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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

INTRA-CELLULAR THERAPIES, INC.,	:	Honorable Michael A. Shipp, U.S.D.J.
Plaintiff.	:	Civil Action No. 24 CV 4314 (MAS)(JBD)
v.	:	
DR. REDDY'S LABORATORIES INC. and DR. REDDY'S LABORATORIES LTD.,	:	**DR. REDDY'S LABORATORIES INC.'S AND DR. REDDY'S LABORATORIES LTD.'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO COMPLAINT FOR PATENT INFRINGEMENT**
Defendants.	:	

Dr. Reddy's Laboratories Inc. ("Dr. Reddy's Inc.") and Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's Ltd.") (collectively, "Defendants" or "DRL"), hereby provide their answers and assert the following defenses to the Complaint for Patent Infringement of Intra-Cellular Therapies, Inc. ("Plaintiff," "Intra-Cellular Therapies," or "ITCI"), as follows.

GENERAL DENIAL

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

Nature of the Action

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

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the Complaint purports to state a claim for alleged patent infringement. DRL further admits that Dr. Reddy's Ltd. submitted an Abbreviated New Drug Application ("DRL's ANDA") through its authorized U.S. Agent Dr. Reddy's Inc. to the United States Food and Drug Administration ("FDA") seeking approval for lumateperone capsules, 10.5 mg, 21 mg and 42 mg ("DRL's ANDA Product") prior to the expiration of U.S. Patent Nos. 8,648,077 ("the '077 patent"), 9,168,258 ("the '258 patent"), 9,199,995 ("the '995 patent"), 9,616,061 ("the '061 patent"), 9,956,227 ("the '227 patent"),

10,117,867 ("the '867 patent"), 10,464,938 ("the '938 patent"), 10,695,345 ("the '345 patent"), 10,960,009 ("the '009 patent"), 11,026,951 ("the '951 patent"), 11,052,084 ("the '084 patent"), 11,690,842 ("the '842 patent"), 11,753,419 ("the '419 patent"), 11,806,348 ("the '348 patent"), RE48,825 ("the RE '825 patent"), and RE48,839 ("the RE '839 patent") (collectively, "Asserted Patents"). DRL denies any and all remaining allegations of Paragraph 1.

2. DRL notified Plaintiff by letter dated February 16, 2024 ("DRL's Notice Letter") that it had submitted to the FDA ANDA No. 219229 ("DRL'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, ("DRL's ANDA Product") prior to the expiration of the Patents-in-Suit.

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

The Parties

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

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

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

ANSWER: Paragraph 4 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL lacks knowledge or information sufficient to form a

belief as to the truth of the allegations of Paragraph 4, and therefore denies any and all allegations of Paragraph 4.

5. Upon information and belief, Defendant Dr. Reddy's Laboratories Inc. is a corporation organized and existing under the laws of New Jersey and having a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that Dr. Reddy's Inc. is an entity organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540. DRL denies any and all remaining allegations of Paragraph 5.

6. Upon information and belief, Defendant Dr. Reddy's Laboratories Ltd. is a corporation organized and existing under the laws of the Republic of India and having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana, India, 500034.

ANSWER: Paragraph 6 contains legal conclusions to which no answer is required. To the extent DRL is required to answer, DRL admits that Dr. Reddy's Ltd. is an entity organized and existing under the laws of India, having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, 500034, India, which is in the state of Telangana. DRL denies any and all remaining allegations of Paragraph 6.

7. Upon information and belief, Dr. Reddy's Laboratories Inc. is the U.S. Regulatory Agent for Dr. Reddy's Laboratories Ltd.

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that Dr. Reddy's Inc. is an authorized U.S. Regulatory Agent for Dr. Reddy's Ltd. with respect to DRL's ANDA. DRL denies any and all remaining allegations of Paragraph 7.

8. Upon information and belief, Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc. acted in concert to prepare and submit DRL's ANDA to the FDA. Upon information and belief, Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc. know and intend that upon approval of DRL's ANDA, Dr. Reddy's Laboratories Ltd. will manufacture

DRL's ANDA Product, and Dr. Reddy's Laboratories Inc. will directly or indirectly market, sell, and distribute DRL's ANDA Product throughout the United States, including in New Jersey.

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

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

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

10. Upon information and belief, following any FDA approval of DRL's ANDA, Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc. will act in concert to distribute and sell DRL's ANDA Product throughout the United States, including within New Jersey.

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

Jurisdiction

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

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

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

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that subject matter jurisdiction is proper solely for the claims against Dr. Reddy's Ltd. under 35 U.S.C. § 271(e)(2)(A). DRL denies any and all remaining allegations of Paragraph 12.

13. This Court has personal jurisdiction over each of Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied. Further answering, DRL does not contest personal jurisdiction solely for the limited purposes of this action only.

14. Dr. Reddy's Laboratories Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Dr. Reddy's Laboratories Ltd., itself and through its subsidiary Dr. Reddy's Laboratories 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, Dr. Reddy's Laboratories Ltd., itself and through its subsidiary Dr. Reddy's Laboratories 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, Dr. Reddy's Laboratories Ltd. is subject to personal jurisdiction in New Jersey because, upon information and belief, it controls Dr. Reddy's Laboratories Inc. and therefore the activities of Dr. Reddy's Laboratories Inc. in this jurisdiction are attributed to Dr. Reddy's Laboratories Ltd.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied. Further answering, DRL does not contest personal jurisdiction solely for the limited purposes of this action only.

15. Dr. Reddy's Laboratories 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. Dr. Reddy's Laboratories Inc. is a corporation organized and existing under the laws of the State of New Jersey, has a principal place of business in the State of New Jersey, is qualified to do business in New Jersey, and has appointed a registered agent for service of process in New Jersey. It therefore has consented to general jurisdiction in New Jersey. In addition, upon information and belief, Dr. Reddy's Laboratories 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 15 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied. Further answering, DRL does not contest personal jurisdiction solely for the limited purposes of this action only. DRL denies any and all remaining allegations of Paragraph 15.

16. DRL 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 16 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that Dr. Reddy's Ltd. has previously submitted abbreviated new drug applications ("ANDAs") to FDA for approval of more affordable medicines, that such ANDAs have contained so-called "Paragraph IV Certifications," that DRL has provided the requisite notice of such submissions, and that DRL has been sued for alleged patent infringement. DRL denies any and all remaining allegations of Paragraph 16.

17. Upon information and belief, DRL, with knowledge of the Hatch-Waxman Act process, directed DRL's Notice Letter to Plaintiff. Upon information and belief, DRL 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. DRL has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending DRL's Notice Letter to Plaintiff it would be sued for patent infringement in New Jersey, where Dr. Reddy's Laboratories Inc. is located and incorporated.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL, by DRL's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Plaintiff Intra-Cellular Therapies, Inc. that DRL submitted DRL's ANDA to FDA seeking approval to market DRL's ANDA Product prior to the expiration of the Asserted Patents. DRL denies the remaining allegations of Paragraph 17.

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

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

19. Upon information and belief, DRL derives substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and which are manufactured by DRL and/or Dr. Reddy's Laboratories Inc. or Dr. Reddy's Laboratories Ltd. Upon information and belief, various products for which Dr. Reddy's Laboratories Ltd. or Dr. Reddy's Laboratories Inc. is the named applicant on approved ANDAs are available at retail pharmacies in New Jersey.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied.

Venue

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

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

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

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied. Further answering, DRL does not contest venue solely for the limited purposes of this action only.

22. Venue is proper in this district as to Dr. Reddy's Laboratories Ltd. pursuant to 28 U.S.C. §§ 1391 and/or 1400(b) because, *inter alia*, Dr. Reddy's Laboratories 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 22 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, denied. Further answering, DRL does not contest venue solely for the limited purposes of this action only.

Factual Background

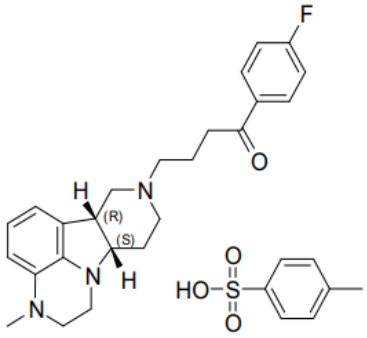
23. Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

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

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

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the CAPLYTA® label (Revised 06/2023) states:

CAPLYTA capsules contains lumateperone, an atypical antipsychotic, present as lumateperone tosylate salt with the chemical name 4-((6b*R*,10a*S*)-3-methyl-2,3,6b,9,10,10*a*-hexahydro-1*H*,7*H*-pyrido[3',4':4,5]pyrrolo[1,2,3-*de*]quinoxalin-8-yl)-1-(4-fluoro-phenyl)-butan-1-one 4-methylbenzenesulfonate. Its molecular formula is $C_{31}H_{36}FN_3O_4S$, and its molecular weight is 565.71 g/mol with the following structure:



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

CAPLYTA is an atypical antipsychotic indicated for the treatment of:

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

DRL denies any and all remaining allegations of Paragraph 24.

