragraph 435 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 436. Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '419 patent was an act of infringement of the '419 patent under 35 U.S.C. § 271(e)(2)(A).

Response: Paragraph 436 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 436.

Complaint ¶ 437. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of its ANDA.

Response: Paragraph 437 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 437.

Complaint ¶ 438. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '419 patent.

Response: Paragraph 438 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 439. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '419 patent.

Response: Paragraph 439 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 440. Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '419 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '419 patent and specific intent to infringe that patent.

Response: Paragraph 440 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 441. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '419 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '419 patent immediately and imminently upon approval of Sandoz's ANDA.

Response: Paragraph 441 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 442. Notwithstanding Sandoz's knowledge of the claims of the '419 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '419 patent.

Response: Paragraph 442 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 443. The foregoing actions by Sandoz 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.

Response: Paragraph 443 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 444. Upon information and belief, Sandoz 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.

Response: Paragraph 444 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 445. Plaintiff will be substantially and irreparably damaged by infringement of the '419 patent.

Response: Paragraph 445 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 446. Unless Sandoz 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.

Response: Paragraph 446 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count XXXII—Declaratory Judgment of Infringement of the '419 Patent

Complaint ¶ 447. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 448. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active

inducement of infringement, contribution to the infringement by others of the '419 patent, and/or the validity of the '419 patent.

Response: Paragraph 448 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that because of Plaintiff's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '419 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 448.

Complaint ¶ 449. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '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.

Response: Paragraph 449 states legal conclusions to which no response is required. To the extent a response is required, denied.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

(a) A judgment that the Patents-in-Suit have been infringed under 35 U.S.C. § 271(e)(2) by Sandoz's submission to the FDA of Sandoz's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Sandoz's ANDA Product, or any other drug product that infringes or the use of which infringes the Patents-in-Suit, be not earlier than the expiration dates of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Sandoz, and all persons acting in concert with Sandoz, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's ANDA Product, or any other drug

product covered by or whose use is covered by the Patents-in-Suit, prior to the expiration of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product, or any other drug product covered by or whose use is covered by the Patents-in-Suit, prior to the expiration of said patents, will infringe, induce the infringement of, and contribute to infringement by others of said patents;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

RESPONSE TO REQUEST FOR RELIEF

Sandoz denies all allegations not specifically admitted herein, and further denies that Plaintiff is entitled to the judgment and relief requested in paragraphs (a)-(g) of its Complaint or to any relief whatsoever.

AFFIRMATIVE DEFENSES

Without any admissions as to burden of proof, and expressly reserving its right to assert additional defenses, Sandoz states the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

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

SECOND AFFIRMATIVE DEFENSE
(Non-Infringement)

The manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product that is the subject of ANDA No. 218938 has not and will not infringe directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner, any valid and enforceable claim of the '077 patent, the '258 patent, the '995 patent, the '061 patent, the '227 patent, the '867 patent, the '938 patent, the '345 patent, the '009 patent, the '951 patent, the '084 patent, the '842 patent, the '419 patent, the '348 patent, the RE '825 patent, or the RE '839 patent.

THIRD AFFIRMATIVE DEFENSE
(Invalidity)

The claims of the '077 patent, the '258 patent, the '995 patent, the '061 patent, the '227 patent, the '867 patent, the '938 patent, the '345 patent, the '009 patent, the '951 patent, the '084 patent, the '842 patent, the '419 patent, the '348 patent, the RE '825 patent, and the RE '839 patents are invalid for failure to satisfy one or more of the conditions for patentability under the patent laws of the United States, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 251, and/or 282(c), *et seq.*, and/or for obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity.

FOURTH AFFIRMATIVE DEFENSE
(No Costs)

Plaintiff is barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

FIFTH AFFIRMATIVE DEFENSE
(No Injunctive Relief)

Plaintiff may not seek injunctive relief against Sandoz, including under 35 U.S.C. §§ 271(3)(4)(B) and/or 283, because Plaintiff's alleged damages are not immediate or irreparable, and Plaintiff therefore has an adequate remedy at law.

