

Rebekah R. Conroy  
**STONE CONROY LLC**  
25A Hanover Road, Suite 301  
Florham Park, New Jersey 07932  
[rconroy@stoneconroy.com](mailto:rconroy@stoneconroy.com)  
Tel.: (973) 400-4181

OF COUNSEL:  
Neal Seth (*pro hac vice forthcoming*)  
Wesley E. Weeks (*pro hac vice forthcoming*)  
**WILEY REIN LLP**  
2050 M Street NW  
Washington, DC 20036  
[nseth@wiley.law](mailto:nseth@wiley.law)  
[wweeks@wiley.law](mailto:wweeks@wiley.law)  
Tel.: (202) 719-7000

*Counsel for Defendants Hetero USA, Inc.,  
Hetero Labs Ltd. Unit-V, and Hetero Labs Ltd.,*

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

Intra-Cellular Therapies, Inc.,

*Plaintiff,*

v.

Hetero USA, Inc., Hetero Labs Ltd. Unit-V, and  
Hetero Labs Ltd.,

*Defendants.*

Civil Action No. 3:24-cv-04317

**(Filed Electronically)**

**DEFENDANTS HETERO USA, INC., HETERO LABS LTD. UNIT-V, AND HETERO  
LABS LIMITED'S ANSWER, DEFENSES AND COUNTERCLAIMS**

Defendants Hetero USA, Inc. Hetero Labs Ltd. Unit-V, and Hetero Labs Limited (collectively, “Hetero”), by their undersigned attorneys, for their Answer to the Complaint for Patent Infringement filed by Plaintiff Intra-Cellular Therapies, Inc. (“Intra-Cellular Therapies,”

“ITCI,” or “Plaintiff”), state as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), Hetero denies all allegations in Plaintiff’s Complaint except those expressly admitted below.

**Nature of the Action**

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

**ANSWER:** Paragraph 1 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that Plaintiff’s Complaint purports to assert an action for patent infringement based on Hetero’s filing of an Abbreviated New Drug Application (“ANDA”) seeking approval from the U.S. Food and Drug Administration (“FDA”) to commercially market generic versions of Caplyta® prior to the expiration of U.S. Patent Nos. 8,648,077 (“the ’077 patent”), 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”). Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations of Paragraph 1 of the Complaint and

therefore denies them.

2. Hetero notified Plaintiff by letter dated February 20, 2024 (“Hetero’s Notice Letter”) that it had submitted to the FDA ANDA No. 219142 (“Hetero’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, (“Hetero’s ANDA Product”) prior to the expiration of the Patents-in-Suit.

**ANSWER:** Hetero admits to sending a Notice Letter on February 20, 2024 to Plaintiff, informing Plaintiff that Hetero is seeking approval to engage in the commercial manufacture, use, and sale of the product described in its ANDA as soon as legally permissible, prior to the expiration of the Patents-in-Suit. Hetero denies the remaining allegations of Paragraph 2 of the Complaint.

### **The Parties**

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 4 of the Complaint and, therefore, denies all allegations.

5. Upon information and belief, Defendant Hetero USA, Inc., is a corporation organized and existing under the laws of Delaware and having a principal place of business at 1035

Centennial Ave, Piscataway, New Jersey 08854.

**ANSWER:** Admitted.

6. Upon information and belief, defendant Hetero Labs Ltd., Unit-V is a division of Hetero Labs Ltd., having a principal place of business at Sy. No.: 439, 440, 441 & 458, TSIIC Formulation SEZ, Polepally Village, Mahabubnagar, Telangana, India, 509301.

**ANSWER:** Denied.

7. Upon information and belief, Defendant Hetero Labs Ltd. is a corporation organized and existing under the laws of the Republic of India and having a principal place of business at 7-2-a2, Hetero Corporate Industrial Estate, Sanathnagar, Hyderabad, Telangana, India, 500018.

**ANSWER:** Admitted.

8. Upon information and belief, Hetero USA Inc. is the U.S. Regulatory Agent for Hetero Labs Ltd., Unit-V, which is a division of Hetero Labs Ltd.

**ANSWER:** Admitted.

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

**ANSWER:** Denied.

10. Upon information and belief, Hetero Labs Ltd., Hetero Labs Ltd., Unit-V, and Hetero USA Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Hetero's ANDA Product, and enter into agreements with

each other that are nearer than arm's length. Upon information and belief, Hetero USA Inc. participated in, assisted, and cooperated with Hetero Labs Ltd. and Hetero Labs Ltd., Unit-V in the acts complained of herein.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

### **Jurisdiction**

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest that this Court has subject matter jurisdiction over this action. Hetero denies any remaining allegations contained in Paragraph 13 of the Complaint.

14. This Court has personal jurisdiction over each of Hetero Labs Ltd., Hetero Labs Ltd., Unit-V, and Hetero USA Inc.

**ANSWER:** Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest personal jurisdiction over Hetero Labs Ltd. and Hetero USA Inc. Hetero denies any remaining allegations contained in Paragraph 14 of the Complaint.

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

**ANSWER:** Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest personal jurisdiction over Hetero Labs Ltd. Hetero denies any remaining allegations contained in Paragraph 15 of the Complaint.

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

belief, it controls Hetero USA Inc. and therefore the activities of Hetero USA Inc. in this jurisdiction are attributed to Hetero Labs Ltd., Unit-V.

**ANSWER:** Denied.

17. Hetero USA Inc. is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Hetero USA Inc. is a corporation having a principal place of business in the State of New Jersey, is qualified to do business in New Jersey, and has appointed a registered agent for service of process in New Jersey. It therefore has consented to general jurisdiction in New Jersey. In addition, upon information and belief, Hetero USA Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey and therefore transacts business within the State of New Jersey related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

**ANSWER:** Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest personal jurisdiction over Hetero USA Inc. Hetero denies any remaining allegations contained in Paragraph 17 of the Complaint.

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

**ANSWER:** Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest personal

jurisdiction over Hetero Labs Ltd. and Hetero USA Inc. Hetero denies any remaining allegations contained in Paragraph 18 of the Complaint.

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

**ANSWER:** Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest personal jurisdiction over Hetero Labs Ltd. and Hetero USA Inc. Hetero denies any remaining allegations contained in Paragraph 19 of the Complaint.

20. Upon information and belief, if Hetero's ANDA is approved, Hetero will directly or indirectly manufacture, market, sell, and/or distribute Hetero's ANDA Product within the United States, including in New Jersey, consistent with Hetero's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Hetero 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, Hetero's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. Upon information and belief, Hetero's ANDA Product will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Each of these activities would have a substantial effect within New

Jersey and would constitute infringement of the Patents-in-Suit in the event that Hetero's ANDA Product is approved before the patents expire.

**ANSWER:** Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest personal jurisdiction over Hetero Labs Ltd. and Hetero USA Inc. Hetero denies any remaining allegations contained in Paragraph 20 of the Complaint.

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

**ANSWER:** Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest personal jurisdiction over Hetero Labs Ltd. and Hetero USA Inc. Hetero denies any remaining allegations contained in Paragraph 21 of the Complaint.

**Venue**

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest the propriety of venue in this District. Hetero denies all remaining allegations of Paragraph 23.

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

**ANSWER:** Denied.

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

**ANSWER:** Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely for purposes of this action, Hetero does not contest the propriety of venue in this District. Hetero denies all remaining allegations of Paragraph 25.

### **Factual Background**

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Hetero admits that the prescribing information for Caplyta® speaks for itself. Hetero denies the remaining allegations of Paragraph 27 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations in Paragraph 28 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations in Paragraph 29 of the Complaint.

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

**ANSWER:** Paragraph 30 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that Hetero filed its ANDA seeking approval from the U.S. Food and Drug Administration ("FDA") to commercially market generic

versions of Caplyta® prior to the expiration of the Patents-in-Suit. Hetero denies the remaining allegations of Paragraph 30 of the Complaint.

31. Upon information and belief, Hetero's ANDA Product is not publicly available, nor is ANDA No. 219142 accessible to the public.