25. In DRL's Notice Letter, DRL stated that the subject of DRL's ANDA is lumateperone capsules, 10.5 mg, 21 mg, and 42 mg. In DRL's Notice Letter, DRL stated that DRL's ANDA was submitted under 21 U.S.C. § 355(j)(1) & (2)(a) [*sic*] and contended that DRL's

ANDA contains bioavailability and/or bioequivalence studies for DRL's ANDA Product. Upon information and belief, DRL's ANDA Product is a generic version of CAPLYTA®.

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that Dr. Reddy's Ltd. submitted DRL's ANDA to FDA seeking approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 25.

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

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL has provided written certifications to FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV). DRL further admits that DRL seeks FDA approval of DRL's ANDA prior to the expiration of the Asserted Patents. DRL denies any and all remaining allegations of Paragraph 26.

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

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL seeks FDA approval of DRL's ANDA prior to the expiration of the Asserted Patents. DRL denies any and all remaining allegations of Paragraph 27.

28. Upon information and belief, DRL's ANDA Product is not publicly available, nor is ANDA No. 219229 accessible to the public.

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that FDA has not approved DRL's ANDA.

DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 28, and therefore denies any and all remaining allegations of Paragraph 28.

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

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, pursuant to 21 C.F.R. § 314.95(c)(8), DRL's Notice Letter included an Offer of Confidential Access ("OCA") to portions of DRL's ANDA that would allow Plaintiff to determine whether an action under 21 U.S.C. § 355 should be filed. DRL denies any and all remaining allegations of Paragraph 29.

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

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's OCA fully complied with all statutory and regulatory requirements, and that Plaintiff rejected the reasonable and appropriate terms and restrictions in such OCA. DRL denies any and all remaining allegations of Paragraph 30.

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

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that Plaintiff filed the Complaint on March 28, 2024. DRL denies the remaining allegations of Paragraph 31.

Count I—RE '839 Patent

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

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

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

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the United States Patent and Trademark Office ("USPTO"), the RE '839 patent, titled "METHODS AND COMPOSITIONS FOR SLEEP DISORDERS AND OTHER DISORDERS," issued on or about December 7, 2021. DRL denies that the RE '839 patent was "duly and legally issued," and any suggestion or implication that the RE '839 patent is valid or enforceable. DRL also admits that a purported copy of the RE '839 patent is attached as Exhibit A to the Complaint. DRL denies any and all remaining allegations of Paragraph 33.

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

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the face of the RE '839 patent lists the purported "Inventors" as Sharon Mates, Allen Fienberg, and Lawrence Wennogle. DRL denies any and all remaining allegations of Paragraph 34.

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

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of

the RE '839 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 35, and therefore denies any and all remaining allegations of Paragraph 35.

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

ANSWER: Paragraph 36 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the electronic version of the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") currently identifies the RE '839 patent in connection with NDA No. 209500 for CAPLYTA®. DRL denies any and all remaining allegations of Paragraph 36.

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

ANSWER: DRL admits that DRL, by DRL's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that DRL submitted DRL's ANDA to FDA seeking approval to market DRL's ANDA Product prior to the expiration of the Asserted Patents. DRL denies any and all remaining allegations of Paragraph 37.

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

ANSWER: Paragraph 38 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL has provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting

that, in its opinion and to the best of its knowledge, the claims of the RE '839 patent are invalid and/or will not be infringed by DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 38.

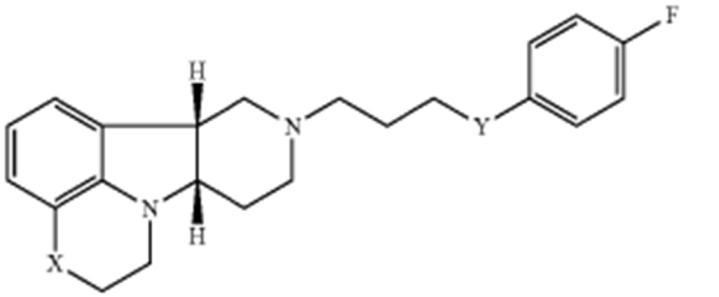
39. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

ANSWER: Paragraph 39 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's Notice Letter states that DRL submitted DRL's ANDA to FDA seeking approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 39.

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

ANSWER: Denied.

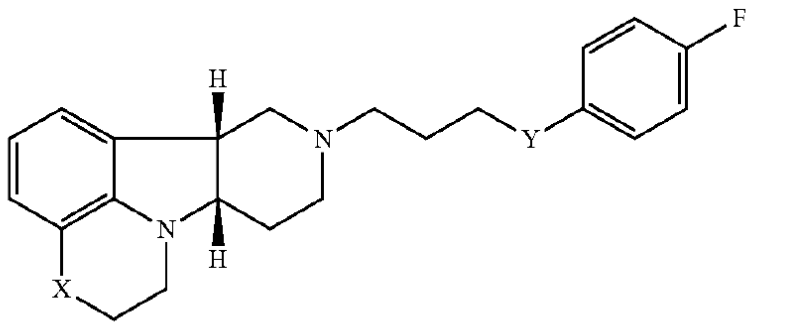
41. As an example, claim 1 of the RE '839 patent recites:

> A method for the treatment of one or more 5-HT_{2A}-related disorders, comprising administering to a patient in need thereof a Compound of Formula I:
>
> Formula I
>
> 
>
>
> wherein X is O, —NH or — N(CH_3); and Y is —O— or —C(O) —, in free or pharmaceutically acceptable salt form, in a dose which selectively blocks the 5-HT_{2A} receptor.

ANSWER: Paragraph 41 contains legal conclusions and allegations to which no answer is required. To the extent that DRL is required to answer, DRL admits that claim 1 of the RE '839 patent reads as follows:

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

Formula I



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

(The RE '839 patent at Claim 1). DRL denies any and all remaining allegations of Paragraph 41.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

51. The foregoing actions by DRL 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.

52. Upon information and belief, DRL 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.

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

ANSWER: Denied.

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

ANSWER: Denied.

Count II—RE '839 Patent

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

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

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

ANSWER: Denied.

57. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL 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—'258 Patent

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

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

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

ANSWER: Paragraph 59 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the '258 patent, titled "METHODS AND COMPOSITIONS FOR SLEEP DISORDERS AND OTHER DISORDERS," issued on or about October 27, 2015. DRL denies that the '258 patent was "duly and legally issued," and any suggestion or implication that the '258 patent is valid or enforceable. DRL also admits that a purported copy of the '258 patent is attached as Exhibit B to the Complaint. DRL denies any and all remaining allegations of Paragraph 59.

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

ANSWER: Paragraph 60 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the face of the '258 patent lists the purported "Inventors" as Sharon Mates, Allen Fienberg and Lawrence P. Wennogle. DRL denies any and all remaining allegations of Paragraph 60.

61. Plaintiff is the owner and assignee of the '258 patent.

ANSWER: Paragraph 61 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '258 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 61, and therefore denies any and all remaining allegations of Paragraph 61.

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

ANSWER: Paragraph 62 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the Orange Book currently identifies

the '258 patent in connection with NDA No. 209500 for CAPLYTA®. DRL denies any and all remaining allegations of Paragraph 62.

63. In DRL's Notice Letter, DRL notified Plaintiff of the submission of DRL'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 DRL's ANDA Product prior to the expiration of the Patents-in-Suit, including the '258 patent.

ANSWER: DRL admits that DRL, by DRL's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that DRL submitted DRL's ANDA to FDA seeking approval to market DRL's ANDA Product prior to the expiration of the Asserted Patents. DRL denies any and all remaining allegations of Paragraph 63.

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

ANSWER: Paragraph 64 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL has provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21f U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '258 patent are invalid and/or will not be infringed by DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 64.

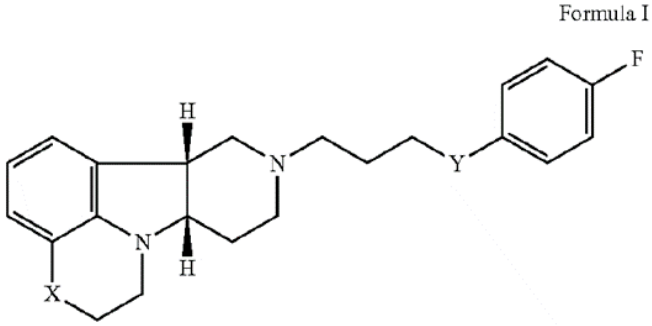
65. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

ANSWER: Paragraph 65 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's Notice Letter states that DRL submitted DRL's ANDA to FDA seeking approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 65.

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

ANSWER: Denied.