SIXTH AFFIRMATIVE DEFENSE
(No Exceptional Case)

Sandoz's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

SEVENTH AFFIRMATIVE DEFENSE
(Equitable Defenses)

Sandoz reserves the right to amend its Answer to include equitable defenses, such as inequitable conduct, unclean hands, laches, estoppel and/or patent misuse, if information obtained in discovery provides support for such a defense.

EIGHTH AFFIRMATIVE DEFENSE
(Reservation of Rights)

Sandoz reserves the right to add or amend its Affirmative Defenses with additional affirmative defenses that discovery may yield, including unenforceability.

* * *

COUNTERCLAIMS

In further response to the Complaint, Defendant/Counterclaim-Plaintiff Sandoz ("Sandoz" or "Counterclaim-Plaintiff"), without admitting any of the allegations of Plaintiff other than as expressly admitted herein, and without prejudice of the rights of Sandoz to plead additional Counterclaims as the facts of the matter warrant, alleges as follows:

THE PARTIES

1. Sandoz is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 100 College Road West, Princeton, NJ 08540.

2. Counterclaim-Defendant Intra-Cellular Therapies, Inc. ("Intra-Cellular Therapies," or "Counterclaim-Defendant") has averred that it is a corporation organized and existing under the

laws of the State of Delaware, with its corporate headquarters at 430 East 29th Street, Suite 900, New York, NY 10016.

JURISDICTION AND VENUE

3. This is a declaratory judgment action arising under the patent laws of the United States, Title 35, United States Code.

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court has personal jurisdiction over Intra-Cellular Therapies because, inter alia, Intra-Cellular Therapies subjected itself to the jurisdiction of this Court by filing this action here and, upon information and belief, either directly or through agents, Intra-Cellular Therapies transacts business in, and derives substantial revenue from, the State of New Jersey.

7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

8. Because of Counterclaim-Defendant's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of United States Patent Nos. 8,648,077 ("the '077 patent"), 9,168,258 ("the '258 patent"), 9,199,995 ("the '995 patent"), 9,616,061 ("the '061 patent"), 9,956,227 ("the '227 patent"), 10,117,867 ("the '867 patent"), 10,464,938 ("the '938 patent"), 10,695,345 ("the '345 patent"), 10,960,009 ("the '009 patent"), 11,026,951 ("the '951 patent"), 11,052,084 ("the '084 patent"), 11,690,842 ("the '842 patent"), 11,753,419 ("the '419 patent"), 11,806,348 ("the '348

patent"), RE48,825 ("the RE '825 patent")[1], and RE48,839 ("the RE '839 patent")[2]. These patents are referred to collectively herein as the "Patents-in-Suit."

FACTUAL BACKGROUND

9. According to the United States Food and Drug Administration ("FDA") publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), Intra-Cellular Therapies is the holder of New Drug Application ("NDA") No. 209500, under which FDA granted approval for lumateperone capsules, 10.5 mg, 21 mg, and 42 mg, marketed in the United States as CAPLYTA® ("CAPLYTA®").

10. Under 21 U.S.C. §§ 355(b)(1)(A)(viii), (c)(2), and 21 C.F.R. § 314.53(b), NDA holders "shall submit" to FDA:

> the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—
>
> > (I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or
> >
> > (II) claims a method of using such drug for which approval is sought or has been granted in the application.

Pursuant to 21 C.F.R. § 314.53(e), "FDA will publish in the [Orange Book] the patent number and expiration date of each patent that is required to be, and is, submitted to FDA by an applicant, and for each method-of-use patent, the description of the method of use claimed by the patent . . . ."

[1] RE 825 is a reissue of U.S. Patent No. 9,586,960 ("the '960 Patent") and thereby replaces the '960 Patent in toto. The '960 Patent is therefore improperly listed in the Orange Book for the 42 mg CAPLYTA product as the '960 Patent was forfeited upon reissue and cannot be infringed. To the extent the claims of the '960 Patent need to be addressed, the same positions apply to those claims as to claims 1 and 2 of RE 825.