**ANSWER:** Admitted.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 32 of the Complaint.

33. Counsel for Plaintiff contacted Hetero to discuss the terms of Hetero's Offer of Confidential Access, but Hetero never responded. The parties therefore could not agree on terms under which Plaintiff could review, among other things, Hetero's unredacted ANDA, any Drug Master File referred to therein, or all relevant characterization data, or under which Hetero could produce samples of Hetero's ANDA Product and other internal documents and material relevant to infringement.

**ANSWER:** Hetero admits that the parties did not agree on terms on the offer of confidential access to Hetero's ANDA. Hetero denies the remaining allegations of Paragraph 33 of the Complaint.

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

**ANSWER:** Admitted.

**Count I—Infringement of the RE '839 Patent**

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Paragraph 36 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the RE '839 patent is entitled “Methods and Compositions for Sleep Disorders and Other Disorders,” that a purported copy is attached as Exhibit A, and that the issue date on the cover of the RE '839 patent is December 7, 2021. Hetero denies the remaining allegations of Paragraph 36 of the Complaint.

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

**ANSWER:** Paragraph 37 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the RE '839 patent identifies Sharon Mates, Allen Fienberg, and Lawrence Wennogle as the inventors. Hetero denies the remaining allegations of Paragraph 37 of the Complaint.

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

**ANSWER:** Paragraph 38 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the RE '839 patent identifies Plaintiff as the assignee. Hetero denies the remaining allegations of Paragraph 38 of the Complaint.

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

**ANSWER:** Paragraph 39 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that electronic FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations,” otherwise known as the electronic “Orange Book,” identifies the RE ’389 patent in connection with the New Drug Application (“NDA”) for Caplyta®. Hetero denies the remaining allegations of Paragraph 39 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 40 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 41 of the Complaint.

42. According to Hetero’s Notice Letter, Hetero’s ANDA Product contains lumateperone.

**ANSWER:** Admitted.

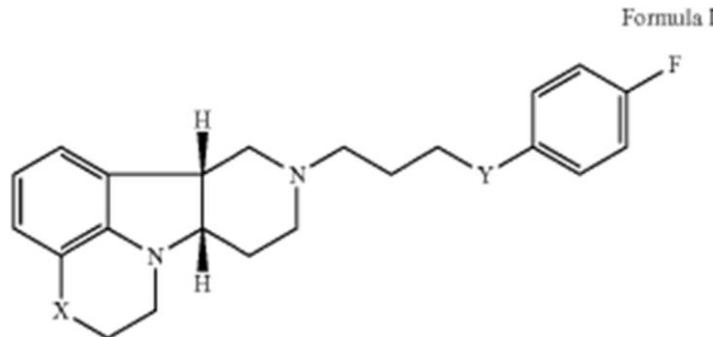
43. Upon information and belief, the use of Hetero’s ANDA Product in accordance with and as directed by Hetero’s proposed labeling for that product would infringe one or more

claims of the RE '839 patent.

**ANSWER:** Denied.

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

A method for the treatment of one or more 5-HT2A-related disorders, comprising administering to a patient in need thereof a Compound of Formula I:



wherein X is O, —NH or —N(CH<sub>3</sub>); and Y is —O— or —C(O)—, in free or pharmaceutically acceptable salt form, in a dose which selectively blocks the 5-HT2A receptor.

**ANSWER:** Hetero admits that the RE '839 patent speaks for itself. Hetero denies the remaining allegations in Paragraph 44 of the Complaint.

45. Upon information and belief, the use of Hetero's ANDA Product in accordance with and as directed by Hetero's proposed label would involve treating one or more 5-HT2A-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-HT2A receptor, as recited in claim 1.

**ANSWER:** Paragraph 45 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that its proposed label speaks for itself. Hetero denies the remaining allegations in Paragraph 45 of the Complaint.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

51. Upon information and belief, Hetero plans and intends to, and will, actively induce infringement of the RE '839 patent when Hetero's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Hetero's activities will be done with

knowledge of the RE '839 patent and specific intent to infringe that patent.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Paragraph 59 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that an actual controversy exists because Plaintiff has asserted a claim for infringement of the RE '839 patent. Hetero denies the remaining allegations of Paragraph 59 of the Complaint.

60. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Product with its proposed labeling, or any other Hetero drug product that is covered by or whose use is covered by the RE '839 patent, will infringe, induce infringement of, and contribute to the infringement by others of the RE '839 patent, and that the

claims of the RE '839 patent are not invalid.

**ANSWER:** Denied.

**Count III—Infringement of the '077 Patent**

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

62. The '077 patent, entitled “4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3',4':4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone Toluenesulfonic Acid Addition Salt and Salt Crystals” (attached as Exhibit B), was duly and legally issued on February 11, 2014.

**ANSWER:** Paragraph 62 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '077 patent is entitled “4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3',4':4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone Toluenesulfonic Acid Addition Salt and Salt Crystals,” that a purported copy is attached as Exhibit B, and that the issue date on the cover of the '077 patent is February 11, 2014. Hetero denies the remaining allegations of Paragraph 62 of the Complaint.

63. The inventors named on the '077 patent are John Tomesch and Lawrence P. Wennogle.

**ANSWER:** Paragraph 63 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '077 patent identifies John Tomesch and Lawrence P. Wennogle as the inventors. Hetero denies the remaining allegations of Paragraph 63 of the Complaint.

64. Plaintiff is the owner and assignee of the '077 patent.

**ANSWER:** Paragraph 64 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '077 patent identifies Plaintiff as the assignee. Hetero denies the remaining allegations of Paragraph 64 of the Complaint.

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

**ANSWER:** Paragraph 65 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that electronic FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations,” otherwise known as the electronic “Orange Book,” identifies the '077 patent in connection with the New Drug Application (“NDA”) for Caplyta®. Hetero denies the remaining allegations of Paragraph 65 of the Complaint.

66. In Hetero’s Notice Letter, Hetero notified Plaintiff of the submission of Hetero’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 Hetero’s ANDA Product prior to the expiration of the Patents-in-Suit, including the '077 patent.

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 66 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 67 of the Complaint.

68. According to Hetero's Notice Letter, Hetero's ANDA Product contains lumateperone.

**ANSWER:** Admitted.

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

**ANSWER:** Denied.

70. As an example, claim 1 of the '077 patent recites:

A toluenesulfonic acid addition salt crystal of 4-((6bR,10aS)-3- methyl-2,3,6b,9,10,10a-hexahydro-1H- pyrido[3',4':4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4- fluorophenyl)-1-butanone, wherein said salt crystal exhibits an X- ray powder diffraction pattern comprising at least two peaks having 2-theta values selected from the group consisting of 5.68°, 12.11°, 16.04°, 17.03°, 18.16°, 19.00°, 21.67°, 22.55°, 23.48° and 24.30°, wherein the X-ray powder diffraction data is collected on a diffractometer operating with a copper anode with a nickel filter.

**ANSWER:** Hetero admits that the '077 patent speaks for itself. Hetero denies the remaining allegations in Paragraph 70 of the Complaint.

71. Upon information and belief, Hetero's ANDA Product contains a crystalline form of the compound recited in claim 1.

**ANSWER:** Paragraph 71 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that its proposed label speaks for itself. Hetero denies the remaining allegations in Paragraph 71 of the Complaint.

72. Upon information and belief, Hetero's ANDA Product infringes one or more claims of the '077 patent, literally or under the doctrine of equivalents.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

78. Upon information and belief, Hetero knows that Hetero's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '077 patent, that Hetero's

ANDA Product is not a staple article or commodity of commerce, and that Hetero's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Hetero plans and intends to, and will, contribute to infringement of the '077 patent immediately and imminently upon approval of Hetero's ANDA.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

80. The foregoing actions by Hetero constitute and/or will constitute infringement of the '077 patent; active inducement of infringement of the '077 patent; and/or contribution to the infringement by others of the '077 patent.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

82. Plaintiff will be substantially and irreparably damaged by infringement of the '077 patent.

**ANSWER:** Denied.

83. Unless Hetero is enjoined from infringing the '077 patent, actively inducing infringement of the '077 patent, and contributing to the infringement by others of the '077 patent,

Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

**ANSWER:** Denied.

**Count IV—Declaratory Judgment of Infringement of the '077 Patent**

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

85. 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 Hetero on the other regarding Hetero's infringement, active inducement of infringement, contribution to the infringement by others of the '077 patent, and/or the validity of the '077 patent.

