R Touhey Myer (NJ Bar ID 028912009)
KRATZ & BARRY LLP
800 N. West Street
Wilmington, DE 19801
(302) 527-9378
tmyer@kratzandbarry.com

Of Counsel:

Timothy H. Kratz *(Pro Hac Vice Expected)*
George J. Barry III *(Pro Hac Vice Expected)*
KRATZ & BARRY LLP
1050 Crown Pointe Parkway, Suite 500
Atlanta, GA 30338
(404) 431-6600
tkratz@kratzandbarry.com
gbarry@kratzandbarry.com

Michael P. Hogan *(Pro Hac Vice Expected)*
KRATZ & BARRY LLP
325 Chestnut Street, Suite 883, #259
Philadelphia, PA 19106
(917) 216-8585
mhogan@kratzandbarry.com

Attorneys for Defendant,
Alkem Laboratories Ltd.

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

INTRA-CELLULAR THERAPIES, INC., *Plaintiff*, v. ALKEM LABORATORIES LTD., *Defendant*.	C.A. No. 3:24-CV-04312-MAS-JBD **DEFENDANT'S ANSWER TO PLAINTIFF'S COMPLAINT FOR FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Defendant Alkem Laboratories Ltd. ("Alkem" or "Defendants"), by and through its undersigned attorneys, hereby respectfully responds to the Complaint filed by Plaintiff Intra-Cellular Therapies, Inc. ("Intra-Cellular Therapies," "ITCI," or "Plaintiff") as follows:

Responses to Allegations Pertaining to the Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, that arises out of Alkem's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture,

use, offer for sale, sell, and/or import a generic version of CAPLYTA® (lumateperone) capsules, 10.5 mg, 21 mg, and 42 mg, prior to the expiration of U.S. Patent Nos. 9,956,227 ("the '227 patent"), 10,695,345 ("the '345 patent"), 10,960,009 ("the '009 patent"), 11,026,951 ("the '951 patent"), 11,052,084 ("the '084 patent"), 11,690,842 ("the '842 patent"), 11,753,419 ("the '419 patent"), 11,806,348 ("the '348 patent"), and RE48,839 ("the RE '839 patent"). These patents are referred to collectively herein as the "Patents-in-Suit."

RESPONSE: Alkem admits Plaintiff purports to bring this action for alleged patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq*., and for a declaratory judgment of alleged 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.* Alkem admits filing an ANDA seeking approval to manufacture, use, offer for sale, sell, and/or import capsules containing an active pharmaceutical ingredient prior to the expiration of the '345, '084, '842, '348, RE '839, '951 and '419 patents (collectively, "PIV Patents"). Alkem denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

2. Alkem notified Plaintiff by letter dated February 16, 2024 ("Alkem's Notice Letter") that it had submitted to the FDA ANDA No. 219200 ("Alkem's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic lumateperone capsules, 10.5 mg, 21 mg, and 42 mg, ("Alkem's ANDA Product") prior to the expiration of the Patents-in-Suit.

RESPONSE: Alkem admits notifying Plaintiff by letter dated February 16, 2024, that it had submitted to the FDA ANDA No. 219200, seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of capsules containing an active pharmaceutical ingredient prior to expiration of the PIV Patents. Alkem denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

Responses to Allegations Pertaining to The Parties

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

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: On information and belief, Alkem admits Plaintiff ITCI is the holder of NDA No. 209500 approved by FDA. Alkem denies NDA No. 209500 describes "lumateperone capsules, 10.5 mg, 21 mg, and 42 mg." Alkem is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

5. Upon information and belief, Defendant Alkem Laboratories Ltd. is a corporation organized and existing under the laws of the Republic of India and having a principal place of business at Alkem House, Senapati Bapat Marg Lower Parel, Mumbai, Maharashtra, India, 400013.

RESPONSE: Alkem admits it is organized and existing under the laws of the Republic of India with a place of business at Alkem House, Senapati Bapat Marg, Lower Parel, Mumbai, Maharashtra, India 400 013. Alkem denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits it is in the business of, among other things, importing, manufacturing, and selling pharmaceutical products including in the United States. This paragraph contains allegations that are speculative in nature and concern future uncertain events, and, therefore, Alkem denies such allegations. Alkem denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

Responses to Allegations Pertaining to Jurisdiction

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

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

RESPONSE: Alkem admits the Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a). Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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 Alkem.

RESPONSE: Alkem denies the facts and causes alleged herein establish personal jurisdiction over Alkem. This paragraph also contains allegations that are speculative in nature and concern uncertain future events, and, therefore, Alkem denies such allegations. Solely for the purpose of this litigation, Alkem does not contest the Court's exercise of personal jurisdiction over Alkem.