[2] RE 839 is a reissue of U.S. Patent No. 8,598,119 ("the '119 Patent") and thereby replaces the '119 patent in toto. The '119 Patent is therefore improperly listed in the Orange Book for the 42 mg CAPLYTA product as the '119 Patent was forfeited upon reissue and cannot be infringed. Patent owner has requested that the '119 Patent be delisted. To the extent the claims of the '119 Patent need to be addressed, the same positions apply to those claims as to claims 1-29 of RE 839.

11. The Orange Book lists the ’077 patent, the ’995 patent, the ’061 patent, the ’227 patent, the ’867 patent, the ’938 patent, the ’345 patent, the ’951 patent, the ’842 patent, the ’419 patent, the ’348 patent, the RE ’825 patent, and the RE ’839 patent in association with NDA No. 209500 for CAPLYTA® 10.5 mg, 21 mg, and 42 mg capsules.

12. The Orange Book lists the ’084 patent in association with NDA No. 209500 for CAPLYTA® 10.5 mg and 21 mg capsules.

13. The Orange Book lists the ’258 patent in association with NDA No. 209500 for CAPLYTA® 10.5 mg capsules.

14. The Orange Book lists the’009 patent in association with NDA No. 209500 for CAPLYTA® 42 mg capsules.

15. The faces of the Patents-in-Suit identify “Intra-Cellular Therapies, Inc.” or “INTRA-CELLULAR THERAPIES, INC.” as the assignee.

16. Intra-Cellular has averred that it is the assignee and owner of each of the Patents-in-Suit.

17. Intra-Cellular has also averred that it owns all rights, title, and interest in and to each of the Patents-in-Suit.

18. The ’077 patent is titled ““4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone Toluenesulfonic Acid Addition Salt and Salt Crystals.” The face of the ’077 patent identifies February 11, 2014 as the “Date of Patent.”

19. The ’258 patent is titled “Methods and Compositions for Sleep Disorders and Other Disorders.” The face of the ’258 patent identifies October 27, 2015 as the “Date of Patent.”

20. The ’995 patent is titled “4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone Toluenesulfonic Acid Addition Salt and Salt Crystals.” The face of the ’995 patent identifies December 1, 2015 as the “Date of Patent.”

21. The ’061 patent is titled “Methods and Compositions for Sleep Disorders and Other Disorders.” The face of the ’061 patent identifies April 11, 2017 as the “Date of Patent.”

22. The ’227 patent is titled “Method for the Treatment of Residual Symptoms of Schizophrenia.” The face of the ’227 patent identifies May 1, 2018 as the “Date of Patent.”

23. The ’867 patent is titled “Methods and Compositions for Sleep Disorders and Other Disorders.” The face of the ’867 patent identifies November 6, 2018 as the “Date of Patent.”

24. The ’938 patent is titled “Pharmaceutical Compositions Comprising ((6bR,10aS)-1-(4-fluorophenyl)-4-(3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)butan-1-one or Pharmaceutically Acceptable Salts Thereof.” The face of the ’938 patent identifies November 5, 2019 as the “Date of Patent.”

25. The ’345 patent is titled “Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate.” The face of the ’345 patent identifies June 30, 2020 as the “Date of Patent.”

26. The ’009 patent is titled “Methods of Treating Schizophrenia and Depression.” The face of the ’009 patent identifies March 30, 2021 as the “Date of Patent.”

27. The ’951 patent is titled “Methods of Treating Bipolar Disorder.” The face of the ’951 patent identifies June 8, 2021 as the “Date of Patent.”

28. The ’084 patent is titled “Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate.” The face of the ’084 patent identifies July 6, 2021 as the “Date of Patent.”

29. The ’842 patent is titled “Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate.” The face of the ’842 patent identifies July 4, 2023 as the “Date of Patent.”

30. The ’419 patent is titled “4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)phenyl)butan-1-one for Treating Conditions of the Central Nervous System and Cardiac Disorders.” The face of the ’419 patent identifies September 12, 2023 as the “Date of Patent.”

31. The ’348 patent is titled “Methods of Treatment Using Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate.” The face of the ’348 patent identifies November 7, 2023 as the “Date of Patent.”