**ANSWER:** Paragraph 85 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that an actual controversy exists because Plaintiff has asserted a claim for infringement of the '077 patent. Hetero denies the remaining allegations of Paragraph 85 of the Complaint.

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

**ANSWER:** Denied.

**Count V—Infringement of the '227 Patent**

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Paragraph 88 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the 277 patent is entitled "Method for the Treatment of Residual Symptoms of Schizophrenia," that a purported copy is attached as Exhibit C, and that the issue date on the cover of the '227 patent is May 1, 2018. Hetero denies the remaining allegations of Paragraph 88 of the Complaint.

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

**ANSWER:** Paragraph 89 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '227 patent identifies Kimberly Vanover, Peng Li, Sharon Mates, Robert Davis, and Lawrence P. Wennogle as the inventors. Hetero denies the remaining allegations of Paragraph 89 of the Complaint.

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

**ANSWER:** Paragraph 90 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '227 patent identifies Plaintiff as the assignee. Hetero denies the remaining allegations of Paragraph 90 of the Complaint.

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

**ANSWER:** Paragraph 91 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that electronic FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations,” otherwise known as the electronic “Orange Book,” identifies the ’227 patent in connection with the New Drug Application (“NDA”) for Caplyta®. Hetero denies the remaining allegations of Paragraph 91 of the Complaint.

92. In Hetero’s Notice Letter, Hetero notified Plaintiff of the submission of Hetero’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 Hetero’s ANDA Product prior to the expiration of the Patents-in-Suit, including the ’227 patent.

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 92 of the Complaint.

93. In Hetero’s Notice Letter, Hetero also notified Plaintiff that, as part of its ANDA, Hetero had filed Paragraph IV certifications with respect to the ’227 patent. Upon information and belief, Hetero submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the ’227 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Hetero’s ANDA Product.

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 93 of the Complaint.

94. According to Hetero’s Notice Letter, Hetero’s ANDA Product contains lumateperone.

**ANSWER:** Admitted.

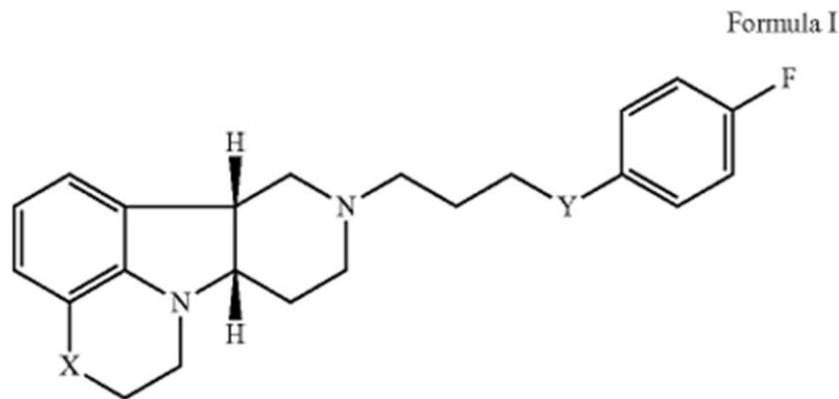
95. Upon information and belief, the use of Hetero’s ANDA Product in accordance with and as directed by Hetero’s proposed labeling for that product would infringe one or more

claims of the '227 patent.

**ANSWER:** Denied.

96. 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:



wherein:

X is —O—, —NH— or —N(CH<sub>3</sub>)—;

Y is —O—, —C(R<sub>2</sub>)(OH)—, —C(R<sub>3</sub>)(OR<sub>1</sub>) or —C(O)—; and

R<sub>1</sub> is —C<sub>1-6</sub> alkyl or —C(O)—C<sub>1-21</sub> alkyl, optionally saturated or unsaturated

and optionally substituted with one or more hydroxyl or C<sub>1-22</sub> alkoxy groups

wherein such compound hydrolyzes to form the residue of a natural or unnatural,

saturated or unsaturated fatty acid; R<sub>2</sub> is H or —C<sub>1-6</sub> alkyl; and R<sub>3</sub> is H or —C<sub>1-6</sub>

alkyl;

in free or pharmaceutically acceptable salt form;

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

**ANSWER:** Hetero admits that the '227 patent speaks for itself. Hetero denies the remaining allegations in Paragraph 96 of the Complaint.

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

**ANSWER:** Paragraph 97 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that its proposed label speaks for itself. Hetero denies the remaining allegations in Paragraph 97 of the Complaint.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

**Count VI—Declaratory Judgment of Infringement of the '227 Patent**

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

111. 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 Hetero on the other regarding Hetero's infringement, active inducement of

infringement, contribution to the infringement by others of the '227 patent, and/or the validity of the '227 patent.

**ANSWER:** Paragraph 111 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that an actual controversy exists because Plaintiff has asserted a claim for infringement of the '227 patent. Hetero denies the remaining allegations of Paragraph 111 of the Complaint.

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

**ANSWER:** Denied.

#### **Count VII—Infringement of the '009 Patent**

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Paragraph 114 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '009 patent is entitled "Methods of Treating Schizophrenia and Depression," that a purported copy is attached as Exhibit D, and that the issue date on the cover of the '009 patent is March 30, 2021. Hetero denies the remaining allegations of Paragraph 114 of the Complaint.

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

**ANSWER:** Paragraph 115 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '009 patent identifies Kimberly Vanover, Peng Li, Sharon Mates, Robert Davis, and Lawrence P. Wennogle as the inventors. Hetero denies the remaining allegations of Paragraph 115 of the Complaint.

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

**ANSWER:** Paragraph 116 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '009 patent identifies Plaintiff as the assignee. Hetero denies the remaining allegations of Paragraph '009 of the Complaint.

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

**ANSWER:** Paragraph 117 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that electronic FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the electronic "Orange Book," identifies the '009 patent in connection with the New Drug Application ("NDA") for Caplyta®. Hetero denies the remaining allegations of Paragraph 117 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 118 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 119 of the Complaint.

120. According to Hetero's Notice Letter, Hetero's ANDA Product contains lumateperone.

**ANSWER:** Admitted.

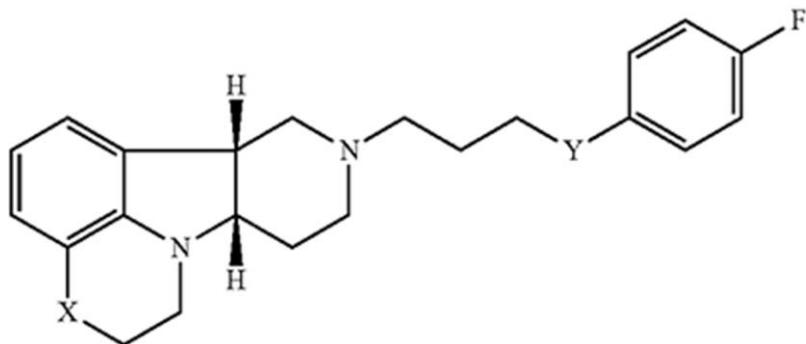
121. Upon information and belief, the use of Hetero's ANDA Product in accordance with and as directed by Hetero's proposed labeling for that product would infringe one or more claims of the '009 patent.

**ANSWER:** Denied.

122. 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<sub>3</sub>)— and Y is —C(O)—;

in free or pharmaceutically acceptable salt form,

wherein the effective amount of the Compound of Formula I is 40 mg to 60 mg per day, measured as the weight of the corresponding free base form of the Compound.

**ANSWER:** Hetero admits that the '009 patent speaks for itself. Hetero denies the remaining allegations in Paragraph 122 of the Complaint.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

expiration of the '009 patent.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

**Count VIII—Declaratory Judgment of Infringement of the '009 Patent**

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Paragraph 137 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that an actual controversy exists because Plaintiff has asserted a claim for infringement of the '009 patent. Hetero denies the remaining allegations of Paragraph 137 of the Complaint.