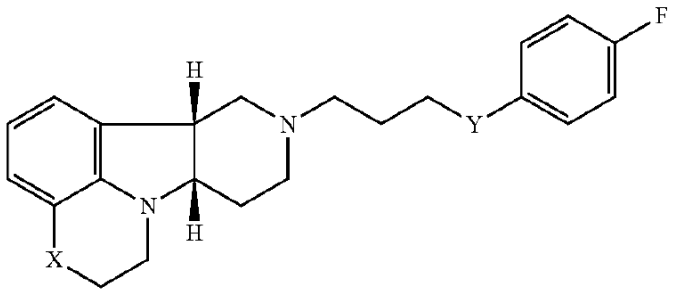
67. As an example, claim 1 of the '258 patent recites:

> A pharmaceutical composition in oral unit dose form comprising an amount of 10 mg or less of a Compound of Formula I:
>
> Formula I
>
> 
>
>
> wherein X is O, —NH or —N(CH_3); and Y is —O— or —C(O) —, in free or pharmaceutically acceptable salt form, in combination or association with a pharmaceutically acceptable diluent or carrier, provided that in the case of a salt, the weight is calculated as the free base, where the amount of the Compound of Formula I:
> a) is sufficient to block the 5-HT_{2A} receptor; and
> b) either does not block, or minimally blocks the dopamine D2 receptor.

ANSWER: Paragraph 67 contains legal conclusions and allegations to which no answer is required. To the extent that DRL is required to answer, DRL admits that claim 1 of the '258 patent reads as follows:

1. A pharmaceutical composition in oral unit dose form comprising an amount of 10 mg or less of a Compound of Formula I:

Formula I



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

a) is sufficient to block the 5-HT_{2A} receptor; and

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

(The '258 patent at Claim 1). DRL denies any and all remaining allegations of Paragraph 67.

68. Upon information and belief, DRL's ANDA Product contains a pharmaceutical composition in oral unit dose form containing an amount of 10 mg or less (calculated as the free base) of a Formula I compound (lumateperone) in pharmaceutically acceptable salt form in combination or association with a pharmaceutically acceptable diluent or carrier and in an amount that is sufficient to block the 5-HT_{2A} receptor and that does not block, or minimally blocks, the dopamine D2 receptor, as recited in claim 1.

ANSWER: Denied.

69. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '258 patent, literally or under the doctrine of equivalents.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

77. The foregoing actions by DRL constitute and/or will constitute infringement of the '258 patent; active inducement of infringement of the '258 patent; and/or contribution to the infringement by others of the '258 patent.

ANSWER: Denied.

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

ANSWER: Denied.

79. Plaintiff will be substantially and irreparably damaged by infringement of the '258 patent.

ANSWER: Denied.

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

ANSWER: Denied.

Count IV—'258 Patent

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

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

82. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the '258 patent, and/or the validity of the '258 patent.

ANSWER: Denied.

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

ANSWER: Denied.

Count V—'061 Patent

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

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

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

ANSWER: Paragraph 85 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the '061 patent, titled "METHODS AND COMPOSITIONS FOR SLEEP DISORDERS AND OTHER DISORDERS," issued on or about April 11, 2017. DRL denies that the '061 patent was "duly and legally issued," and any suggestion or implication that the '061 patent is valid or enforceable. DRL also admits that a purported copy of the '061 patent is attached as Exhibit C to the Complaint. DRL denies any and all remaining allegations of Paragraph 85.

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

ANSWER: Paragraph 86 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the face of the '061 patent lists the purported "Inventors" as Sharon Mates, Allen Fienberg, and Lawrence Wennogle. DRL denies any and all remaining allegations of Paragraph 86.

87. Plaintiff is the owner and assignee of the '061 patent.

ANSWER: Paragraph 87 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '061 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 87, and therefore denies any and all remaining allegations of Paragraph 87.

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

ANSWER: Paragraph 88 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the Orange Book currently identifies the '061 patent in connection with NDA No. 209500 for CAPLYTA®. DRL denies any and all remaining allegations of Paragraph 88.

89. In DRL's Notice Letter, DRL notified Plaintiff of the submission of DRL'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 DRL's ANDA Product prior to the expiration of the Patents-in-Suit, including the '061 patent.

ANSWER: DRL admits that DRL, by DRL's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that DRL submitted DRL's ANDA to FDA seeking approval to market DRL's ANDA Product prior to the expiration of the Asserted Patents. DRL denies any and all remaining allegations of Paragraph 89.

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

ANSWER: Paragraph 90 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL has provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '061 patent are invalid and/or will not be infringed by DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 90.

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

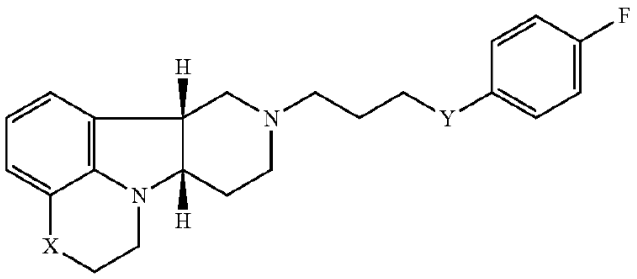
ANSWER: Paragraph 91 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's Notice Letter states that DRL

submitted DRL's ANDA to FDA seeking approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 91.

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

ANSWER: Denied.

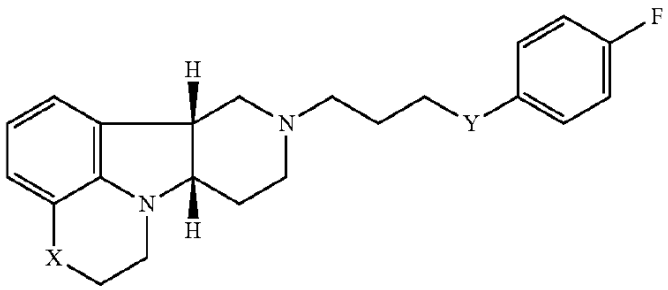
93. As an example, claim 1 of the '061 patent recites:

> A pharmaceutical composition in oral unit dose form comprising an amount of from 0.1-20 mg of a Compound of Formula I:
>
> Formula I
>
> 
>
>
> wherein X is — $N(CH_3)$; and Y is —C(O)—, in free or pharmaceutically acceptable salt form, in combination or association with a pharmaceutically acceptable diluent or carrier, provided that in the case of a salt, the weight is calculated as the free base.

ANSWER: Paragraph 93 contains legal conclusions and allegations to which no answer is required. To the extent that DRL is required to answer, DRL admits that claim 1 of the '061 patent reads as follows:

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

Formula I



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

(The '061 patent at Claim 1). DRL denies any and all remaining allegations of Paragraph 93.

94. Upon information and belief, DRL's ANDA Product contains a pharmaceutical composition in oral unit dose form containing an amount of from 0.1-20 mg (calculated as the free base) of a Formula I compound (lumateperone) in pharmaceutically acceptable salt form in combination or association with a pharmaceutically acceptable diluent or carrier, as recited in claim 1.

ANSWER: Denied.

95. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '061 patent, literally or under the doctrine of equivalents.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

103. The foregoing actions by DRL constitute and/or will constitute infringement of the '061 patent; active inducement of infringement of the '061 patent; and/or contribution to the infringement by others of the '061 patent.

ANSWER: Denied.

104. Upon information and belief, DRL has acted with full knowledge of the '061 patent and without a reasonable basis for believing that it would not be liable for infringement of the '061 patent; active inducement of infringement of the '061 patent; and/or contribution to the infringement by others of the '061 patent.

ANSWER: Denied.

105. Plaintiff will be substantially and irreparably damaged by infringement of the '061 patent

ANSWER: Denied.

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

ANSWER: Denied.

Count VI—'061 Patent

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

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

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

ANSWER: Denied.

109. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the '061 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '061 patent, and that the claims of the '061 patent are not invalid.

ANSWER: Denied.

Count VII—'867 Patent

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

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

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

ANSWER: Paragraph 111 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the '867 patent, titled "METHODS AND COMPOSITIONS FOR SLEEP DISORDERS AND OTHER DISORDERS," issued on or about November 6, 2018. DRL denies that the '867 patent was "duly and legally issued," and any suggestion or implication that the '867 patent is valid or enforceable. DRL also admits that a purported copy of the '867 patent is attached as Exhibit D to the Complaint. DRL denies any and all remaining allegations of Paragraph 111.

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

ANSWER: Paragraph 112 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the face of the '867 patent lists the purported "Inventors" as Sharon Mates, Allen Fienberg and Lawrence P. Wennogle. DRL denies any and all remaining allegations of Paragraph 112.

113. Plaintiff is the owner and assignee of the '867 patent.

ANSWER: Paragraph 113 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '867 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 113, and therefore denies any and all remaining allegations of Paragraph 113.

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

ANSWER: Paragraph 114 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the Orange Book currently identifies

the '867 patent in connection with NDA No. 209500 for CAPLYTA®. DRL denies any and all remaining allegations of Paragraph 114.

115. In DRL's Notice Letter, DRL notified Plaintiff of the submission of DRL'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 DRL's ANDA Product prior to the expiration of the Patents-in-Suit, including the '867 patent.

ANSWER: DRL admits that DRL, by DRL's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that DRL submitted DRL's ANDA to FDA seeking approval to market DRL's ANDA Product prior to the expiration of the Asserted Patents. DRL denies any and all remaining allegations of Paragraph 115.