Alkem denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits Alkem's business operations include developing, manufacturing, obtaining regulatory approval for, marketing, selling, and distributing pharmaceutical products including for and in the United States. Alkem objects to this paragraph of the Complaint as including allegations that are vague and ambiguous, and, therefore, Alkem denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits preparing and filing Alkem's ANDA. Alkem admits Alkem continues to seek FDA approval of Alkem's ANDA. This paragraph contains allegations that are speculative in nature and concern future uncertain events, and, therefore, Alkem denies such allegations. Alkem denies all remaining allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits preparing and submitting Alkem's ANDA. Alkem admits Alkem's ANDA included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Alkem

denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: This paragraph of the complaint contains allegations that are speculative in nature, concern future uncertain events and is vague and ambiguous, and, therefore, Alkem denies all allegations in this paragraph of the Complaint. Solely for the purpose of this litigation, Alkem does not contest the Court's exercise of personal jurisdiction over Alkem. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem is without knowledge or information sufficient to form a belief as to the truth of the allegations as to where Alkem's products are "used and/or consumed," and, therefore, Alkem denies such allegations. This paragraph of the Complaint contains allegations that are vague and ambiguous, and, therefore, Alkem denies such allegations. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

15. Alkem is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Upon information and belief,

Alkem develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

RESPONSE: Solely for the purpose of this litigation, Alkem does not contest the Court's exercise of personal jurisdiction over Alkem. Alkem denies all allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Solely for the purpose of this litigation, Alkem does not contest the Court's exercise of personal jurisdiction over Alkem. Alkem denies all allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

17. This Court also has personal jurisdiction over Alkem because Alkem has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of

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

RESPONSE: Solely for the purpose of this litigation, Alkem does not contest the Court's exercise of personal jurisdiction over Alkem. Alkem denies all allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

18. Alkem is also subject to personal jurisdiction in New Jersey because it (1) engages in patent litigation concerning Alkem's generic versions of branded pharmaceutical products in this District, (2) does not contest personal jurisdiction in this District, and (3) purposefully avails itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Janssen Pharms., Inc. v. Alkem Lab'ys Ltd.*, No. 23-cv-02939, ECF No. 11 (D.N.J. July 20, 2023); *Jazz Pharms. Rsch. UK Ltd. v. Teva Pharms., Inc.*, No. 23-cv-00018, ECF No. 118 (D.N.J. Apr. 5, 2023).

RESPONSE: Solely for the purpose of this litigation, Alkem does not contest the Court's exercise of personal jurisdiction over Alkem. Alkem denies all allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Solely for the purpose of this litigation, Alkem does not contest the Court's exercise of personal jurisdiction over Alkem. Alkem denies all allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

Responses to Allegations Pertaining to Venue

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

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

RESPONSE: Solely for the purpose of this litigation, Alkem does not contest venue in this judicial district. Alkem denies all allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

Responses to Allegations Pertaining to the Factual Background

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

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

RESPONSE: Upon information and belief, Alkem admits the Caplyta brand product 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. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits stating in its notice letter that the subject of Alkem's ANDA is capsules containing an active pharmaceutical ingredient. Alkem denies describing its ANDA

product as "lumateperone capsules, 10.5 mg, 21 mg, and 42 mg" in its Notice Letter. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

25. In Alkem's Notice Letter, Alkem stated that it had submitted Paragraph IV certifications to the FDA alleging that the '345 patent, '951 patent, '084 patent, '842 patent, '419 patent, '348 patent, and RE '839 patent are invalid, unenforceable, and/or not infringed, and that Alkem is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Alkem's ANDA Product prior to the expiration of those patents.

RESPONSE: Admitted.

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

RESPONSE: Alkem admits the purpose of Alkem's submission of Alkem's ANDA is to obtain FDA approval to engage in the manufacture, use, offer for sale, sale, and/or importation of Alkem's ANDA Product prior to the expiration of the PIV Patents. Alkem denies the PIV Patents include all of the Patents-in-Suit. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

27. Upon information and belief, Alkem's ANDA Product is not publicly available, nor is ANDA No. 219200 accessible to the public.

RESPONSE: Admitted.

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

RESPONSE: Alkem admits Alkem's Notice Letter included an Offer of Confidential Access. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

29. Counsel for Plaintiff contacted counsel for Alkem to discuss the terms of Alkem's Offer of Confidential Access, but counsel for Alkem never responded. The parties

therefore could not agree on terms under which Plaintiff could review, among other things, Alkem's unredacted ANDA, any Drug Master File referred to therein, or all relevant characterization data, or under which Alkem could produce samples of Alkem's ANDA Product and other internal documents and material relevant to infringement.

RESPONSE: Alkem admits the parties were unable to reach agreement on the terms under which Alkem would be willing to produce Alkem's ANDA to Plaintiff pursuant to Alkem's Offer of Confidential Access. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

30. Nor could Plaintiff ascertain whether Alkem had filed Paragraph III certifications as to the Patents-in-Suit for which Alkem did not state that it had submitted Paragraph IV certifications (the '227 patent and '009 patent), or whether it instead provided a statement to the FDA regarding the '227 patent and '009 patent pursuant to 21 U.S.C. § 355(j)(2)(A)(viii).

RESPONSE: Alkem is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Upon information and belief, admitted.

Response to Allegations Pertaining to
Count I—Alleged Infringement of the RE '839 Patent

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

33. 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: Alkem admits Exhibit A to the Complaint appears to be a copy of the RE '839 patent, which Alkem admits is titled "Methods and Compositions for Sleep Disorders and Other Disorders." Alkem admits the face of the RE '839 patent states the RE '839 patent issued December 7, 2021. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Admitted.