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

**ANSWER:** Denied.

#### **Count IX—Infringement of the '951 Patent**

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Paragraph 140 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '951 patent is entitled "Methods of Treating Bipolar Disorder," that a purported copy is attached as Exhibit E, and that the issue date on the cover of the '951 patent is June 8, 2021. Hetero denies the remaining allegations of Paragraph 140 of the Complaint.

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

**ANSWER:** Paragraph 141 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '951 patent identifies Kimberly Vanover, Peng Li, Sharon Mates, Robert Davis, and Lawrence P. Wennogle as the inventors. Hetero denies the remaining allegations of Paragraph 141 of the Complaint.

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

**ANSWER:** Paragraph 142 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '951 patent identifies Plaintiff as the assignee. Hetero denies the remaining allegations of Paragraph 142 of the Complaint.

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

**ANSWER:** Paragraph 143 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that electronic FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the electronic "Orange Book," identifies the '951 patent in connection with the New Drug Application ("NDA") for Caplyta®. Hetero denies the remaining allegations of Paragraph 143 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 144 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 145 of the Complaint.

146. According to Hetero's Notice Letter, Hetero's ANDA Product contains lumateperone.

**ANSWER:** Admitted.

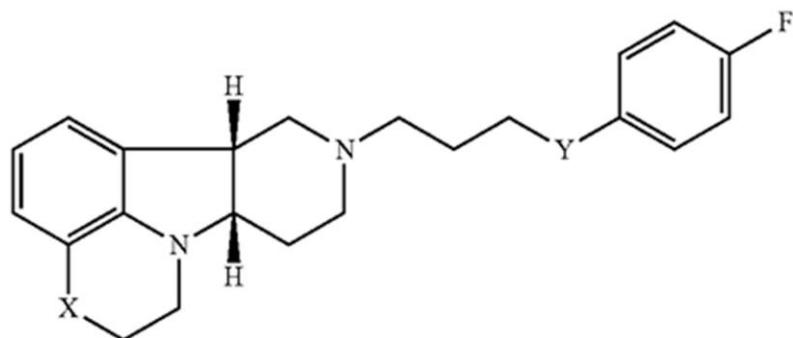
147. Upon information and belief, the use of Hetero's ANDA Product in accordance with and as directed by Hetero's proposed labeling for that product would infringe one or more claims of the '951 patent.

**ANSWER:** Denied.

148. 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<sub>3</sub>)— and Y is —C(O)—;

in free or pharmaceutically acceptable salt form, wherein said Compound is not used in combination with another antipsychotic agent.

**ANSWER:** Hetero admits that the '951 patent speaks for itself. Hetero denies the remaining allegations in Paragraph 148 of the Complaint.

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

**ANSWER:** Paragraph 149 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that its proposed label speaks for itself. Hetero denies the remaining allegations in Paragraph 149 of the Complaint.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

152. Upon information and belief, Hetero will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Hetero's ANDA Product immediately and

imminently upon approval of its ANDA.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

157. Notwithstanding Hetero's knowledge of the claims of the '951 patent, Hetero has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Hetero's

ANDA Product with its product labeling following FDA approval of Hetero's ANDA prior to the expiration of the '951 patent.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

**Count X—Declaratory Judgment of Infringement of the '951 Patent**

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Paragraph 163 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that an actual controversy exists because Plaintiff has asserted a claim for infringement of the '951 patent. Hetero denies the remaining allegations of Paragraph 163 of the Complaint.

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

**ANSWER:** Denied.

#### **Count XI—Infringement of the '345 Patent**

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Paragraph 166 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '345 patent is entitled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate," that a purported copy is attached as Exhibit F, and that the issue date on the cover of the '345 patent is June 30, 2020.

Hetero denies the remaining allegations of Paragraph 166 of the Complaint.

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

**ANSWER:** Paragraph 167 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '345 patent identifies S Peng Li and Robert Davis as the inventors. Hetero denies the remaining allegations of Paragraph 167 of the Complaint.

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

**ANSWER:** Paragraph 168 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '345 patent identifies Plaintiff as the assignee. Hetero denies the remaining allegations of Paragraph 168 of the Complaint.

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

**ANSWER:** Paragraph 169 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that electronic FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the electronic "Orange Book," identifies the '345 patent in connection with the New Drug Application ("NDA") for Caplyta®. Hetero denies the remaining allegations of Paragraph 169 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 170 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 171 of the Complaint.

172. According to Hetero's Notice Letter, Hetero's ANDA Product contains lumateperone.

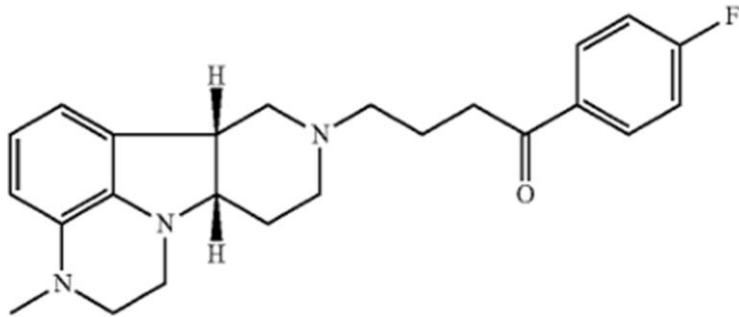
**ANSWER:** Admitted.

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

**ANSWER:** Denied.

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

A pharmaceutical capsule for oral administration, comprising lumateperone:



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

wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium,

0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule.

**ANSWER:** Hetero admits that the '345 patent speaks for itself. Hetero denies the remaining allegations in Paragraph 174 of the Complaint.

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

**ANSWER:** Paragraph 175 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that its proposed label speaks for itself. Hetero denies the remaining allegations in Paragraph 175 of the Complaint.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

expiration of the '345 patent.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

189. 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 Hetero on the other regarding Hetero's infringement, active inducement of infringement, contribution to the infringement by others of the '345 patent, and/or the validity of the '345 patent.

**ANSWER:** Paragraph 189 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that an actual controversy exists because Plaintiff has asserted a claim for infringement of the '345 patent. Hetero denies the remaining allegations of Paragraph 189 of the Complaint.

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

**ANSWER:** Denied.

### **Count XIII—Infringement of the '084 Patent**

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Paragraph 192 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '084 patent is entitled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate," that a purported copy is attached as Exhibit G, and that the issue date on the cover of the '084 patent is July 6, 2021. Hetero

denies the remaining allegations of Paragraph 192 of the Complaint.

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

**ANSWER:** Paragraph 193 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '084 patent identifies S Peng Li and Robert Davis as the inventors. Hetero denies the remaining allegations of Paragraph 193 of the Complaint.

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

**ANSWER:** Paragraph 194 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '084 patent identifies Plaintiff as the assignee. Hetero denies the remaining allegations of Paragraph 194 of the Complaint.

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

**ANSWER:** Paragraph 195 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that electronic FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the electronic "Orange Book," identifies the '084 patent in connection with the New Drug Application ("NDA") for Caplyta®. Hetero denies the remaining allegations of Paragraph 195 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 196 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 197 of the Complaint.

198. According to Hetero's Notice Letter, Hetero's ANDA Product contains lumateperone.

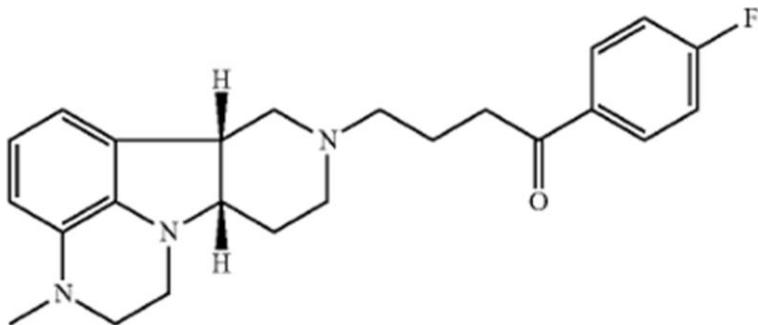
**ANSWER:** Admitted.