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

ANSWER: Paragraph 116 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL has provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '867 patent are invalid and/or will not be infringed by DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 116.

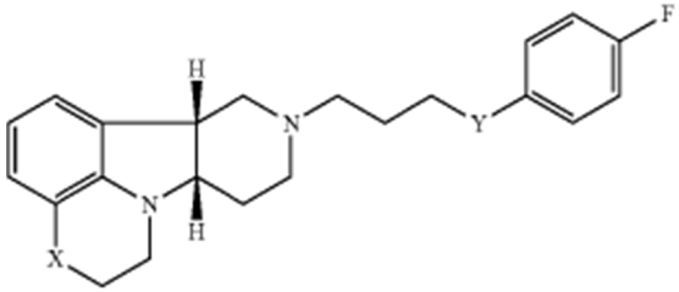
117. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

ANSWER: Paragraph 117 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's Notice Letter states that DRL submitted DRL's ANDA to FDA seeking approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 117.

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

ANSWER: Denied.

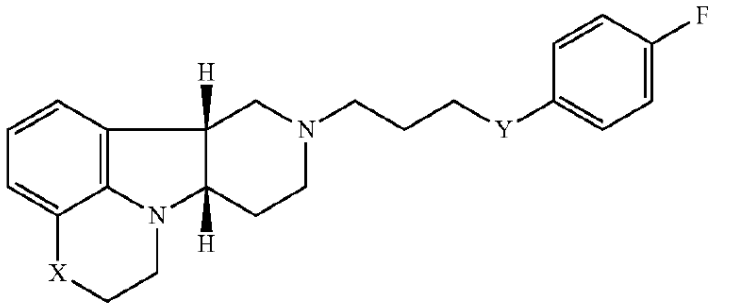
119. As an example, claim 1 of the '867 patent recites:

> A method for the treatment of bipolar depression, comprising administering to a patient in need thereof a Compound of Formula I:
>
> Formula I
>
> 
>
>
> wherein X is O, —NH or — N(CH_3); and Y is —O— or —C(O)—, in free or pharmaceutically acceptable salt form.

ANSWER: Paragraph 119 contains legal conclusions and allegations to which no answer is required. To the extent that DRL is required to answer, DRL admits that claim 1 of the '867 patent reads as follows:

1. A method for the treatment of bipolar depression, comprising administering to a patient in need thereof a Compound of Formula I:

Formula I



wherein X is O, —NH or —N(CH_3); and Y is —O— or —C(O)—, in free or pharmaceutically acceptable salt form.

(The '867 patent at Claim 1). DRL denies any and all remaining allegations of Paragraph 119.

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

ANSWER: Denied.

121. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '867 patent, literally or under the doctrine of equivalents.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

129. The foregoing actions by DRL constitute and/or will constitute infringement of the '867 patent; active inducement of infringement of the '867 patent; and/or contribution to the infringement by others of the '867 patent.

ANSWER: Denied.

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

ANSWER: Denied.

131. Plaintiff will be substantially and irreparably damaged by infringement of the '867 patent.

ANSWER: Denied.

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

ANSWER: Denied.

Count VIII—'867 Patent

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

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

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

ANSWER: Denied.

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

ANSWER: Denied.

Count IX—'077 Patent

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

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

137. The '077 patent, 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" (attached as Exhibit E), was duly and legally issued on February 11, 2014.

ANSWER: Paragraph 137 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the '077 patent, titled "4-((6bR,10aS)-3-Methyl-2,3,6b,9,10,10a-Hexahydro-1H-Pyrido[3',4':4,5]Pyrrolo[1,2,3-De]Quinoxalin-8(7H)-yl)-1-(4-Fluorophenyl)-1-Butanone Toluenesulfonic Acid Addition Salt and Salt Crystals," issued on or about February 11, 2014. DRL denies that the '077 patent was "duly and legally issued," and any suggestion or implication that the '077 patent is valid or enforceable. DRL also admits that a purported copy of the '077 patent is attached as Exhibit E to the Complaint. DRL denies any and all remaining allegations of Paragraph 137.

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

ANSWER: Paragraph 138 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the face of the '077 patent lists the purported "Inventors" as John Tomesch and Lawrence P. Wennogle. DRL denies any and all remaining allegations of Paragraph 138.

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

ANSWER: Paragraph 139 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '077 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 139, and therefore denies any and all remaining allegations of Paragraph 139.

140. 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 140 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the Orange Book currently identifies the '077 patent in connection with NDA No. 209500 for CAPLYTA®. DRL denies any and all remaining allegations of Paragraph 140.

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

ANSWER: DRL admits that DRL, by DRL's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that DRL submitted DRL's ANDA to FDA seeking approval to market DRL's ANDA Product prior to the expiration of the Asserted Patents. DRL denies any and all remaining allegations of Paragraph 141.

142. In DRL's Notice Letter, DRL also notified Plaintiff that, as part of its ANDA, DRL had filed Paragraph IV certifications with respect to the '077 patent. Upon information and belief, DRL 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 DRL's ANDA Product.

ANSWER: Paragraph 142 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL has provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '077 patent are invalid and/or will not be infringed by DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 142.

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

ANSWER: Paragraph 143 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's Notice Letter states that DRL

submitted DRL's ANDA to FDA seeking approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 143.

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

ANSWER: Denied.

145. 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-1Hpyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4- fluorophenyl)-1-butanone, wherein said salt crystal exhibits an Xray 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: Paragraph 145 contains legal conclusions and allegations to which no answer is required. To the extent that DRL is required to answer, DRL admits that claim 1 of the '077 patent reads as follows:

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

(The '077 patent at Claim 1). DRL denies any and all remaining allegations of Paragraph 145.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

155. The foregoing actions by DRL 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.

156. Upon information and belief, DRL 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.

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

ANSWER: Denied.

158. Unless DRL 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 X—'077 Patent

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

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

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

161. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL 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 XI—'995 Patent

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

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

163. The '995 patent, entitled "4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone Toluenesulfonic Acid Addition Salt and Salt Crystals" (attached as Exhibit F), was duly and legally issued on December 1, 2015.

ANSWER: Paragraph 163 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the '995 patent, titled "4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3',4':4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone toluenesulfonic acid addition salt and salt crystals," issued on or about December 1, 2015. DRL denies that the '995 patent was "duly and legally issued," and any suggestion or implication that the '995 patent is valid or enforceable. DRL also admits that a purported copy of the '995 patent is attached as Exhibit F to the Complaint. DRL denies any and all remaining allegations of Paragraph 163.

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

ANSWER: Paragraph 164 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the face of the '995 patent lists the purported "Inventors" as John Tomesch and Lawrence P. Wennogle. DRL denies any and all remaining allegations of Paragraph 164.

165. Plaintiff is the owner and assignee of the '995 patent.

ANSWER: Paragraph 165 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '995 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 165, and therefore denies any and all remaining allegations of Paragraph 165.

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

ANSWER: Paragraph 166 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the Orange Book currently identifies the '995 patent in connection with NDA No. 209500 for CAPLYTA®. DRL denies any and all remaining allegations of Paragraph 166.

167. In DRL's Notice Letter, DRL notified Plaintiff of the submission of DRL'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 DRL's ANDA Product prior to the expiration of the Patents-in-Suit, including the '995 patent.

ANSWER: DRL admits that DRL, by DRL's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that DRL submitted DRL's ANDA to FDA seeking approval to market DRL's ANDA Product prior to the expiration of the Asserted Patents. DRL denies any and all remaining allegations of Paragraph 167.

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

ANSWER: Paragraph 168 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL has provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '995 patent are invalid and/or will not be infringed by DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 168.

169. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

ANSWER: Paragraph 169 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's Notice Letter states that DRL submitted DRL's ANDA to FDA seeking approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 169.

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

ANSWER: Denied.

171. As an example, claim 2 of the '995 patent recites:

> A method for modulating 5-hydroxytryptamine 2A receptor activity in a patient, comprising administering to a patient in need thereof an effective amount of 4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′: 4,5]pyrrolo[1,2,3-de]quinoxalin- 8(7H)-yl)-1-(4-fluorophenyl)-1-butanone toluene sulfonic acid salt crystal, wherein said salt crystal exhibits an X-ray powder diffraction pattern comprising at least two peaks having 2-theta values selected from the group consisting of 5.68°, 12.11°, 16.04°, 17.03°, 18.16°, 19.00°, 21.67°, 22.55°, 23.48° and 24.30°, wherein the X-ray powder diffraction data is collected on a diffractometer operating with a copper anode with a nickel filter.

ANSWER: Paragraph 171 contains legal conclusions and allegations to which no answer is required. To the extent that DRL is required to answer, DRL admits that claim 2 of the '995 patent reads as follows:

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

(The '995 patent at Claim 2). DRL denies any and all remaining allegations of Paragraph 171.

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

ANSWER: Denied.

173. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '995 patent, literally or under the doctrine of equivalents.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

181. The foregoing actions by DRL constitute and/or will constitute infringement of the '995 patent; active inducement of infringement of the '995 patent; and/or contribution to the infringement by others of the '995 patent.