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

RESPONSE: Alkem is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

36. 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: Alkem admits the RE '839 patent is listed in the Orange Book in connection with the Caplyta brand product. Alkem is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits its Notice Letter notified Plaintiff of the submission of Alkem's ANDA to the FDA. Alkem admits the purpose of submitting its ANDA is to obtain FDA

approval of the drug product that is the subject of the ANDA. Alkem admits that its ANDA seeks approval of Alkem's ANDA prior to expiration of the RE '839 patent. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits its Notice Letter notified Plaintiff that Alkem had filed a Paragraph IV certification with respect to the RE '839 patent. Alkem admits its ANDA includes a Paragraph IV certification 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 Alkem's ANDA Product. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Denied.

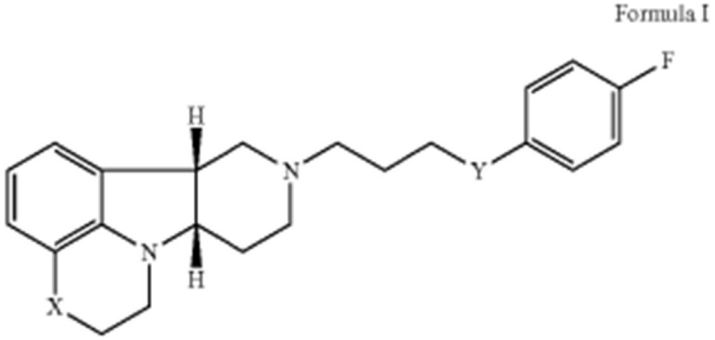
40. Upon information and belief, the use of Alkem's ANDA Product in accordance with and as directed by Alkem's proposed labeling for that product would infringe one or more claims of the RE '839 patent.

RESPONSE: Denied.

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

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

Formula I



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

RESPONSE: Alkem admits this paragraph accurately describes claim 1 of the RE '839 patent. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

42. Upon information and belief, the use of Alkem's ANDA Product in accordance with and as directed by Alkem's proposed label would involve treating one or more 5-HT_{2A}-related disorders, including by administering to the patient in need thereof a free or pharmaceutically acceptable salt form of a Formula I compound (which includes lumateperone) in a dose which selectively blocks the 5-HT_{2A} receptor, as recited in claim 1.

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Alkem avers the allegations in this paragraph of the Complaint are speculative in nature, concern uncertain future events and are contingent upon the actions of third parties, and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

51. The foregoing actions by Alkem 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: Denied.

52. Upon information and belief, Alkem 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: Denied.

53. Plaintiff will be substantially and irreparably damaged by infringement of the RE ’839 patent.

RESPONSE: Denied.

54. Unless Alkem 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: Denied.

Responses to Allegations Pertaining to
Count II—Declaratory Judgment of Alleged Infringement of the RE ’839 Patent

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

56. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Alkem on the other regarding Alkem’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: Denied.

57. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Alkem’s ANDA Product with its proposed labeling, or any other Alkem drug product that is covered by or whose use is covered by the 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: Denied.

Responses to Allegations Pertaining to Count III— Alleged Infringement of the '227 Patent

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

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

RESPONSE: Alkem admits Exhibit B to the Complaint appears to be a copy of the '227 patent, which Alkem admits is titled "Method for the Treatment of Residual Symptoms of Schizophrenia." Alkem admits the face of the '227 patent states the '227 patent issued May 1, 2018. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Admitted.

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

RESPONSE: Alkem is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

62. 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: Alkem admits the '227 patents is listed in the Orange Book in connection with the Caplyta brand product. Alkem is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits its Notice Letter notified Plaintiff of the submission of Alkem's ANDA to the FDA. Alkem admits the purpose of submitting its ANDA is to obtain FDA approval of the drug product that is the subject of the ANDA. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Denied.

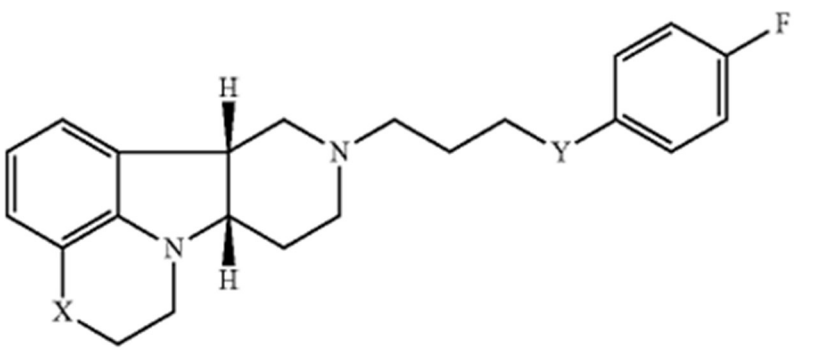
65. Upon information and belief, the use of Alkem's ANDA Product in accordance with and as directed by Alkem's proposed labeling for that product would infringe one or more claims of the '227 patent.

RESPONSE: Denied.

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

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

Formula I



wherein:

X is —O—, —NH— or —N(CH_3)—;

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

R_1 is —C_{1-6} alkyl or —C(O)—C_{1-21} alkyl, optionally saturated or unsaturated and optionally substituted with one or more hydroxyl or C_{1-22} alkoxy groups wherein such compound hydrolyzes to form the residue of a natural or unnatural, saturated or unsaturated fatty acid;
R_2 is H or —C_{1-6} alkyl; and R_3 is H or —C_{1-6} alkyl;
in free or pharmaceutically acceptable salt form;

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

RESPONSE: Alkem admits this paragraph accurately describes claim 1 of the '227 patent. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

67. Upon information and belief, the use of Alkem's ANDA Product in accordance with and as directed by Alkem's proposed label would involve treating 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: Denied.