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

**ANSWER:** Denied.

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

A pharmaceutical capsule for oral administration, comprising lumateperone:



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

wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium,

0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule,

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

**ANSWER:** Hetero admits that the '084 patent speaks for itself. Hetero denies the remaining allegations in Paragraph 200 of the Complaint.

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

**ANSWER:** Paragraph 201 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that its proposed label speaks for itself. Hetero denies the remaining allegations in Paragraph 201 of the Complaint.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Paragraph 215 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that an actual controversy exists because Plaintiff has asserted a claim for infringement of the '084 patent. Hetero denies the remaining allegations of Paragraph 215 of the Complaint.

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

**ANSWER:** Denied.

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

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

218. The '842 patent, entitled "Pharmaceutical Capsule Compositions Comprising

Lumateperone Mono-Tosylate” (attached as Exhibit H), was duly and legally issued on July 4, 2023.

**ANSWER:** Paragraph 218 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the ’842 patent is entitled “Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate,” that a purported copy is attached as Exhibit H, and that the issue date on the cover of the ’842 patent is July 4, 2023. Hetero denies the remaining allegations of Paragraph 218 of the Complaint.

219. The inventors named on the ’842 patent are Peng Li and Robert Davis.

**ANSWER:** Paragraph 219 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the ’842 patent identifies Peng Li and Robert Davis as the inventors. Hetero denies the remaining allegations of Paragraph 219 of the Complaint.

220. Plaintiff is the owner and assignee of the ’842 patent.

**ANSWER:** Paragraph 220 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the ’842 patent identifies Plaintiff as the assignee. Hetero denies the remaining allegations of Paragraph 220 of the Complaint.

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

**ANSWER:** Paragraph 221 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that electronic FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations,” otherwise known as the electronic “Orange Book,” identifies the ’842 patent in connection with the New Drug Application (“NDA”) for Caplyta®. Hetero denies the remaining allegations of Paragraph 221 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 222 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 223 of the Complaint.

224. According to Hetero's Notice Letter, Hetero's ANDA Product contains lumateperone.

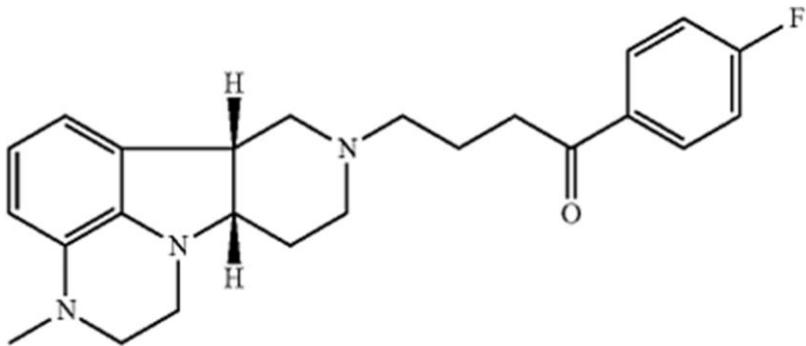
**ANSWER:** Admitted.

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

**ANSWER:** Denied.

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

A pharmaceutical capsule for oral administration, comprising lumateperone:



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

wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium,

0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule, and

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

**ANSWER:** Hetero admits that the '842 patent speaks for itself. Hetero denies the remaining allegations in Paragraph 226 of the Complaint.

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

**ANSWER:** Paragraph 227 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that its proposed label speaks for itself. Hetero denies the remaining allegations in Paragraph 227 of the Complaint.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

infringement by others of the '842 patent.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Paragraph 241 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that an actual controversy exists because Plaintiff has asserted a claim for infringement of the '842 patent. Hetero denies the remaining allegations of Paragraph 241 of the Complaint.

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

product that is covered by or whose use is covered by the '842 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '842 patent, and that the claims of the '842 patent are not invalid.

**ANSWER:** Denied.

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

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Paragraph 244 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '348 patent is entitled "Methods of Treatment Using Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate," that a purported copy is attached as Exhibit I, and that the issue date on the cover of the '348 patent is November 7, 2023. Hetero denies the remaining allegations of Paragraph 244 of the Complaint.

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

**ANSWER:** Paragraph 245 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '348 patent identifies S Peng Li and Robert Davis as the inventors. Hetero denies the remaining allegations of Paragraph 245 of the Complaint.

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

**ANSWER:** Paragraph 246 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '348 patent identifies Plaintiff as the

assignee. Hetero denies the remaining allegations of Paragraph 246 of the Complaint.

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

**ANSWER:** Paragraph 247 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that electronic FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations,” otherwise known as the electronic “Orange Book,” identifies the '348 patent in connection with the New Drug Application (“NDA”) for Caplyta®. Hetero denies the remaining allegations of Paragraph 247 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 248 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 249 of the Complaint.

250. According to Hetero’s Notice Letter, Hetero’s ANDA Product contains lumateperone.

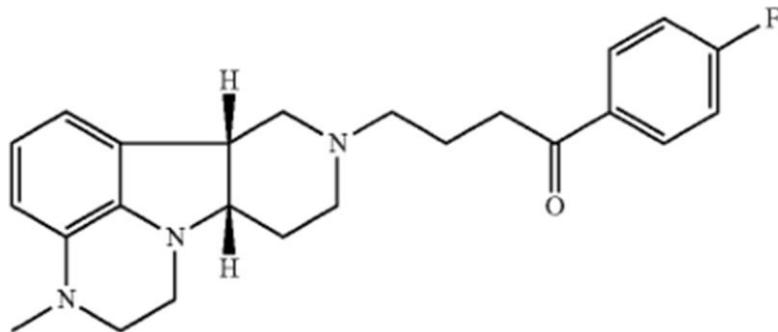
**ANSWER:** Admitted.

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

**ANSWER:** Denied.

252. 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<sub>2A</sub> receptor, serotonin transporter (SERT), and/or dopamine D<sub>1/D<sub>2</sub></sub> receptor signaling pathways, comprising administering to a patient in need thereof a pharmaceutical capsule for oral administration, comprising lumateperone:



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

wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, 60 to 90% by weight of mannitol, 0.5 to 10% by weight of croscarmellose sodium,

0.1 to 1% by weight of talc, and 0.1 to 3% by weight of magnesium stearate, filled into a gelatin capsule,

wherein the capsule comprises the lumateperone mono-tosylate in an amount

equivalent to 0.01 to 30 mg or 35 to 45 mg of lumateperone free base.

**ANSWER:** Hetero admits that the '348 patent speaks for itself. Hetero denies the remaining allegations in Paragraph 252 of the Complaint.

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

**ANSWER:** Paragraph 253 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that its proposed label speaks for itself. Hetero denies the remaining allegations in Paragraph 253 of the Complaint.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

expiration of the '348 patent.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Paragraph 267 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that an actual controversy exists because Plaintiff has asserted a claim for infringement of the '348 patent. Hetero denies the remaining allegations of Paragraph 267 of the Complaint.

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

**ANSWER:** Denied.

#### **Count XIX—Infringement of the '419 Patent**

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

270. 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 J), was duly and legally issued on September 12, 2023.

**ANSWER:** Paragraph 270 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the '419 patent is 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” that a purported copy is attached as Exhibit J, and that the issue date on the cover of the ’419 patent is September 12, 2023. Hetero denies the remaining allegations of Paragraph 270 of the Complaint.

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

**ANSWER:** Paragraph 271 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the ’419 patent identifies S Peng Li, Robert E. Davis, and Kimberly Vanover as the inventors. Hetero denies the remaining allegations of Paragraph 271 of the Complaint.

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

**ANSWER:** Paragraph 272 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the ’419 patent identifies Plaintiff as the assignee. Hetero denies the remaining allegations of Paragraph 272 of the Complaint.