ANSWER: Denied.

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

ANSWER: Denied.

183. Plaintiff will be substantially and irreparably damaged by infringement of the '995 patent.

ANSWER: Denied.

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

ANSWER: Denied.

Count XII—'995 Patent

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

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

186. 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 DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the '995 patent, and/or the validity of the '995 patent.

ANSWER: Denied.

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

ANSWER: Denied.

Count XIII—RE '825 Patent

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

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

189. The RE '825 patent, entitled "4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone Toluenesulfonic Acid Salt Crystal Forms" (attached as Exhibit G), was duly and legally issued on November 23, 2021.

ANSWER: Paragraph 189 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the RE '825 patent, titled "4-((6bR,10aS)-3-METHYL-2,3,6b,9,10,10a-

HEXAHYDRO-1H-PYRIDO[3',4':4,5]PYRROLO[1,2,3-de]QUINOXALIN-8(7H)-YL)-1-(4-FLUOROPHENYL)-1-BUTANONE TOLUENESULFONIC ACID SALT CRYSTAL FORMS," issued on or about November 23, 2021. DRL denies that the RE '825 patent was "duly and legally issued," and any suggestion or implication that the RE '825 patent is valid or enforceable. DRL also admits that a purported copy of the RE '825 patent is attached as Exhibit G to the Complaint. DRL denies any and all remaining allegations of Paragraph 189.

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

ANSWER: Paragraph 190 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the face of the RE '825 patent lists the purported "Inventors" as John Tomesch and Lawrence P. Wennogle. DRL denies any and all remaining allegations of Paragraph 190.

191. Plaintiff is the owner and assignee of the RE '825 patent.

ANSWER: Paragraph 191 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the RE '825 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 191, and therefore denies any and all remaining allegations of Paragraph 191.

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

ANSWER: Paragraph 192 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the Orange Book currently identifies the RE '825 patent in connection with NDA No. 209500 for CAPLYTA®. DRL denies any and all remaining allegations of Paragraph 192.

193. In DRL's Notice Letter, DRL notified Plaintiff of the submission of DRL'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 DRL's ANDA Product prior to the expiration of the Patents-in-Suit, including the RE '825 patent.

ANSWER: DRL admits that DRL, by DRL's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that DRL submitted DRL's ANDA to FDA seeking approval to market DRL's ANDA Product prior to the expiration of the Asserted Patents. DRL denies any and all remaining allegations of Paragraph 193.

194. In DRL's Notice Letter, DRL also notified Plaintiff that, as part of its ANDA, DRL had filed Paragraph IV certifications with respect to the RE '825 patent. Upon information and belief, DRL submitted its ANDA to the FDA containing Paragraph IV certifications asserting that the RE '825 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

ANSWER: Paragraph 194 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL has provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the RE '825 patent are invalid and/or will not be infringed by DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 194.

195. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

ANSWER: Paragraph 195 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's Notice Letter states that DRL submitted DRL's ANDA to FDA seeking approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 195.

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

ANSWER: Denied.

197. As an example, claim 1 of the RE '825 patent recites:

> A 4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3′,4′:4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone toluenesulfonic acid addition salt crystal form, wherein said salt crystal form exhibits an X-ray powder diffraction pattern comprising at least two peaks selected from the group consisting of 5.68°, 12.11°, 16.04°, 17.03°, 18.16°, 19.00°, 21.67°, 22.55°, 23.48° and 24.30°±0.2° 2θ.

ANSWER: Paragraph 197 contains legal conclusions and allegations to which no answer is required. To the extent that DRL is required to answer, DRL admits that claim 1 of the RE '825 patent reads as follows:

> **1**. A 4-((6bR,10aS)-3-methyl-2,3,6b,9,10,10a-hexahydro-1H-pyrido[3',4':4,5]pyrrolo[1,2,3-de]quinoxalin-8(7H)-yl)-1-(4-fluorophenyl)-1-butanone toluenesulfonic acid addition salt crystal form, wherein said salt crystal form exhibits an X-ray powder diffraction pattern comprising at least two peaks selected from the group consisting of 5.68°, 12.11°, 16.04°, 17.03°, 18.16°, 19.00°, 21.67°, 22.55°, 23.48° and 24.30°±0.2° 2θ.

(The RE '825 patent at Claim 1). DRL denies any and all remaining allegations of Paragraph 197.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

207. The foregoing actions by DRL constitute and/or will constitute infringement of the RE '825 patent; active inducement of infringement of the RE '825 patent; and/or contribution to the infringement by others of the RE '825 patent.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

Count XIV—RE '825 Patent

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

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

212. 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 DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the RE '825 patent, and/or the validity of the RE '825 patent.

ANSWER: Denied.

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

ANSWER: Denied.

Count XV—'938 Patent

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

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

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

ANSWER: Paragraph 215 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the '938 patent, titled "PHARMACEUTICAL COMPOSITIONS COMPRISING ((6bR,10aS)-1-(4-FLUOROPHENYL)-4-(3-METHYL-2,3,6b,9,10,10a-HEXAHYDRO-1H-PYRIDO[3',4':4,5]PYRROLO[1,2,3-de]QUINOXALIN-8(7H)-YL)BUTAN-1-ONE OR PHARMACEUTICALLY ACCEPTABLE SALTS THEREOF," issued on or about November 5, 2019. DRL denies that the '938 patent was "duly and legally issued," and any suggestion or implication that the '938 patent is valid or enforceable. DRL also admits that a purported copy of the '938 patent is attached as Exhibit H to the Complaint. DRL denies any and all remaining allegations of Paragraph 215.

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

ANSWER: Paragraph 216 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the face of the '938 patent lists the purported "Inventors" as John Charles Tomesch, Peng Li, Wei Yao, Qiang Zhang, James David Beard, Andrew S. Thompson, Hua Cheng, and Lawrence P. Wennogle. DRL denies any and all remaining allegations of Paragraph 216.

217. Plaintiff is the owner and assignee of the '938 patent.

ANSWER: Paragraph 217 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '938 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 217, and therefore denies any and all remaining allegations of Paragraph 217.

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

ANSWER: Paragraph 218 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the Orange Book currently identifies the '938 patent in connection with NDA No. 209500 for CAPLYTA®. DRL denies any and all remaining allegations of Paragraph 218.

219. In DRL's Notice Letter, DRL notified Plaintiff of the submission of DRL'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 DRL's ANDA Product prior to the expiration of the Patents-in-Suit, including the '938 patent.

ANSWER: DRL admits that DRL, by DRL's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that DRL submitted DRL's ANDA to FDA seeking approval to market DRL's ANDA Product prior to the expiration of the Asserted Patents. DRL denies any and all remaining allegations of Paragraph 219.

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

ANSWER: Paragraph 220 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL has provided written certifications

to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '938 patent are invalid and/or will not be infringed by DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 220.

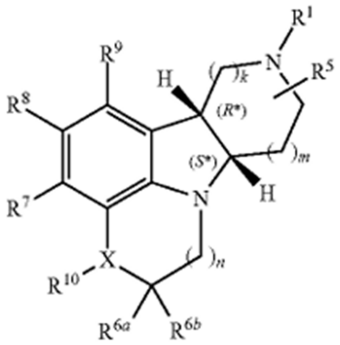
221. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

ANSWER: Paragraph 221 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's Notice Letter states that DRL submitted DRL's ANDA to FDA seeking approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 221.

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

ANSWER: Denied.

223. As an example, claim 1 of the '938 patent recites:

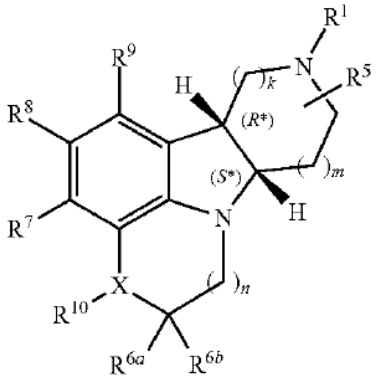
> A pharmaceutical composition comprising toluenesulfonic acid and the compound of Formula 2J:
>
> Formula 2J
>
> 
>
> or a pharmaceutically acceptable salt thereof,
> wherein:
> k is 1;
> m is 1;
> n is 1;
> R^1 is 4-(4-fluorophenyl)-4-oxobutyl;
> R^5 is H;
> R^{6a} and R^{6b} are independently H;

R^7, R^8 and R^9 are independently H;
R^{10} is CH3; and
X is —N—.

ANSWER: Paragraph 223 contains legal conclusions and allegations to which no answer is required. To the extent that DRL is required to answer, DRL admits that claim 1 of the '938 patent reads as follows:

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

Formula 2J



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

(The '938 patent at Claim 1). DRL denies any and all remaining allegations of Paragraph 223.

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

ANSWER: Denied.

225. Upon information and belief, DRL's ANDA Product infringes one or more claims of the '938 patent, literally or under the doctrine of equivalents.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

233. The foregoing actions by DRL constitute and/or will constitute infringement of the '938 patent; active inducement of infringement of the '938 patent; and/or contribution to the infringement by others of the '938 patent.