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

RESPONSE: Denied.

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

Alkem's ANDA Product before the expiration of the '227 patent was an act of infringement of the '227 patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE: Denied.

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

RESPONSE: Alkem avers the allegations in this paragraph of the Complaint are speculative in nature, concern uncertain future events and are contingent upon the actions of third parties, and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

75. Notwithstanding Alkem's knowledge of the claims of the '227 patent, Alkem has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import

Alkem's ANDA Product with its product labeling following FDA approval of Alkem's ANDA prior to the expiration of the '227 patent.

RESPONSE: Denied.

76. The foregoing actions by Alkem 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: Denied.

77. Upon information and belief, Alkem 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: Denied.

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

RESPONSE: Denied.

79. Unless Alkem 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: Denied.

Responses to Allegations Pertaining to
Count IV—Declaratory Judgment of Alleged Infringement of the '227 Patent

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

81. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on

the one hand and Alkem on the other regarding Alkem'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: Denied.

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

Response to Allegations Pertaining to
Count V—Alleged Infringement of the '009 Patent

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

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

RESPONSE: Alkem admits Exhibit C to the Complaint appears to be a copy of the '009 patent, which Alkem admits is titled "Methods of Treating Schizophrenia and Depression." Alkem admits the face of the '009 patent states the '009 patent issued March 30, 2021. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Admitted.

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

RESPONSE: Alkem is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits the '009 patent is listed in the Orange Book in connection with the Caplyta brand product. Alkem is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits its Notice Letter notified Plaintiff of the submission of Alkem's ANDA to the FDA. Alkem admits the purpose of submitting its ANDA is to obtain FDA approval of the drug product that is the subject of the ANDA. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

89. According to Alkem's Notice Letter, Alkem's ANDA Product contains lumateperone.

RESPONSE: Denied.

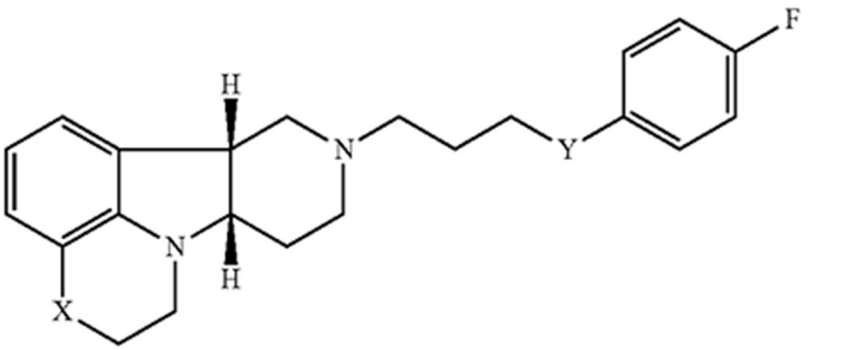
90. Upon information and belief, the use of Alkem's ANDA Product in accordance with and as directed by Alkem's proposed labeling for that product would infringe one or more claims of the '009 patent.

RESPONSE: Denied.

91. 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: Alkem denies this paragraph accurately describes claim 1 of the ’009 patent. Allegations not expressly admitted are denied.

92. Upon information and belief, the use of Alkem’s ANDA Product in accordance with and as directed by Alkem’s proposed label would involve treating 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: Denied.

93. Upon information and belief, Alkem’s ANDA Product infringes one or more claims of the ’009 patent, literally or under the doctrine of equivalents.

RESPONSE: Denied.

94. Alkem's submission of Alkem's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's ANDA Product before the expiration of the '009 patent was an act of infringement of the '009 patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE: Denied.

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

RESPONSE: Alkem avers the allegations in this paragraph of the Complaint are speculative in nature, concern uncertain future events and are contingent upon the actions of third parties, and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

101. The foregoing actions by Alkem 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: Denied.

102. Upon information and belief, Alkem 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: Denied.

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

RESPONSE: Denied.

104. Unless Alkem 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: Denied.

Responses to Allegations Pertaining to
Count VI—Declaratory Judgment of Alleged Infringement of the '009 Patent

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

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

RESPONSE: Denied.

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

Count VII—Infringement of the '951 Patent

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

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

RESPONSE: Alkem admits Exhibit D to the Complaint appears to be a copy of the '951 patent, which Alkem admits is titled "Methods of Treating Bipolar Disorder." Alkem admits the face of the '951 patent states the '951 patent issued June 8, 2021. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Admitted.

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

RESPONSE: Alkem is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

112. 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: Alkem admits the '951 patent is listed in the Orange Book in connection with the Caplyta brand product. Alkem is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits its Notice Letter notified Plaintiff of the submission of Alkem's ANDA to the FDA. Alkem admits the purpose of submitting its ANDA is to obtain FDA approval of the drug product that is the subject of the ANDA. Alkem admits that its ANDA seeks approval of Alkem's ANDA prior to expiration of the '951 patent. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits its Notice Letter notified Plaintiff that Alkem had filed a Paragraph IV certification with respect to the '951 patent. Alkem admits its ANDA includes a Paragraph IV certification 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 Alkem's ANDA Product. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

115. According to Alkem's Notice Letter, Alkem's ANDA Product contains lumateperone.

RESPONSE: Denied.