32. The RE ’825 patent is titled “4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone Toluenesulfonic Acid Salt Crystal Forms.” The face of the RE ’825 patent identifies November 23, 2021 as the “Date of Reissued Patent.”

33. The RE ’839 is titled “Methods and Compositions for Sleep Disorders and Other Disorders.” The face of the RE ’839 patent identifies December 7, 2021 as the “Date of Reissued Patent.”

34. Upon information and belief, Intra-Cellular caused the ’077 patent, the ’258 patent, the ’995 patent, the ’061 patent, the ’227 patent, the ’867 patent, the ’938 patent, the ’345 patent,

the ’009 patent, the ’951 patent, the ’084 patent, the ’842 patent, the ’419 patent, the ’348 patent, the RE ’825 patent, and the RE ’839 patent to be listed in the Orange Book in connection with NDA No. 209500.

35. Sandoz submitted Abbreviated New Drug Application (“ANDA”) No. 218938 (“Sandoz’s ANDA”) to the FDA seeking approval for lumateperone capsules, 10.5 mg, 21 mg, and 42 mg (“Sandoz’s ANDA Product”).

36. Sandoz’s ANDA includes a Paragraph IV certification under 21 U.S.C. § 355(b)(2)(A)(iv) (“Paragraph IV certification”) with respect to the ’077 patent, the ’258 patent, the ’995 patent, the ’061 patent, the ’227 patent, the ’867 patent, the ’938 patent, the ’345 patent, the ’009 patent, the ’951 patent, the ’084 patent, the ’842 patent, the ’419 patent, the ’348 patent, the RE ’825 patent, and the RE ’839 patent.

37. Sandoz sent notice of the Paragraph IV certification to Intra-Cellular regarding the ’077 patent, the ’258 patent, the ’995 patent, the ’061 patent, the ’227 patent, the ’867 patent, the ’938 patent, the ’345 patent, the ’009 patent, the ’951 patent, the ’084 patent, the ’842 patent, the ’419 patent, the ’348 patent, the RE ’825 patent, and the RE ’839 patent on February 15, 2024 (“Sandoz’s Notice Letter”). Sandoz’s Notice Letter provided a detailed statement of the factual and legal bases for its opinion that (i) the aforementioned patents are invalid and/or (ii) the aforementioned patents are not infringed, directly or indirectly either literally or under the doctrine of equivalents, by the commercial manufacture, use, offer for sale, and/or sale of the 10.5 mg, 21 mg, and 42 mg drug product described in Sandoz’s ANDA; (iii) the ’084 patent is not infringed, directly or indirectly either literally or under the doctrine of equivalents, by the commercial manufacture, use, offer for sale, and/or sale of the 10.5 mg and 21 mg drug products described in Sandoz’s ANDA; (iv) the ’258 patent is not infringed, directly or indirectly either literally or under

the doctrine of equivalents, by the commercial manufacture, use, offer for sale, and/or sale of the 10.5 mg drug products described in Sandoz's ANDA and (v) the '009 patent is not infringed, directly or indirectly either literally or under the doctrine of equivalents, by the commercial manufacture, use, offer for sale, and/or sale of the 42 mg drug products described in Sandoz's ANDA. Sandoz incorporates by reference Sandoz's Notice Letter.

38. Counterclaim-Defendant initiated the present litigation by filing a complaint against Sandoz on March 28, 2024 alleging infringement of the Patens-in-Suit.

39. Counterclaim-Defendant has alleged in the present action that Sandoz has infringed and will infringe the Patens-in-Suit by filing Sandoz's ANDA with the FDA and/or by manufacturing, using, offering for sale, selling, or importing Sandoz's ANDA Product.

40. As a consequence of the foregoing, there is an actual and justiciable controversy between Sandoz and Counterclaim-Defendant as to whether the claims of the Patens-in-Suit are invalid, and whether those claims are being infringed or will be infringed by Sandoz's ANDA or by the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product.

COUNT 1
Declaratory Judgment of Non-Infringement of the '077 Patent

41. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1-40 as though fully set forth herein.

42. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, whether the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would infringe any valid or enforceable claim of the '077 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

43. The manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the '077 patent, either directly or indirectly.

44. Sandoz is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the '077 patent.

COUNT 2
Declaratory Judgment of Non-Infringement of the '258 Patent

45. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–44 as though fully set forth herein.

46. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, whether the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would infringe any valid or enforceable claim of the '258 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

47. The manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the '258 patent, either directly or indirectly.

48. Sandoz is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the '258 patent.

COUNT 3
Declaratory Judgment of Non-Infringement of the '995 Patent

49. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–48 as though fully set forth herein.

50. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, whether the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would infringe any valid or enforceable claim of the '995 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

51. The manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the '995 patent, either directly or indirectly.

52. Sandoz is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the '995 patent.

COUNT 4
Declaratory Judgment of Non-Infringement of the '061 Patent

53. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–52 as though fully set forth herein.

54. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, whether the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would infringe any valid or enforceable claim of the '061 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

55. The manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the '061 patent, either directly or indirectly.

56. Sandoz is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the ’061 patent.

COUNT 5
Declaratory Judgment of Non-Infringement of the ’227 Patent

57. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–56 as though fully set forth herein.

58. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, whether the manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product would infringe any valid or enforceable claim of the ’227 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

59. The manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product would not infringe any valid or enforceable claim of the ’227 patent, either directly or indirectly.

60. Sandoz is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the ’227 patent.

COUNT 6
Declaratory Judgment of Non-Infringement of the ’867 Patent

61. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–60 as though fully set forth herein.

62. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, whether the manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product would infringe any valid or enforceable claim of

the ’867 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

63. The manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product would not infringe any valid or enforceable claim of the ’867 patent, either directly or indirectly.

64. Sandoz is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the ’867 patent.

COUNT 7
Declaratory Judgment of Non-Infringement of the ’938 Patent

65. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–64 as though fully set forth herein.

66. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, whether the manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product would infringe any valid or enforceable claim of the ’938 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

67. The manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product would not infringe any valid or enforceable claim of the ’938 patent, either directly or indirectly.

68. Sandoz is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the ’938 patent.

COUNT 8
Declaratory Judgment of Non-Infringement of the ’345 Patent

69. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–68 as though fully set forth herein.

70. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, whether the manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product would infringe any valid or enforceable claim of the ’345 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

71. The manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product would not infringe any valid or enforceable claim of the ’345 patent, either directly or indirectly.

72. Sandoz is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the ’345 patent.

COUNT 9
Declaratory Judgment of Non-Infringement of the ’009 Patent

73. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–72 as though fully set forth herein.

74. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, whether the manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product would infringe any valid or enforceable claim of the ’009 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

75. The manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the '009 patent, either directly or indirectly.

76. Sandoz is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the '009 patent.

COUNT 10
Declaratory Judgment of Non-Infringement of the '951 Patent

77. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–76 as though fully set forth herein.

78. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, whether the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would infringe any valid or enforceable claim of the '951 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

79. The manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the '951 patent, either directly or indirectly.

80. Sandoz is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the '951 patent.

COUNT 11
Declaratory Judgment of Non-Infringement of the '084 Patent

81. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–80 as though fully set forth herein.

82. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, whether the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would infringe any valid or enforceable claim of the '084 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

83. The manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the '084 patent, either directly or indirectly.

84. Sandoz is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the '084 patent.

COUNT 12
Declaratory Judgment of Non-Infringement of the '842 Patent

85. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–84 as though fully set forth herein.

86. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, whether the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would infringe any valid or enforceable claim of the '842 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

87. The manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the '842 patent, either directly or indirectly.

88. Sandoz is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the ’842 patent.

COUNT 13
Declaratory Judgment of Non-Infringement of the ’419 Patent

89. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–88 as though fully set forth herein.

90. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, whether the manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product would infringe any valid or enforceable claim of the ’419 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

91. The manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product would not infringe any valid or enforceable claim of the ’419 patent, either directly or indirectly.

92. Sandoz is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the ’419 patent.

COUNT 14
Declaratory Judgment of Non-Infringement of the ’348 Patent

93. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–92 as though fully set forth herein.

94. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, whether the manufacture, use, offer for sale, sale, and/or importation, of Sandoz’s ANDA Product would infringe any valid or enforceable claim of

the ’348 patent either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

95. The manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product would not infringe any valid or enforceable claim of the ’348 patent, either directly or indirectly.

96. Sandoz is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the ’348 patent.

COUNT 15
Declaratory Judgment of Non-Infringement of the RE ’825 Patent

97. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–96 as though fully set forth herein.

98. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, whether the manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product would infringe any valid or enforceable claim of the RE ’825 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

99. The manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product would not infringe any valid or enforceable claim of the RE ’825 patent, either directly or indirectly.

100. Sandoz is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the RE ’825 patent.

COUNT 16
Declaratory Judgment of Non-Infringement of the RE '839 Patent

101. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–100 as though fully set forth herein.

102. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, whether the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would infringe any valid or enforceable claim of the RE '839 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

103. The manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the RE '839 patent, either directly or indirectly.

104. Sandoz is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the RE '839 patent.

COUNT 17
Declaratory Judgment of Invalidity of the '077 Patent

105. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–104 as though fully set forth herein.

106. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, the invalidity of the '077 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

107. The claims of the '077 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, 112, 251,

and/or 282(c), the doctrine of obviousness-type double-patenting, and/or for judicially-created doctrines and/or non-statutory bases of invalidity or unenforceability.

108. By way of non-limiting examples, one or more claims of the ’077 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in view of prior art to the ’077 patent. Non-limiting examples of such art include U.S. Patent Number 7,183,282 (“Robichaud”) in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

109. Sandoz is entitled to a judicial declaration that the claims of the ’077 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability, including double-patenting.

COUNT 18
Declaratory Judgment of Invalidity of the ’258 Patent

110. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–109 as though fully set forth herein.

111. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, the invalidity of the ’258 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

112. The claims of the ’258 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or for judicially-created doctrines and/or non-statutory bases of invalidity or unenforceability.

113. By way of non-limiting examples, one or more claims of the ’258 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in view of prior art to

the ’258 patent. Non-limiting examples of such art include Robichaud in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

114. Sandoz is entitled to a judicial declaration that the claims of the ’258 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability, including double-patenting.

COUNT 19
Declaratory Judgment of Invalidity of the ’995 Patent

115. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–114 as though fully set forth herein.

116. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, the invalidity of the ’995 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

117. The claims of the ’995 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or for judicially-created doctrines and/or non-statutory bases of invalidity or unenforceability.

118. By way of non-limiting examples, one or more claims of the ’995 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in view of prior art to the ’995 patent. Non-limiting examples of such art include Robichaud in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

119. Sandoz is entitled to a judicial declaration that the claims of the ’995 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United

States Code and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability, including double-patenting, including double-patenting.

COUNT 20
Declaratory Judgment of Invalidity of the '061 Patent

120. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–119 as though fully set forth herein.

121. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, the invalidity of the '061 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

122. The claims of the '061 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or for judicially-created doctrines and/or non-statutory bases of invalidity or unenforceability.

123. By way of non-limiting examples, one or more claims of the '061 patent are invalid as obvious under 35 U.S.C. § 103 in view of prior art to the '061 patent. Non-limiting examples of such art include Robichaud in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

124. Sandoz is entitled to a judicial declaration that the claims of the '061 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability, including double-patenting.

COUNT 21
Declaratory Judgment of Invalidity of the '227 Patent

125. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–124 as though fully set forth herein.

126. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, the invalidity of the ’227 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

127. The claims of the ’227 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or for judicially-created doctrines and/or non-statutory bases of invalidity or unenforceability.

128. By way of non-limiting examples, one or more claims of the ’227 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in view of prior art to the ’227 patent. Non-limiting examples of such art include Robichaud and U.S. Patent Publication Number 2011/0071080 (“Mates”) in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

129. Sandoz is entitled to a judicial declaration that the claims of the ’227 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability, including double-patenting.

COUNT 22
Declaratory Judgment of Invalidity of the ’867 Patent

130. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–129 as though fully set forth herein.

131. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, the invalidity of the ’867 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

132. The claims of the ’867 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or for judicially-created doctrines and/or non-statutory bases of invalidity or unenforceability.

133. By way of non-limiting examples, one or more claims of the ’867 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in view of prior art to the ’867 patent. Non-limiting examples of such art include Robichaud in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

134. Sandoz is entitled to a judicial declaration that the claims of the ’867 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability, including double-patenting.

COUNT 23
Declaratory Judgment of Invalidity of the ’938 Patent

135. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–134 as though fully set forth herein.

136. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, the invalidity of the ’938 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

137. The claims of the ’938 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or for judicially-created doctrines and/or non-statutory bases of invalidity or unenforceability.

138. By way of non-limiting examples, one or more claims of the '938 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in view of prior art to the '938 patent. Non-limiting examples of such art include Robichaud in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

139. Sandoz is entitled to a judicial declaration that the claims of the '938 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability, including double-patenting.

COUNT 24
Declaratory Judgment of Invalidity of the '345 Patent

140. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–139 as though fully set forth herein.

141. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, the invalidity of the '345 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

142. The claims of the '345 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or for judicially-created doctrines and/or non-statutory bases of invalidity or unenforceability.

143. Sandoz is entitled to a judicial declaration that the claims of the '345 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability, including double-patenting.

COUNT 25
Declaratory Judgment of Invalidity of the '009 Patent

144. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–143 as though fully set forth herein.

145. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, the invalidity of the '009 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

146. The claims of the '009 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or for judicially-created doctrines and/or non-statutory bases of invalidity or unenforceability.

147. By way of non-limiting examples, one or more claims of the '009 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in view of prior art to the '009 patent. Non-limiting examples of such art include International PCT publication WO 2009/114181 ("Wennogle") and Vanover *et al.*, "*ITI-007, an Investigational new antipsychotic drug with a novel pharmacological profile, is safe and well-tolerated with early clinical signs for efficacy in patients with stabilized schizophrenia*," ACNP 49th Annual Conference Poster 2010 ("Vanover") in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

148. Sandoz is entitled to a judicial declaration that the claims of the '009 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability, including double-patenting.

COUNT 26
Declaratory Judgment of Invalidity of the '951 Patent

149. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–148 as though fully set forth herein.

150. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, the invalidity of the '951 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

151. The claims of the '951 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or for judicially-created doctrines and/or non-statutory bases of invalidity or unenforceability.

152. By way of non-limiting examples, one or more claims of the '951 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in view of prior art to the '951 patent. Non-limiting examples of such art include Mates, Wennogle, and the April 9, 2008 *Intra-Cellular Therapies Announces the Discovery of Potent Antidepressant Activity in ITI-007* press release ("Intra-Cellular Press Release") in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

153. Sandoz is entitled to a judicial declaration that the claims of the '951 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability, including double-patenting.

COUNT 27
Declaratory Judgment of Invalidity of the '084 Patent

154. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–153 as though fully set forth herein.

155. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, the invalidity of the ’084 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

156. The claims of the ’084 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or for judicially-created doctrines and/or non-statutory bases of invalidity or unenforceability.

157. Sandoz is entitled to a judicial declaration that the claims of the ’084 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability, including double-patenting.

COUNT 28
Declaratory Judgment of Invalidity of the ’842 Patent

158. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–157 as though fully set forth herein.

159. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, the invalidity of the ’842 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

160. The claims of the ’842 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or for judicially-created doctrines and/or non-statutory bases of invalidity or unenforceability.

161. Sandoz is entitled to a judicial declaration that the claims of the ’842 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United

States Code and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability, including double-patenting.

COUNT 29
Declaratory Judgment of Invalidity of the '419 Patent

162. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–161 as though fully set forth herein.

163. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, the invalidity of the '419 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

164. The claims of the '419 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or for judicially-created doctrines and/or non-statutory bases of invalidity or unenforceability.