ANSWER: Denied.

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

ANSWER: Denied.

235. Plaintiff will be substantially and irreparably damaged by infringement of the '938 patent.

ANSWER: Denied.

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

ANSWER: Denied.

Count XVI—'938 Patent

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

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

238. 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 DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the '938 patent, and/or the validity of the '938 patent.

ANSWER: Denied.

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

ANSWER: Denied.

Count XVII—'227 Patent

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

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

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

ANSWER: Paragraph 241 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the '227 patent, titled "METHOD FOR THE TREATMENT OF RESIDUAL SYMPTOMS OF SCHIZOPHRENIA," issued on or about May 1, 2018. DRL denies that the '227 patent was "duly and legally issued," and any suggestion or implication that the '227 patent is valid or enforceable. DRL also admits that a purported copy of the '227 patent is attached as Exhibit I to the Complaint. DRL denies any and all remaining allegations of Paragraph 241.

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

ANSWER: Paragraph 242 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the face of the '227 patent lists the purported "Inventors" as Kimberly Vanover, Peng Li, Sharon Mates, Robert Davis, and Lawrence P. Wennogle. DRL denies any and all remaining allegations of Paragraph 242.

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

ANSWER: Paragraph 243 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '227 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of

the remaining allegations of Paragraph 243, and therefore denies any and all remaining allegations of Paragraph 243.

244. 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 244 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the Orange Book currently identifies the '227 patent in connection with NDA No. 209500 for CAPLYTA®. DRL denies any and all remaining allegations of Paragraph 244.

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

ANSWER: DRL admits that DRL, by DRL's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that DRL submitted DRL's ANDA to FDA seeking approval to market DRL's ANDA Product prior to the expiration of the Asserted Patents. DRL denies any and all remaining allegations of Paragraph 245.

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

ANSWER: Paragraph 246 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL has provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '227 patent are invalid and/or will not be infringed by DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 246.

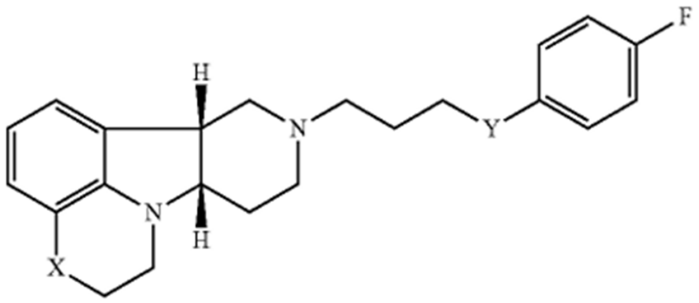
247. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

ANSWER: Paragraph 247 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's Notice Letter states that DRL submitted DRL's ANDA to FDA seeking approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 247.

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

ANSWER: Denied.

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

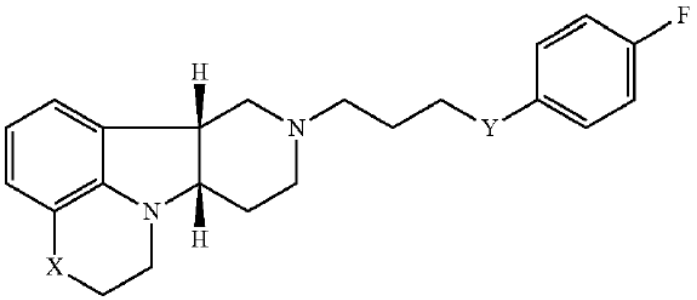
> A method for the treatment of residual symptoms of schizophrenia as defined in the Positive and Negative Syndrome Scale (PANSS) for Schizophrenia, comprising administering to a patient in need thereof, after treatment of acute symptoms of schizophrenia with an antipsychotic agent, an effective amount of a compound of Formula I:
>
> Formula I
>
> 
>
>
> wherein:
> X is —O—, —NH— or —N(CH^3)—;
> Y is —O—, —C(R^2)(OH)—, —C(R^3)(OR^1) or —C(O)—; and
> R^1 is —C1-6 alkyl or —C(O)—C1-21 alkyl, optionally saturated or
> unsaturated and optionally substituted with one or more hydroxyl or C1-22 alkoxy groups wherein such compound hydrolyzes to form
> the residue of a natural or unnatural, saturated or unsaturated fatty acid;
> R^2 is H or —C1-6 alkyl; and
> R^3 is H or —C1-6 alkyl;
> in free or pharmaceutically acceptable salt form;

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

ANSWER: Paragraph 249 contains legal conclusions and allegations to which no answer is required. To the extent that DRL is required to answer, DRL admits that claim 1 of the '227 patent reads as follows:

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

Formula I



wherein:

X is —O—, —NH— or —N(CH_3)—;

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

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

R_2 is H or —C_{1-6}alkyl; and

R_3 is H or —C_{1-6}alkyl;

in free or pharmaceutically acceptable salt form;

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

(The '227 patent at Claim 1). DRL denies any and all remaining allegations of Paragraph 249.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

257. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '227 patent, that DRL's

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

ANSWER: Denied.

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

ANSWER: Denied.

259. The foregoing actions by DRL 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.

260. Upon information and belief, DRL 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.

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

ANSWER: Denied.

262. Unless DRL 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 XVIII—'227 Patent

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

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

264. 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 DRL on the other regarding DRL's infringement, active inducement of infringement, contribution to the infringement by others of the '227 patent, and/or the validity of the '227 patent.

ANSWER: Denied.

265. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL 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 XIX—'009 Patent

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

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

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

ANSWER: Paragraph 267 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the '009 patent, titled "METHODS OF TREATING SCHIZOPHRENIA AND DEPRESSION," issued on or about March 30, 2021. DRL denies that the '009 patent was "duly and legally issued," and any suggestion or implication that the '009 patent is valid or enforceable. DRL also admits that a purported copy of the '009 patent is attached as Exhibit J to the Complaint. DRL denies any and all remaining allegations of Paragraph 267.

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

ANSWER: Paragraph 268 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the face of the '009 patent lists the purported "Inventors" as Kimberly Vanover, Peng

Li, Sharon Mates, Robert Davis, and Lawrence P. Wennogle. DRL denies any and all remaining allegations of Paragraph 268.

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

ANSWER: Paragraph 269 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '009 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 269, and therefore denies any and all remaining allegations of Paragraph 269.

270. 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 270 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the Orange Book currently identifies the '009 patent in connection with NDA No. 209500 for CAPLYTA®. DRL denies any and all remaining allegations of Paragraph 270.

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

ANSWER: DRL admits that DRL, by DRL's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that DRL submitted DRL's ANDA to FDA seeking approval to market DRL's ANDA Product prior to the expiration of the Asserted Patents. DRL denies any and all remaining allegations of Paragraph 271.

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

ANSWER: Paragraph 272 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL has provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '009 patent are invalid and/or will not be infringed by DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 272.

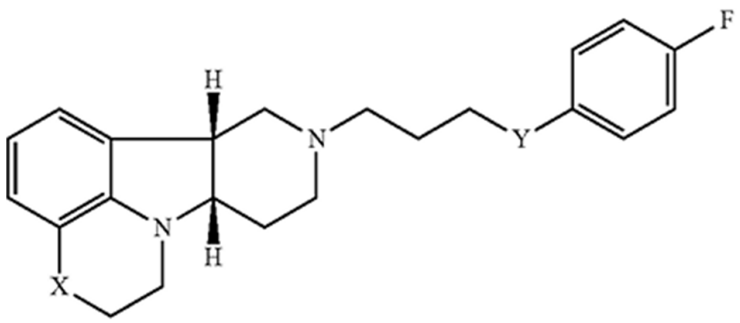
273. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

ANSWER: Paragraph 273 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's Notice Letter states that DRL submitted DRL's ANDA to FDA seeking approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 273.

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

ANSWER: Denied.

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

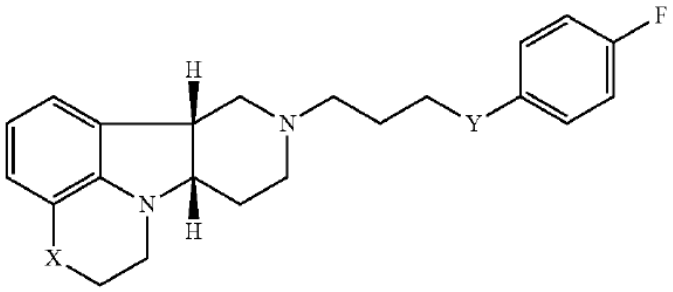
> A method for the treatment of the negative symptoms of schizophrenia comprising administering to a schizophrenic patient in need thereof an effective amount of a Compound of Formula I:
>
> Formula I
>
> 
>
>
> wherein:

X is —N(CH3)— and Y is —C(O)—;
in free or pharmaceutically acceptable salt form,
wherein the effective amount of the Compound of Formula I
is 40 mg to 60 mg per day, measured as the weight of the
corresponding free base form of the Compound.