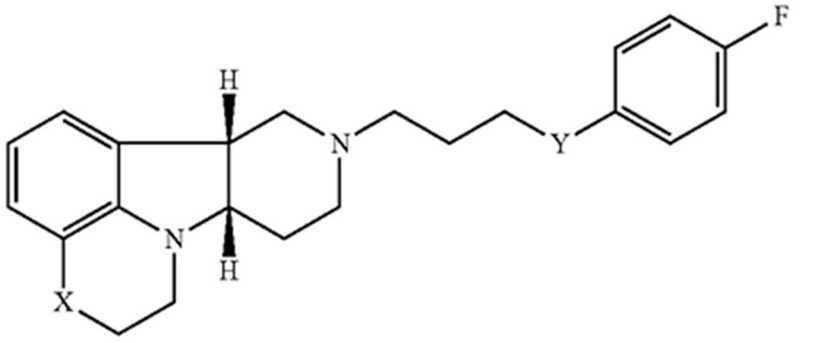
116. Upon information and belief, the use of Alkem's ANDA Product in accordance with and as directed by Alkem's proposed labeling for that product would infringe one or more claims of the '951 patent.

RESPONSE: Denied.

117. 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: Alkem admits this paragraph accurately describes claim 1 of the '951 patent. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Alkem avers the allegations in this paragraph of the Complaint are speculative in nature, concern uncertain future events and are contingent upon the actions of third parties, and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

127. The foregoing actions by Alkem 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: Denied.

128. Upon information and belief, Alkem 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: Denied.

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

RESPONSE: Denied.

130. Unless Alkem 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: Denied.

Response to Allegations Pertaining to
Count VIII—Declaratory Judgment of Alleged Infringement of the '951 Patent

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

132. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Alkem on the other regarding Alkem's infringement, active inducement of infringement, contribution to the infringement by others of the '951 patent, and/or the validity of the '951 patent.

RESPONSE: Denied.

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

Responses to Allegations Pertaining to
Count IX—Alleged Infringement of the '345 Patent

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

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

RESPONSE: Alkem admits Exhibit E to the Complaint appears to be a copy of the '345 patent, which Alkem admits is titled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate." Alkem admits the face of the '345 patent states the '345 patent issued June 30, 2020. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Admitted.

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

RESPONSE: Alkem is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

138. 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: Alkem admits the '345 patent is listed in the Orange Book in connection with the Caplyta brand product. Alkem is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits its Notice Letter notified Plaintiff of the submission of Alkem's ANDA to the FDA. Alkem admits the purpose of submitting its ANDA is to obtain FDA approval of the drug product that is the subject of the ANDA. Alkem admits that its ANDA seeks approval of Alkem's ANDA prior to expiration of the '345 patent. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits its Notice Letter notified Plaintiff that Alkem had filed a Paragraph IV certification with respect to the '345 patent. Alkem admits its ANDA includes a Paragraph IV certification 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 Alkem's ANDA Product. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

141. According to Alkem's Notice Letter, Alkem's ANDA Product contains lumateperone.

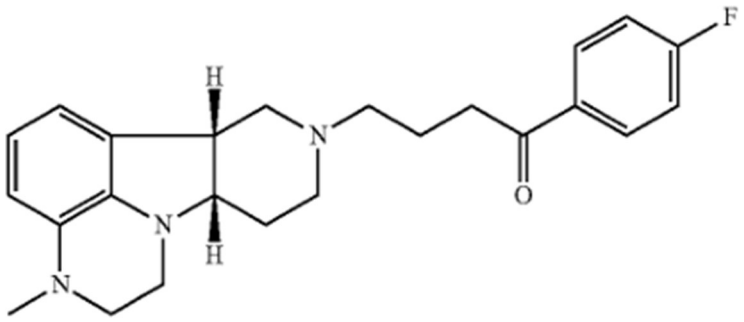
RESPONSE: Denied.

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

RESPONSE: Denied.

143. 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: Alkem admits this paragraph accurately describes claim 1 of the '345 patent. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Alkem avers the allegations in this paragraph of the Complaint are speculative in nature, concern uncertain future events and are contingent upon the actions of third parties, and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

153. The foregoing actions by Alkem 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: Denied.

154. Upon information and belief, Alkem 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: Denied.

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

RESPONSE: Denied.

156. Unless Alkem 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: Denied.

Responses to Allegations Pertaining to
Count X—Declaratory Judgment of Alleged Infringement of the '345 Patent

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

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

RESPONSE: Denied.

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

Response to Allegations Pertaining to Count XI—Alleged Infringement of the '084 Patent

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

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

RESPONSE: Alkem admits Exhibit F to the Complaint appears to be a copy of the '084 patent, which Alkem admits is titled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate." Alkem admits the face of the '084 patent states the '084 patent issued July 6, 2021. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Admitted.