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

**ANSWER:** Paragraph 273 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that electronic FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations,” otherwise known as the electronic “Orange Book,” identifies the ’419 patent in connection with the New Drug Application (“NDA”) for Caplyta®. Hetero denies the remaining allegations of Paragraph 273 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 274 of the Complaint.

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

**ANSWER:** Hetero admits that its Notice Letter speaks for itself. Hetero denies the remaining allegations of Paragraph 275 of the Complaint.

276. According to Hetero's Notice Letter, Hetero's ANDA Product contains lumateperone.

**ANSWER:** Admitted.

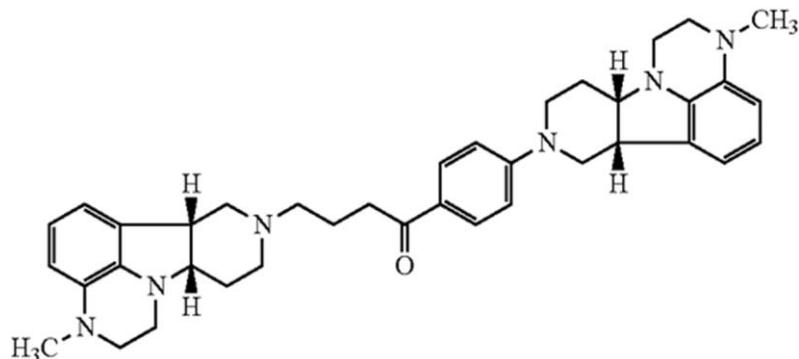
277. Upon information and belief, Hetero's ANDA Product and the use of Hetero's ANDA Product are covered by one or more claims of the '419 patent, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

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

A compound of Formula I:

Formula I



in free base or pharmaceutically acceptable salt form.

**ANSWER:** Hetero admits that the '419 patent speaks for itself. Hetero denies the remaining allegations in Paragraph 278 of the Complaint.

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

**ANSWER:** Paragraph 279 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that its proposed label speaks for itself. Hetero denies the remaining allegations in Paragraph 279 of the Complaint.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

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

**ANSWER:** Hetero incorporates its answers to the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Paragraph 293 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that an actual controversy exists because Plaintiff has asserted a claim for infringement of the '419 patent. Hetero denies the remaining allegations of Paragraph 293 of the Complaint.

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

**ANSWER:** Denied.

\* \* \*

Hetero denies all allegations not expressly admitted herein. Hetero further denies that Plaintiff is entitled to any of the relief requested, and requests that the Complaint be dismissed with prejudice and that Hetero be awarded its fees and costs under 35 U.S.C. § 285 for defending this suit.

**HETERO'S DEFENSES**

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

**FIRST SEPARATE DEFENSE**  
**(INVALIDITY OF THE '077 PATENT)**

One or more claims of the '077 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**SECOND SEPARATE DEFENSE**  
**(NO DIRECT INFRINGEMENT OF THE '077 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '077 Patent.

**THIRD SEPARATE DEFENSE**  
**(NO INDIRECT INFRINGEMENT OF THE '077 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '077 Patent.

**FOURTH SEPARATE DEFENSE**  
**(INVALIDITY OF THE '227 PATENT)**

One or more claims of the '227 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**FIFTH SEPARATE DEFENSE**  
**(NO DIRECT INFRINGEMENT OF THE '227 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '227 Patent.

**SIXTH SEPARATE DEFENSE**  
**(NO INDIRECT INFRINGEMENT OF THE '227 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '227 Patent.

**SEVENTH SEPARATE DEFENSE**  
**(INVALIDITY OF THE '345 PATENT)**

One or more claims of the '345 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**EIGHTH SEPARATE DEFENSE**  
**(NO DIRECT INFRINGEMENT OF THE '345 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '345 Patent.

**NINTH SEPARATE DEFENSE**  
**(NO INDIRECT INFRINGEMENT OF THE '345 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '345 Patent.

**TENTH SEPARATE DEFENSE**  
**(INVALIDITY OF THE '009 PATENT)**

One or more claims of the '009 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**ELEVENTH SEPARATE DEFENSE**  
**(NO DIRECT INFRINGEMENT OF THE '009 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '009 Patent.

**TWELFTH SEPARATE DEFENSE**  
**(NO INDIRECT INFRINGEMENT OF THE '009 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '009 Patent.

**THIRTEENTH SEPARATE DEFENSE**  
**(INVALIDITY OF THE '951 PATENT)**

One or more claims of the '951 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**FOURTEENTH SEPARATE DEFENSE**  
**(NO DIRECT INFRINGEMENT OF THE '951 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '951 Patent.

**FIFTEENTH SEPARATE DEFENSE**  
**(NO INDIRECT INFRINGEMENT OF THE '951 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '951 Patent.

**SIXTEENTH SEPARATE DEFENSE**  
**(INVALIDITY OF THE '084 PATENT)**

One or more claims of the '084 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**SEVENTEENTH SEPARATE DEFENSE**  
**(NO DIRECT INFRINGEMENT OF THE '084 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '084 Patent.

**EIGHTEENTH SEPARATE DEFENSE**  
**(NO INDIRECT INFRINGEMENT OF THE '084 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '084 Patent.

**NINETEENTH SEPARATE DEFENSE**  
**(INVALIDITY OF THE '842 PATENT)**

One or more claims of the '842 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**TWENTIETH SEPARATE DEFENSE**  
**(NO DIRECT INFRINGEMENT OF THE '842 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '842 Patent.

**TWENTY-FIRST SEPARATE DEFENSE**  
**(NO INDIRECT INFRINGEMENT OF THE '842 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '842 Patent.

**TWENTY-SECOND SEPARATE DEFENSE**  
**(INVALIDITY OF THE '419 PATENT)**

One or more claims of the '419 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**TWENTY-THIRD SEPARATE DEFENSE**  
**(NO DIRECT INFRINGEMENT OF THE '419 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '419 Patent.

**TWENTY-FOURTH SEPARATE DEFENSE**  
**(NO INDIRECT INFRINGEMENT OF THE '419 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '419 Patent.

**TWENTY-FIFTH SEPARATE DEFENSE**  
**(INVALIDITY OF THE '348 PATENT)**

One or more claims of the '348 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**TWENTY-SIXTH SEPARATE DEFENSE**  
**(NO DIRECT INFRINGEMENT OF THE '348 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '348 Patent.

**TWENTY-SEVENTH SEPARATE DEFENSE**  
**(NO INDIRECT INFRINGEMENT OF THE '348 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '348 Patent.

**TWENTY-EIGHTH SEPARATE DEFENSE**  
**(INVALIDITY OF THE RE '839 PATENT)**

One or more claims of the RE '839 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**TWENTY-NINTH SEPARATE DEFENSE**  
**(NO DIRECT INFRINGEMENT OF THE RE '839 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the RE '839 Patent.

**THIRTIETH SEPARATE DEFENSE**  
**(NO INDIRECT INFRINGEMENT OF THE RE '839 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 219142 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the RE '839 Patent.

**THIRTY-FIRST SEPARATE DEFENSE**  
**(FAILURE TO STATE A CLAIM)**

Plaintiff's Complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

**THIRTY-SECOND SEPARATE DEFENSE**  
**(LACK OF SUBJECT MATTER JURISDICTION)**

Plaintiff's Complaint lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), and/or (c).

**THIRTY-THIRD SEPARATE DEFENSE**  
**(PROSECUTION HISTORY ESTOPPEL)**

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the '077, '227, '345, '009, '951, '084, '842, '419, '348, and RE '839 patents, Plaintiff is estopped from maintaining that any valid or enforceable claim of the '077, '227, '345, '009, '951, '084, '842, '419, '348, and RE '839 patents is infringed by the product that is the subject of ANDA No. 219142.