ANSWER: Paragraph 275 contains legal conclusions and allegations to which no answer is required. To the extent that DRL is required to answer, denied. DRL further responds that claim 1 of the '009 patent reads as follows:

1. A method for the treatment of the negative symptoms of schizophrenia comprising administering to a schizophrenic patient in need thereof an effective amount

Formula I



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

(The '009 patent at Claim 1). DRL denies any and all remaining allegations of Paragraph 275.

276. Upon information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL'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.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

285. The foregoing actions by DRL 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.

286. Upon information and belief, DRL 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.

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

ANSWER: Denied.

288. Unless DRL 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 XX—'009 Patent

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

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

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

ANSWER: Denied.

291. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL 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 XXI—'951 Patent

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

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

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

ANSWER: Paragraph 293 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the '951 patent, titled "METHODS OF TREATING BIPOLAR DISORDER," issued on or about June 8, 2021. DRL denies that the '951 patent was "duly and legally issued," and any suggestion or implication that the '951 patent is valid or enforceable. DRL also admits that a purported copy of the '951 patent is attached as Exhibit K to the Complaint. DRL denies any and all remaining allegations of Paragraph 293.

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

ANSWER: Paragraph 294 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the face of the '951 patent lists the purported "Inventors" as Kimberly Vanover, Peng Li, Sharon Mates, Robert Davis, and Lawrence P. Wennogle. DRL denies any and all remaining allegations of Paragraph 294.

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

ANSWER: Paragraph 295 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '951 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 295, and therefore denies any and all remaining allegations of Paragraph 295.

296. 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 296 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the Orange Book currently identifies the '951 patent in connection with NDA No. 209500 for CAPLYTA®. DRL denies any and all remaining allegations of Paragraph 296.

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

ANSWER: DRL admits that DRL, by DRL's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that DRL submitted DRL's ANDA to FDA seeking approval to market DRL's ANDA Product prior to the expiration of the Asserted Patents. DRL denies any and all remaining allegations of Paragraph 297.

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

ANSWER: Paragraph 298 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL has provided written certifications

to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '951 patent are invalid and/or will not be infringed by DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 298.

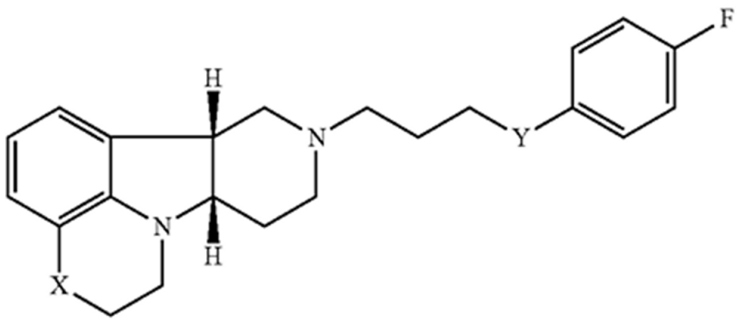
299. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

ANSWER: Paragraph 299 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's Notice Letter states that DRL submitted DRL's ANDA to FDA seeking approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 299.

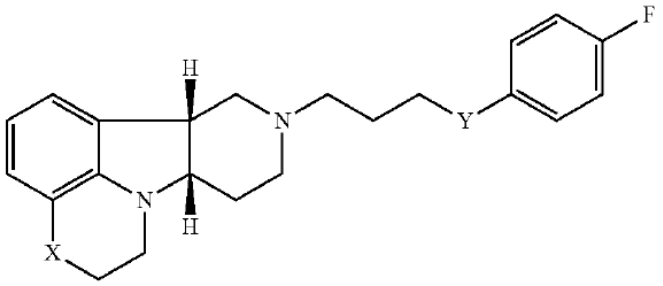
300. Upon information and belief, the use of DRL's ANDA Product in accordance with and as directed by DRL's proposed labeling for that product would infringe one or more claims of the '951 patent.

ANSWER: Denied.

301. 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(CH3)— and Y is —C(O)—;
> in free or pharmaceutically acceptable salt form,
> wherein said Compound is not used in combination with another antipsychotic agent.

ANSWER: Paragraph 301 contains legal conclusions and allegations to which no answer is required. To the extent that DRL is required to answer, DRL admits that claim 1 of the '951 patent reads as follows:

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

(The '951 patent at Claim 1). DRL denies any and all remaining allegations of Paragraph 301.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

311. The foregoing actions by DRL 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.

312. Upon information and belief, DRL 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.

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

ANSWER: Denied.

314. Unless DRL 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 XXII—'951 Patent

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

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

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

ANSWER: Denied.

317. The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL 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 XXIII—'345 Patent

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

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

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

ANSWER: Paragraph 319 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the '345 patent, titled "PHARMACEUTICAL CAPSULE COMPOSITIONS COMPRISING LUMATEPERONE MONO-TOSYLATE," issued on or about June 30, 2020. DRL denies that the '345 patent was "duly and legally issued," and any suggestion or implication that the '345 patent is valid or enforceable. DRL also admits that a purported copy of the '345 patent is attached as Exhibit L to the Complaint. DRL denies any and all remaining allegations of Paragraph 319.

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

ANSWER: Paragraph 320 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the face of the '345 patent lists the purported "Inventors" as Peng Li and Robert Davis. DRL denies any and all remaining allegations of Paragraph 320.

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

ANSWER: Paragraph 321 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '345 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 321, and therefore denies any and all remaining allegations of Paragraph 321.

322. 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 322 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the Orange Book currently identifies the '345 patent in connection with NDA No. 209500 for CAPLYTA®. DRL denies any and all remaining allegations of Paragraph 322.

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

ANSWER: DRL admits that DRL, by DRL's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that DRL submitted DRL's ANDA to FDA seeking approval to market DRL's ANDA Product prior to the expiration of the Asserted Patents. DRL denies any and all remaining allegations of Paragraph 323.

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

ANSWER: Paragraph 324 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL has provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '345 patent are invalid and/or will not be infringed by DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 324.

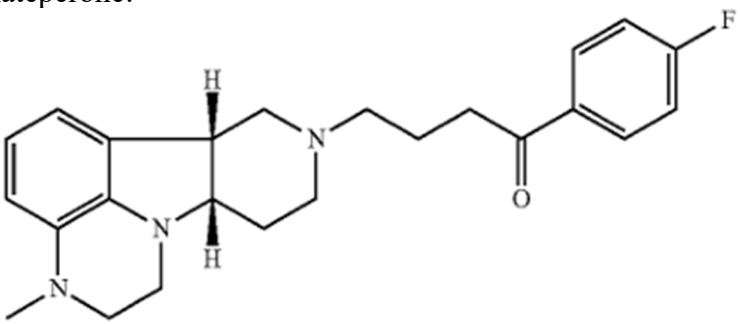
325. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

ANSWER: Paragraph 325 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's Notice Letter states that DRL submitted DRL's ANDA to FDA seeking approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 325.

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

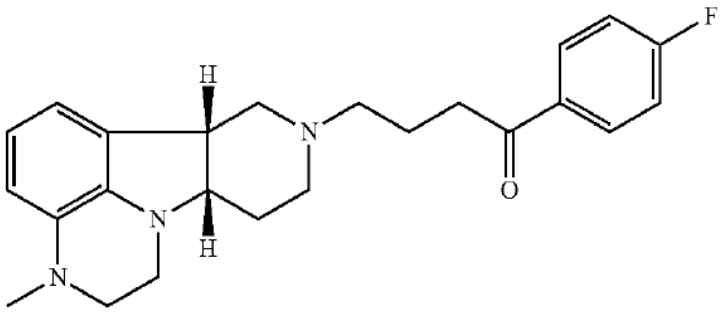
ANSWER: Denied.

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

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

ANSWER: Paragraph 327 contains legal conclusions and allegations to which no answer is required. To the extent that DRL is required to answer, DRL admits that claim 1 of the '345 patent reads as follows:

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



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

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

(The '345 patent at Claim 1). DRL denies any and all remaining allegations of Paragraph 327.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

337. The foregoing actions by DRL 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.

338. Upon information and belief, DRL 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.

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

ANSWER: Denied.

340. Unless DRL 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 XXIV—'345 Patent

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

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

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

ANSWER: Denied.

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

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

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

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

ANSWER: Paragraph 345 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the '084 patent, titled "PHARMACEUTICAL CAPSULE COMPOSITIONS COMPRISING LUMATEPERONE MONO-TOSYLATE," issued on or about July 6, 2021. DRL denies that the '084 patent was "duly and legally issued," and any suggestion or implication that the '084 patent is valid or enforceable. DRL also admits that a purported copy of the '084 patent is attached as Exhibit M to the Complaint. DRL denies any and all remaining allegations of Paragraph 345.

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

ANSWER: Paragraph 346 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the face of the '084 patent lists the purported "Inventors" as Peng Li and Robert Davis. DRL denies any and all remaining allegations of Paragraph 346.

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

ANSWER: Paragraph 347 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '084 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 347, and therefore denies any and all remaining allegations of Paragraph 347.