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

RESPONSE: Alkem is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

164. 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: Alkem admits the '084 patent is listed in the Orange Book in connection with the Caplyta brand product. Alkem is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits its Notice Letter notified Plaintiff of the submission of Alkem's ANDA to the FDA. Alkem admits the purpose of submitting its ANDA is to obtain FDA approval of the drug product that is the subject of the ANDA. Alkem admits that its ANDA seeks approval of Alkem's ANDA prior to expiration of the '084 patent. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits its Notice Letter notified Plaintiff that Alkem had filed a Paragraph IV certification with respect to the '084 patent. Alkem admits its ANDA includes a Paragraph IV certification 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 Alkem's ANDA Product. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

167. According to Alkem's Notice Letter, Alkem's ANDA Product contains lumateperone.

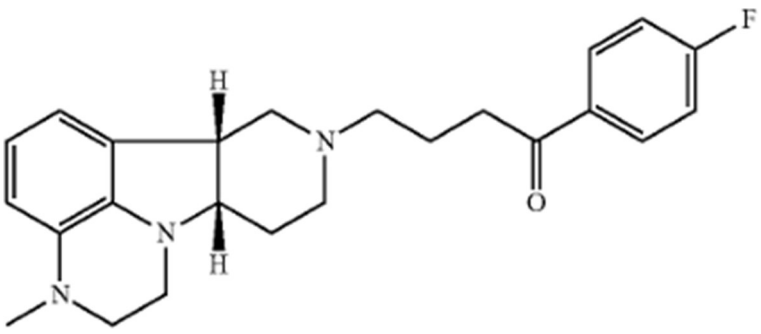
RESPONSE: Denied.

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

RESPONSE: Denied.

169. 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: Alkem admits this paragraph accurately describes claim 1 of the '084 patent. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

170. Upon information and belief, Alkem'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: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Alkem avers the allegations in this paragraph of the Complaint are speculative in nature, concern uncertain future events and are contingent upon the actions of third parties, and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

179. The foregoing actions by Alkem 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: Denied.

180. Upon information and belief, Alkem 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: Denied.

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

RESPONSE: Denied.

182. Unless Alkem 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: Denied.

Responses to Allegations Pertaining to
Count XII—Declaratory Judgment of Infringement of the '084 Patent

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

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

RESPONSE: Denied.

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

Responses to Allegations Pertaining to
Count XIII—Alleged Infringement of the '842 Patent

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the

preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

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

RESPONSE: Alkem admits Exhibit G to the Complaint appears to be a copy of the '842 patent, which Alkem admits is titled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate." Alkem admits the face of the '842 patent states the '842 patent issued July 4, 2023. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Admitted.

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

RESPONSE: Alkem is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

190. 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: Alkem admits the '842 patent is listed in the Orange Book in connection with the Caplyta brand product. Alkem is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

191. In Alkem's Notice Letter, Alkem notified Plaintiff of the submission of Alkem's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's ANDA Product prior to the expiration of the Patents-in-Suit, including the '842 patent.

RESPONSE: Alkem admits its Notice Letter notified Plaintiff of the submission of Alkem's ANDA to the FDA. Alkem admits the purpose of submitting its ANDA is to obtain FDA approval of the drug product that is the subject of the ANDA. Alkem admits that its ANDA seeks approval of Alkem's ANDA prior to expiration of the '842 patent. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits its Notice Letter notified Plaintiff that Alkem had filed a Paragraph IV certification with respect to the '842 patent. Alkem admits its ANDA includes a Paragraph IV certification 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 Alkem's ANDA Product. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

193. According to Alkem's Notice Letter, Alkem's ANDA Product contains lumateperone.

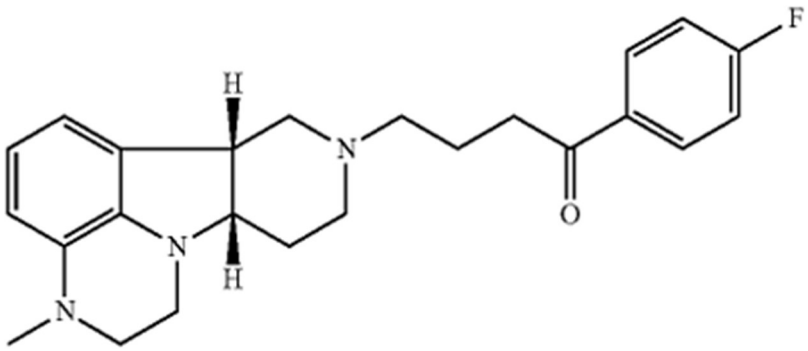
RESPONSE: Denied.

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

RESPONSE: Denied.

195. 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: Alkem admits this paragraph accurately describes claim 1 of the '842 patent. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

196. Upon information and belief, Alkem'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: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Alkem avers the allegations in this paragraph of the Complaint are speculative in nature, concern uncertain future events and are contingent upon the actions of third parties, and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

205. The foregoing actions by Alkem 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: Denied.

206. Upon information and belief, Alkem 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: Denied.

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

RESPONSE: Denied.

208. Unless Alkem 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: Denied.

Responses to Allegations Pertaining to
Count XIV—Declaratory Judgment of Alleged Infringement of the '842 Patent

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

210. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Alkem on the other regarding Alkem's infringement, active inducement of infringement, contribution to the infringement by others of the '842 patent, and/or the validity of the '842 patent.