**RESERVATION OF ADDITIONAL SEPARATE DEFENSES**

Hetero reserves the right to plead additional separate defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

## **COUNTERCLAIMS**

For its counterclaims against Counterclaim-Defendant Intra-Cellular Therapies, Inc. (“ITCI” or “Counterclaim-Defendant”), Counterclaim-Plaintiff Hetero USA, Inc. and Hetero Labs Ltd. (collectively, “Hetero” or “Counterclaim-Plaintiffs”), state as follows:

### **THE PARTIES**

1. On information and belief, 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.

2. Counterclaim-Plaintiff Hetero Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad - 500018, Telangana, India.

3. Counterclaim-Plaintiff Hetero USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

### **NATURE OF THE ACTION**

4. Hetero seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, that United States Patent Nos. 8,648,077 (“the ’077 patent”), 9,956,227 (“the ’227 patent”), 10,695,345 (“the ’345 patent”), 10,960,009 (“the ’009 patent”), 11,026,951 (“the ’951 patent”), 11,052,084 (“the ’084 patent”), 11,690,842 (“the ’842 patent”), 11,753,419 (“the ’419 patent”), 11,806,348 (“the ’348 patent”), and RE48,839 (“the RE ’839 patent”) (collectively, the “Patents-In-Suit”) are invalid and/or not infringed.

## **JURISDICTION AND VENUE**

5. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over ITCI because, among other reasons, ITCI subjected itself to the jurisdiction of this Court by filing its complaint here.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b), and by Plaintiff's choice of forum.

8. There is an actual and justiciable controversy between the parties as to the infringement and invalidity of the Patents-in-Suit.

## **BACKGROUND**

### **A. FDA Approval of New Brand Name Drugs**

9. The Federal Food, Drug, and Cosmetic Act (“FFDCA”), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration (“FDA”) follows when considering whether to approve the marketing of both brand-name and generic drugs.

10. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application (“NDA”) for consideration by the FDA. *See* 21 U.S.C. § 355.

11. An NDA must include, among other things, the number of any patent that allegedly claims the “drug” or a “method of using [the] drug” for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b)(1), (c)(2).

12. Upon approval of the NDA, the FDA publishes patent information for the approved drug in “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the “Orange Book.” 21 C.F.R. § 314.53(e).

13. FDA's duties with respect to the Orange Book are purely ministerial. If the NDA holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)-(f). FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or “reference listed drug”), but instead relies on the NDA holder to properly list the patents.

#### **B. FDA Approval of New Generic Drugs**

14. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

15. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application (“ANDA”).

16. Among other things, an ANDA must also contain a “certification” to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

17. A “paragraph IV” certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

18. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of each of its paragraph IV certifications. *See* 21

U.S.C. § 355(j)(2)(B).

19. Upon receiving notice of the paragraph IV certifications, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

20. Patent holders have a significant strategic incentive to file suit within 45 days of receiving notice of the paragraph IV certifications because doing so, regardless of merit, prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions requiring court actions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

21. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the proposed product in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id.* If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

### C. Hetero's ANDA and Plaintiff's Complaint

22. Hetero submitted Abbreviated New Drug Application ("ANDA") No. 219142 ("Hetero's ANDA") to obtain FDA approval to engage in the commercial manufacture, use, and sale of generic lumateperone capsules, 10.5 mg, 21 mg, and 42 mg ("Hetero's ANDA Product").

23. On information and belief, ITCI holds approved New Drug Application ("NDA") No. 209500 for Caplyta® under Section 505(b) of the Federal Food Drug and Cosmetic Act ("FFDCA").

24. Hetero's ANDA shows that Hetero's ANDA Product are bioequivalent to the products that are the subject of NDA No. 209500.

25. On information and belief, ITCI caused the Patents-in-Suit to be listed in the publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly called the “Orange Book,” as patents that purportedly claim the drug listed in, and/or purportedly claim a method of using the drug for which ITCI submitted, NDA No. 209500.

26. The RE '839 patent is entitled “Methods and Compositions for Sleep Disorders and Other Disorders”; the issue date identified on the cover of the RE '839 patent is December 7, 2021; and ITCI is identified as the assignee of the RE '839 patent.

27. The '077 patent is entitled “4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1Hpyrido[3',4':4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone Toluenesulfonic Acid Addition Salt and Salt Crystals”; the issue date identified on the cover of the '077 patent is February 11, 2014; and ITCI is identified as the assignee of the '077 patent.

28. The '227 patent is entitled “Method for the Treatment of Residual Symptoms of Schizophrenia”; the issue date identified on the cover of the '227 patent is May 1, 2018; and ITCI is identified as the assignee of the '227 patent.

29. The '009 patent is entitled “Methods of Treating Schizophrenia and Depression”; the issue date identified on the cover of the '009 patent is March 30, 2021; and ITCI is identified as the assignee of the '009 patent.

30. The '951 patent is entitled “Methods of Treating Bipolar Disorder”; the issue date identified on the cover of the '951 patent is June 8, 2021; and ITCI is identified as the assignee of the '951 patent.

31. The '345 patent is entitled “Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate”; the issue date identified on the cover of the '345 patent is June 30, 2020; and ITCI is identified as the assignee of the '345 patent.

32. The '084 patent is entitled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate"; the issue date identified on the cover of the '084 patent is July 6, 2021; and ITCI is identified as the assignee of the '084 patent.

33. The '842 patent is entitled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate"; the issue date identified on the cover of the '842 patent is July 4, 2023; and ITCI is identified as the assignee of the '842 patent.

34. The '348 patent is entitled "Methods of Treatment Using Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate"; the issue date identified on the cover of the '348 patent is November 7, 2023; and ITCI is identified as the assignee of the '348 patent.

35. The '419 patent is entitled "4-((6br,10as)-3-methyl-2,3,6b,9,10,10a-hexahydro-1hpyrido[3',4':4,5]pyrrolo[1,2,3-de]quinoxalin-8(7h)-yl)-1-(4-((6br,10as)-3-methyl 2,3,6b,9,10,10a-hexahydro-1h-pyrido[3'4':4,5]pyrrolo[1,2,3-de]quinoxalin-8(7h)-yl)phenyl)butan-1-one for Treating Conditions of the Central Nervous System and Cardiac Disorders"; the issue date identified on the cover of the '419 patent is September 12, 2023; and ITCI is identified as the assignee of the '419 patent.

36. Hetero's ANDA contains "Paragraph IV" certifications under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Hetero's ANDA Product.

37. On February 20, 2024, Hetero sent Plaintiff's written notice of Hetero's Paragraph IV Certifications ("Hetero's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Hetero's Notice Letter asserted that the claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by Hetero's ANDA or the products or activities described therein.

38. Hetero's Notice Letter included a detailed statement of the legal and factual basis for the Paragraph IV certifications included in Hetero's ANDA pursuant to 21 U.S.C.

§ 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

39. On March 28, 2024, Plaintiff filed the present lawsuit alleging infringement of the Patents-in-Suit. There has been and now is an actual and justiciable controversy between Hetero and Plaintiff as to whether Hetero's ANDA Product infringe, induce infringement, or contribute to the infringement of any valid and enforceable claim of the Patents-in-Suit.

**COUNT I: DECLARATORY JUDGMENT OF  
NON-INFRINGEMENT OF THE '077 PATENT**

40. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

41. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '077 patent.

42. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '077 patent is not infringed by Hetero's ANDA or the products or activities described therein.

43. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '077 patent and is not liable for such infringement.

**COUNT II: DECLARATORY JUDGMENT OF  
INVALIDITY OF THE '077 PATENT**

44. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

45. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Hetero regarding whether the claims of the '077 patent are invalid.

46. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '077 patent are invalid.

47. Hetero is entitled to a declaration that all claims of the '077 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

**COUNT III: DECLARATORY JUDGMENT OF  
NON-INFRINGEMENT OF THE '227 PATENT**

48. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

49. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '227 patent.

50. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '227 patent is not infringed by Hetero's ANDA or the products or activities described therein.

51. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '227 patent and is not liable for such infringement.

**COUNT IV: DECLARATORY JUDGMENT OF  
INVALIDITY OF THE '227 PATENT**

52. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

53. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Hetero regarding whether the claims of the '227 patent are invalid.

54. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '227 patent are invalid.