165. By way of non-limiting examples, one or more claims of the '419 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in view of prior art to the '419 patent. Non-limiting examples of such art include Robichaud, International PCT publication WO 2019/241278 ("WO '278"), and Mates, in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

166. Sandoz is entitled to a judicial declaration that the claims of the '419 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability, including double-patenting.

COUNT 30
Declaratory Judgment of Invalidity of the '348 Patent

167. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–166 as though fully set forth herein.

168. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, the invalidity of the '348 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

169. The claims of the '348 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or for judicially-created doctrines and/or non-statutory bases of invalidity or unenforceability.

170. Sandoz is entitled to a judicial declaration that the claims of the '348 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability, including double-patenting.

COUNT 31
Declaratory Judgment of Invalidity of the RE '825 Patent

171. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–170 as though fully set forth herein.

172. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, the invalidity of the RE '825 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

173. The claims of the RE '825 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112,

the doctrine of obviousness-type double-patenting, and/or for judicially-created doctrines and/or non-statutory bases of invalidity or unenforceability.

174. By way of non-limiting examples, one or more claims of the RE '825 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in view of prior art to the RE '825 patent. Non-limiting examples of such art include Robichaud in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

175. Sandoz is entitled to a judicial declaration that the claims of the RE '825 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability, including double-patenting.

COUNT 32
Declaratory Judgment of Invalidity of the RE '839 Patent

176. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–175 as though fully set forth herein.

177. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, the invalidity of the RE '839 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

178. The claims of the RE '839 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or for judicially-created doctrines and/or non-statutory bases of invalidity or unenforceability.

179. By way of non-limiting examples, one or more claims of the RE '839 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in view of prior

art to the RE '839 patent. Non-limiting examples of such art include Robichaud in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

180. Sandoz is entitled to a judicial declaration that the claims of the RE '839 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability, including double-patenting.

PRAYER FOR RELIEF

WHEREFORE, Sandoz respectfully prays for judgment in its favor and against Counterclaim-Defendant:

a) Declaring that the filing of Sandoz's ANDA did not infringe any valid and enforceable claim of the Patents-in-Suit;

b) Declaring that the manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product described in Sandoz's ANDA has not infringed, does not infringe, and would not–if made, used, sold, offered for sale, imported, or marketed–infringe, either directly or indirectly, any valid and enforceable claim of the Patents-in-Suit either literally or under the doctrine of equivalents;

c) Declaring that the claims of the '077 patent are invalid;

d) Declaring that the claims of the '258 patent are invalid;

e) Declaring that the claims of the '995 patent are invalid;

f) Declaring that the claims of the '061 patent are invalid;

g) Declaring that the claims of the '227 patent are invalid;

h) Declaring that the claims of the '867 patent are invalid;

i) Declaring that the claims of the '938 patent are invalid;

j) Declaring that the claims of the '345 patent are invalid;

k) Declaring that the claims of the ’009 patent are invalid;

l) Declaring that the claims of the ’951 patent are invalid;

m) Declaring that the claims of the ’084 patent are invalid;

n) Declaring that the claims of the ’842 patent are invalid;

o) Declaring that the claims of the ’419 patent are invalid;

p) Declaring that the claims of the ’348 patent are invalid;

q) Declaring that the claims of the RE ’825 patent are invalid;

r) Declaring that the claims of the RE ’839 patent are invalid;

s) Ordering that the Complaint be dismissed with prejudice and judgment entered in favor of Sandoz;

t) Denying Plaintiff/Counterclaim-Defendant any of the relief requested in the Complaint;

u) Declaring this case exceptional in favor of Sandoz pursuant to 35 U.S.C. § 285;

v) Awarding costs and attorneys’ fees to Sandoz; and

w) Awarding Sandoz such other and further relief the Court may deem just and proper.

Dated: June 10, 2024

Respectfully submitted,

/s/ William Murtha

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CERTIFICATE OF SERVICE

I, William P. Murtha, of full age, hereby certify that on June 10, 2024, Defendant, Sandoz Inc.'s, Answer and supporting documents were filed via electronic filing system. A copy of same was served via e-filing upon the following counsel of record for Plaintiff.

By: *William Murtha*
William P. Murtha

Dated: June 10, 2024