RESPONSE: Denied.

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

Responses to Allegations Pertaining to Count XV—Alleged Infringement of the '348 Patent

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

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

RESPONSE: Alkem admits Exhibit H to the Complaint appears to be a copy of the '348 patent, which Alkem admits is titled "Methods of Treatment Using Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-tosylate." Alkem admits the face of the '348 patent states the '348 patent issued November 7, 2023. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Admitted.

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

RESPONSE: Alkem is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

216. 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: Alkem admits the '348 patent is listed in the Orange Book in connection with the Caplyta brand product. Alkem is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

217. In Alkem's Notice Letter, Alkem notified Plaintiff of the submission of Alkem's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's ANDA Product prior to the expiration of the Patents-in-Suit, including the '348 patent.

RESPONSE: Alkem admits its Notice Letter notified Plaintiff of the submission of Alkem's ANDA to the FDA. Alkem admits the purpose of submitting its ANDA is to obtain FDA approval of the drug product that is the subject of the ANDA. Alkem admits that its ANDA seeks approval of Alkem's ANDA prior to expiration of the '348 patent. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits its Notice Letter notified Plaintiff that Alkem had filed a Paragraph IV certification with respect to the '348 patent. Alkem admits its ANDA includes a Paragraph IV certification 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 Alkem's ANDA Product. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

219. According to Alkem's Notice Letter, Alkem's ANDA Product contains lumateperone.

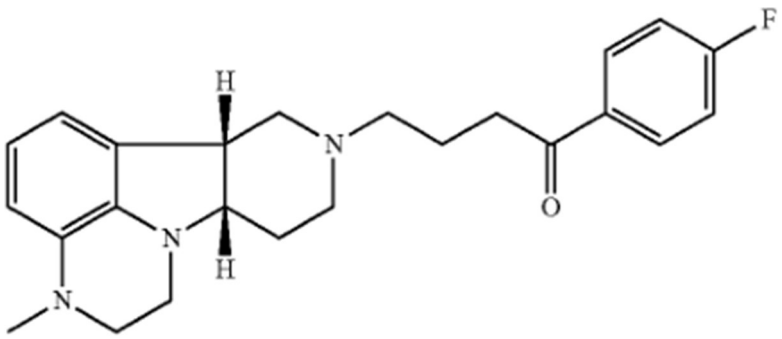
RESPONSE: Denied.

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

RESPONSE: Denied.

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

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



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

RESPONSE: Alkem admits this paragraph accurately describes claim 1 of the '348 patent. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Alkem avers the allegations in this paragraph of the Complaint are speculative in nature, concern uncertain future events and are contingent upon the actions of third parties, and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

231. The foregoing actions by Alkem 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: Denied.

232. Upon information and belief, Alkem 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: Denied.

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

RESPONSE: Denied.

234. Unless Alkem 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: Denied.

Responses to Allegations Pertaining to Count XVI—Declaratory Judgment of Alleged Infringement of the '348 Patent

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

236. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Alkem on the other regarding Alkem's infringement, active inducement of infringement, contribution to the infringement by others of the '348 patent, and/or the validity of the '348 patent.

RESPONSE: Denied.

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

Responses to Allegations Pertaining to Count XVII—Alleged Infringement of the '419 Patent

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

239. The ’419 patent, entitled “4-((6br,10as)-3-methyl-2,3,6b,9,10,10a-hexahydro-1h-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7h)-yl)-1-(4-((6br,10as)-3-methyl-2,3,6b,9,10,10a-hexahydro-1h-pyrido[3′4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7h)-yl)phenyl)butan-1-one for Treating Conditions of the Central Nervous System and Cardiac Disorders” (attached as Exhibit I), was duly and legally issued on September 12, 2023.

RESPONSE: Alkem admits Exhibit I to the Complaint appears to be a copy of the ’419 patent, which Alkem admits 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.” Alkem admits the face of the ’419 patent states the ’419 patent issued September 12, 2023. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Admitted.

241. Plaintiff is the owner and assignee of the ’419 patent.

RESPONSE: Alkem is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

242. 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: Alkem admits the ’419 patent is listed in the Orange Book in connection with the Caplyta brand product. Alkem is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph of the Complaint and, therefore, denies the same. Allegations not expressly admitted are denied.

243. In Alkem's Notice Letter, Alkem notified Plaintiff of the submission of Alkem's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's ANDA Product prior to the expiration of the Patents-in-Suit, including the '419 patent.

RESPONSE: Alkem admits its Notice Letter notified Plaintiff of the submission of Alkem's ANDA to the FDA. Alkem admits the purpose of submitting its ANDA is to obtain FDA approval of the drug product that is the subject of the ANDA. Alkem admits that its ANDA seeks approval of Alkem's ANDA prior to expiration of the '419 patent. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Alkem admits its Notice Letter notified Plaintiff that Alkem had filed a Paragraph IV certification with respect to the '419 patent. Alkem admits its ANDA includes a Paragraph IV certification 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 Alkem's ANDA Product. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

245. According to Alkem's Notice Letter, Alkem's ANDA Product contains lumateperone.

RESPONSE: Denied.