55. Hetero is entitled to a declaration that all claims of the '227 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

**COUNT V: DECLARATORY JUDGMENT OF  
NON-INFRINGEMENT OF THE '345 PATENT**

56. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

57. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '345 patent.

58. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '345 patent is not infringed by Hetero's ANDA or the products or activities described therein.

59. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '345 patent and is not liable for such infringement.

**COUNT VI: DECLARATORY JUDGMENT OF  
INVALIDITY OF THE '345 PATENT**

60. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

61. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Hetero regarding whether the claims of the '345 patent are invalid.

62. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '345 patent are invalid.

63. Hetero is entitled to a declaration that all claims of the '345 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

**COUNT VII: DECLARATORY JUDGMENT OF  
NON-INFRINGEMENT OF THE '009 PATENT**

64. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

65. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '009 patent.

66. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '009 patent is not infringed by Hetero's ANDA or the products or activities described therein.

67. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '009 patent and is not liable for such infringement.

**COUNT VIII: DECLARATORY JUDGMENT OF  
INVALIDITY OF THE '009 PATENT**

68. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

69. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Hetero regarding whether the claims of the '009 patent are invalid.

70. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '009 patent are invalid.

71. Hetero is entitled to a declaration that all claims of the '009 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

**COUNT IX: DECLARATORY JUDGMENT OF  
NON-INFRINGEMENT OF THE '951 PATENT**

72. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

73. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '951 patent.

74. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '951 patent is not infringed by Hetero's ANDA or the products or activities described therein.

75. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '951 patent and is not liable for such infringement.

**COUNT X: DECLARATORY JUDGMENT OF  
INVALIDITY OF THE '951 PATENT**

76. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

77. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Hetero regarding whether the claims of the '951 patent are invalid.

78. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '951 patent are invalid.

79. Hetero is entitled to a declaration that all claims of the '951 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

**COUNT XI: DECLARATORY JUDGMENT OF  
NON-INFRINGEMENT OF THE '084 PATENT**

80. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

81. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '084 patent.

82. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '084 patent is not infringed by Hetero's ANDA or the products or activities described therein.

83. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '084 patent and is not liable for such infringement.

**COUNT XII: DECLARATORY JUDGMENT OF  
INVALIDITY OF THE '084 PATENT**

84. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

85. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Hetero regarding whether the claims of the '084 patent are invalid.

86. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '084 patent are invalid.

87. Hetero is entitled to a declaration that all claims of the '084 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

**COUNT XIII: DECLARATORY JUDGMENT OF  
NON-INFRINGEMENT OF THE '842 PATENT**

88. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

89. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '842 patent.

90. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '842 patent is not infringed by Hetero's ANDA or the products or activities described therein.

91. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '842 patent and is not liable for such infringement.

**COUNT XIV: DECLARATORY JUDGMENT OF  
INVALIDITY OF THE '842 PATENT**

92. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

93. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Hetero regarding whether the claims of the '842 patent are invalid.

94. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '842 patent are invalid.

95. Hetero is entitled to a declaration that all claims of the '842 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

**COUNT XV: DECLARATORY JUDGMENT OF  
NON-INFRINGEMENT OF THE '419 PATENT**

96. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

97. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '419 patent.

98. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '419 patent is not infringed by Hetero's ANDA or the products or activities described therein.

99. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '419 patent and is not liable for such infringement.

**COUNT XVI: DECLARATORY JUDGMENT OF  
INVALIDITY OF THE '419 PATENT**

100. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

101. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Hetero regarding whether the claims of the '419 patent are invalid.

102. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '419 patent are invalid.

103. Hetero is entitled to a declaration that all claims of the '419 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

**COUNT XVII: DECLARATORY JUDGMENT OF  
NON-INFRINGEMENT OF THE '348 PATENT**

104. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

105. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '348 patent.

106. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '348 patent is not infringed by Hetero's ANDA or the products or activities described therein.

107. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '348 patent and is not liable for such infringement.

**COUNT XVIII: DECLARATORY JUDGMENT OF  
INVALIDITY OF THE '348 PATENT**

108. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

109. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Hetero regarding whether the claims of the '348 patent are invalid.

110. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '348 patent are invalid.

111. Hetero is entitled to a declaration that all claims of the '348 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

**COUNT XIX: DECLARATORY JUDGMENT OF  
NON-INFRINGEMENT OF THE RE '839 PATENT**

112. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

113. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the RE '839 patent.

114. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the RE '839 patent is not infringed by Hetero's ANDA or the products or activities described therein.

115. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the RE '839 patent and is not liable for such infringement.

**COUNT XX: DECLARATORY JUDGMENT OF  
INVALIDITY OF THE RE '839 PATENT**

116. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

117. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Hetero regarding whether the claims of the RE '839 patent are invalid.

118. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the RE '839 patent are invalid.

119. Hetero is entitled to a declaration that all claims of the RE '839 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

**PRAAYER FOR RELIEF**

WHEREFORE, Hetero respectfully requests that this Court enter a judgment in its favor and against Plaintiff as follows:

- (a) Dismissing the Complaint with prejudice and entering judgment for Hetero;
- (b) Declaring that no valid claim of the Patents-in-Suit would be infringed by the manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Products pursuant to ANDA No. 219142;
- (c) Declaring that the claims of the Patents-in-Suit are invalid;
- (d) Entering judgment for Hetero on its affirmative defenses and any and all additional defenses and counterclaims that discovery may reveal;
- (e) Enjoining Counterclaim-Defendant, its officers, agents, servants, employees, attorneys and any person who acts in concert or participation with Counterclaim-Defendant from threatening to assert or otherwise attempting to enforce the Patents-in-Suit against Hetero, its customers, suppliers, or anyone in privity with Hetero;
- (f) Declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding Hetero its reasonable attorneys' fees and costs incurred in this action;
- (g) Awarding Hetero its costs and expenses incurred in this action; and
- (h) Awarding Hetero such other and further relief as this Court may deem proper.

Dated: June 4, 2024

By: /s/ Rebekah R. Conroy

Rebekah R. Conroy  
**STONE CONROY LLC**  
25A Hanover Road, Suite 301  
Florham Park, New Jersey 07932  
[rconroy@stoneconroy.com](mailto:rconroy@stoneconroy.com)  
Tel.: (973) 400-4181

OF COUNSEL:  
Neal Seth (*pro hac vice forthcoming*)  
Wesley E. Weeks (*pro hac vice forthcoming*)  
**WILEY REIN LLP**  
2050 M Street NW  
Washington, DC 20036  
[nseth@wiley.law](mailto:nseth@wiley.law)  
[wweeks@wiley.law](mailto:wweeks@wiley.law)  
Tel.: (202) 719-7000

**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2**

Pursuant to Local Civil Rule 11.2, Defendants Hetero USA, Inc. and Hetero Labs Ltd., by and through their undersigned counsel, hereby certify that the matter in controversy is not subject to any other action pending in any court, or any pending arbitration or administrative proceeding known to Defendant.

Respectfully submitted,

Dated: June 4, 2024

/s/ Rebekah R. Conroy  
Rebekah R. Conroy  
**STONE CONROY LLC**  
25A Hanover Road, Suite 301  
Florham Park, New Jersey 07932  
[rconroy@stoneconroy.com](mailto:rconroy@stoneconroy.com)  
Tel.: (973) 400-4181

*Counsel for Defendants Hetero USA, Inc.,  
Hetero Labs Ltd. Unit-V, and Hetero Labs Ltd.,*

**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1**

Pursuant to Local Civil Rule 201.1, Defendants Hetero USA, Inc. and Hetero Labs Ltd., by and through their undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Respectfully submitted,

Dated: June 4, 2024

/s/ Rebekah R. Conroy  
Rebekah R. Conroy  
**STONE CONROY LLC**  
25A Hanover Road, Suite 301  
Florham Park, New Jersey 07932  
[rconroy@stoneconroy.com](mailto:rconroy@stoneconroy.com)  
Tel.: (973) 400-4181

*Counsel for Defendants Hetero USA, Inc.,  
Hetero Labs Ltd. Unit-V, and Hetero Labs Ltd.,*