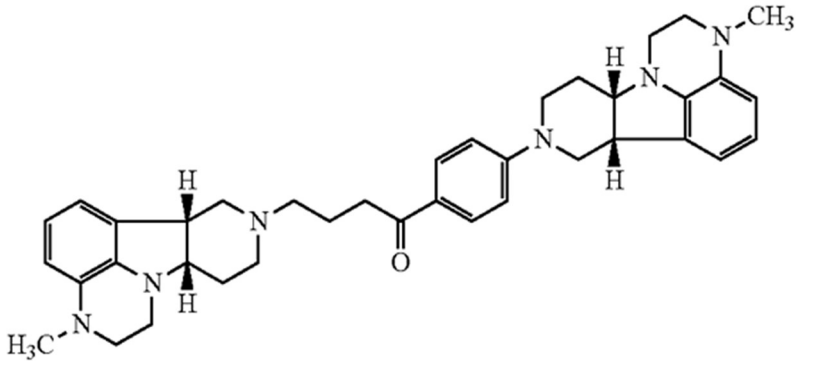
246. Upon information and belief, Alkem's ANDA Product and the use of Alkem's ANDA Product are covered by one or more claims of the '419 patent, either literally or under the doctrine of equivalents.

RESPONSE: Denied.

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

A compound of Formula I:

Formula I



in free base or pharmaceutically acceptable salt form.

RESPONSE: Alkem admits this paragraph accurately describes claim 1 of the '419 patent. Alkem denies all further allegations remaining in this paragraph of the Complaint. Allegations not expressly admitted are denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Alkem avers the allegations in this paragraph of the Complaint are speculative in nature, concern uncertain future events and are contingent upon the actions of third parties, and, therefore, denies the same. Allegations not expressly admitted are denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

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

RESPONSE: Denied.

257. The foregoing actions by Alkem 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: Denied.

258. Upon information and belief, Alkem 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: Denied.

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

RESPONSE: Denied.

260. Unless Alkem 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: Denied.

Responses to Allegations Pertaining to
Count XVIII—Declaratory Judgment of Alleged Infringement of the '419 Patent

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

RESPONSE: Alkem objects to the incorporation of previous facts, which renders the Complaint vague and ambiguous. Alkem incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein. Alkem avers this paragraph of the Complaint contains no allegations to which a response is required.

262. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Alkem on the other regarding Alkem's infringement, active inducement of infringement, contribution to the infringement by others of the '419 patent, and/or the validity of the '419 patent.

RESPONSE: Denied.

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

GENERAL DENIAL AND RESPONSE TO PLAINTIFF'S REQUEST FOR RELIEF

All allegations in Plaintiff's Complaint not expressly admitted by Alkem are hereby denied. Having answered Plaintiff's Complaint, Alkem denies Plaintiff is entitled to any of the relief requested in the Complaint or any relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not expressly admitted, Alkem asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest on Plaintiff.

FIRST SEPARATE DEFENSE

The manufacture, use, or sale, offer for sale, or importation of the product(s) that is the subject of Alkem's ANDA has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the Patents-in-Suit.

SECOND SEPARATE DEFENSE

Each of the claim of the Patents-in-Suit is invalid for failure to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code or Obviousness Type Double Patenting.

THIRD SEPARATE DEFENSE

Each of claim of the Patents-in-Suit is invalid as anticipated or obvious, pursuant to 35 U.S.C. §§ 102 or 103, respectively, for example, for at least the reasons set forth in Alkem's Notice Letter.

FOURTH SEPARATE DEFENSE

Each of claim of the Patents-in-Suit is invalid, pursuant to 35 U.S.C. § 112, as, for example, indefinite, not enabled and/or failing to provide adequate written description.

FIFTH SEPARATE DEFENSE

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the Patents-in-suit, and specifically prosecution history estoppel, Plaintiffs are estopped from maintaining that any valid or enforceable claim of the Asserted Patents is infringed by the product that is the subject of Alkem's ANDA.

SIXTH SEPARATE DEFENSE

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

SEVENTH SEPARATE DEFENSE

Any and all additional defenses and counterclaims that discovery may reveal.

WHEREFORE, Alkem hereby demands judgment in its favor based on a finding of non-infringement and/or invalidity and/or unenforceability of the Patents-in-Suit, an award of all costs and fees incurred in defense of this Action and for such other relief as the Court may deem just and proper.

Dated: June 3, 2024

KRATZ & BARRY LLP

/s/ R Touhey Myer
R Touhey Myer (NJ Bar ID 028912009)
800 N. West Street
Wilmington, DE 19801
(302) 527-9378
tmyer@kratzandbarry.com

Of Counsel:

Timothy H. Kratz *(Pro Hac Vice Expected)*
George J. Barry III *(Pro Hac Vice Expected)*
KRATZ & BARRY, LLP
1050 Crown Pointe Parkway, Suite 500
Atlanta, GA 30338
(404) 431-6600
tkratz@kratzandbarry.com
gbarry@kratzandbarry.com

Michael P. Hogan *(Pro Hac Vice Expected)*
KRATZ & BARRY LLP
325 Chestnut Street, Suite 883, #259
Philadelphia, PA 19106
(917) 216-8585
mhogan@kratzandbarry.com

Attorneys for Defendant,
Alkem Laboratories Ltd.