348. 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 348 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the Orange Book currently identifies

the '084 patent in connection with NDA No. 209500 for CAPLYTA®. DRL denies any and all remaining allegations of Paragraph 348.

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

ANSWER: DRL admits that DRL, by DRL's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that DRL submitted DRL's ANDA to FDA seeking approval to market DRL's ANDA Product prior to the expiration of the Asserted Patents. DRL denies any and all remaining allegations of Paragraph 349.

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

ANSWER: Paragraph 350 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL has provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '084 patent are invalid and/or will not be infringed by DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 350.

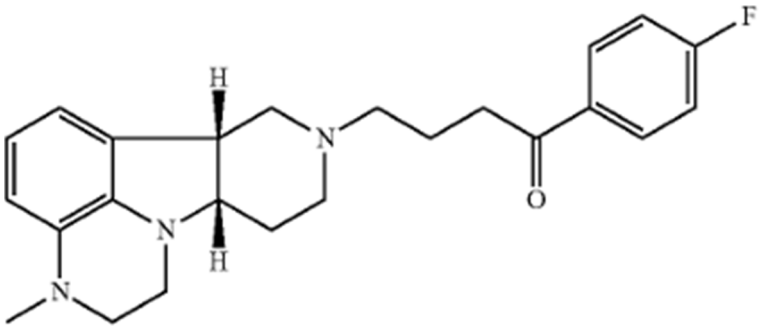
351. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

ANSWER: Paragraph 351 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's Notice Letter states that DRL submitted DRL's ANDA to FDA seeking approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 351.

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

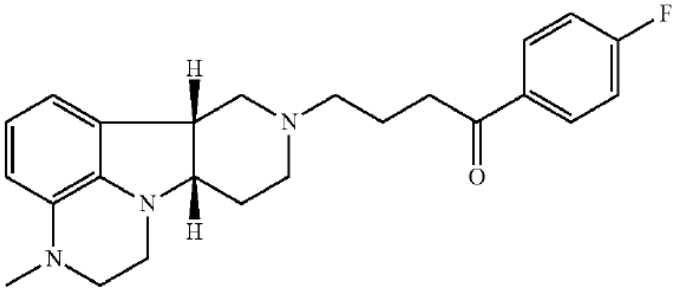
ANSWER: Denied.

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

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

ANSWER: Paragraph 353 contains legal conclusions and allegations to which no answer is required. To the extent that DRL is required to answer, DRL admits that claim 1 of the '084 patent reads as follows:

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



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

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

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

(The '084 patent at Claim 1). DRL denies any and all remaining allegations of Paragraph 353.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

363. The foregoing actions by DRL 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.

364. Upon information and belief, DRL 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.

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

ANSWER: Denied.

366. Unless DRL 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 XXVI—'084 Patent

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

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

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

ANSWER: Denied.

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

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

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

371. The ’842 patent, entitled “Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate” (attached as Exhibit N), was duly and legally issued on July 4, 2023.

ANSWER: Paragraph 371 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the ’842 patent, titled “PHARMACEUTICAL CAPSULE COMPOSITIONS COMPRISING LUMATEPERONE MONO-TOSYLATE,” issued on or about July 4, 2023. DRL denies that the ’842 patent was “duly and legally issued,” and any suggestion or implication that the ’842 patent is valid or enforceable. DRL also admits that a purported copy of the ’842 patent is attached as Exhibit N to the Complaint. DRL denies any and all remaining allegations of Paragraph 371.

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

ANSWER: Paragraph 372 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the face of the ’842 patent lists the purported “Inventors” as Peng Li and Robert Davis. DRL denies any and all remaining allegations of Paragraph 372.

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

ANSWER: Paragraph 373 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, “INTRA-CELLULAR THERAPIES, INC.” is identified as the current assignee of the ’842 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 373, and therefore denies any and all remaining allegations of Paragraph 373.

374. 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 374 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the Orange Book currently identifies the '842 patent in connection with NDA No. 209500 for CAPLYTA®. DRL denies any and all remaining allegations of Paragraph 374.

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

ANSWER: DRL admits that DRL, by DRL's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that DRL submitted DRL's ANDA to FDA seeking approval to market DRL's ANDA Product prior to the expiration of the Asserted Patents. DRL denies any and all remaining allegations of Paragraph 375.

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

ANSWER: Paragraph 376 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL has provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '842 patent are invalid and/or will not be infringed by DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 376.

377. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

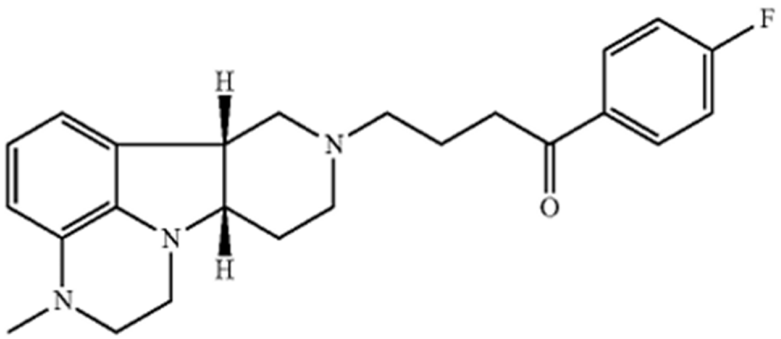
ANSWER: Paragraph 377 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's Notice Letter states that DRL

submitted DRL's ANDA to FDA seeking approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 377.

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

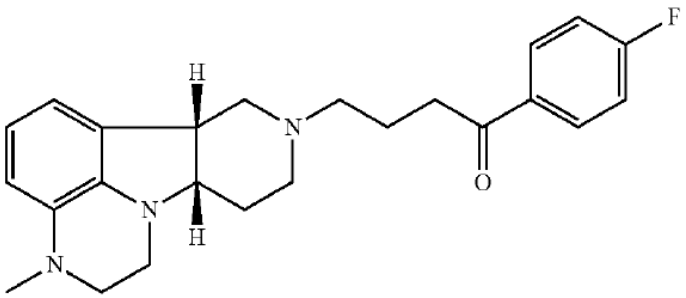
ANSWER: Denied.

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

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

ANSWER: Paragraph 379 contains legal conclusions and allegations to which no answer is required. To the extent that DRL is required to answer, DRL admits that claim 1 of the '842 patent reads as follows:

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



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

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

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

(The '842 patent at Claim 1). DRL denies any and all remaining allegations of Paragraph 379.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

389. The foregoing actions by DRL 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.

390. Upon information and belief, DRL 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.

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

ANSWER: Denied.

392. Unless DRL 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 XXVIII—'842 Patent

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

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

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

ANSWER: Denied.

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

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

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

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

ANSWER: Paragraph 397 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the '348 patent, titled "METHODS OF TREATMENT USING PHARMACEUTICAL CAPSULE COMPOSITIONS COMPRISING LUMATEPERONE MONO-TOSYLATE," issued on or about November 7, 2023. DRL denies that the '348 patent was "duly and legally issued," and any suggestion or implication that the '348 patent is valid or enforceable. DRL also admits that a purported copy of the '348 patent is attached as Exhibit O to the Complaint. DRL denies any and all remaining allegations of Paragraph 397.

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

ANSWER: Paragraph 398 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the face of the '348 patent lists the purported "Inventors" as Peng Li and Robert Davis. DRL denies any and all remaining allegations of Paragraph 398.

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

ANSWER: Paragraph 399 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '348 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 399, and therefore denies any and all remaining allegations of Paragraph 399.

400. 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 400 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the Orange Book currently identifies the '348 patent in connection with NDA No. 209500 for CAPLYTA®. DRL denies any and all remaining allegations of Paragraph 400.

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

ANSWER: DRL admits that DRL, by DRL's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that DRL submitted DRL's ANDA to FDA seeking approval to market DRL's ANDA Product prior to the expiration of the Asserted Patents. DRL denies any and all remaining allegations of Paragraph 401.

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

ANSWER: Paragraph 402 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL has provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '348 patent are invalid and/or will not be infringed by DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 402.

403. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

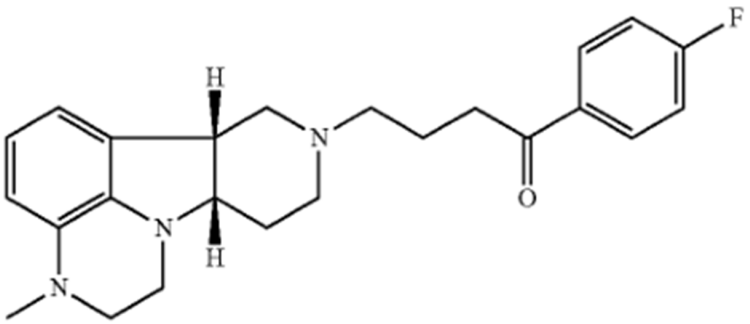
ANSWER: Paragraph 403 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's Notice Letter states that DRL

submitted DRL's ANDA to FDA seeking approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 403.

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

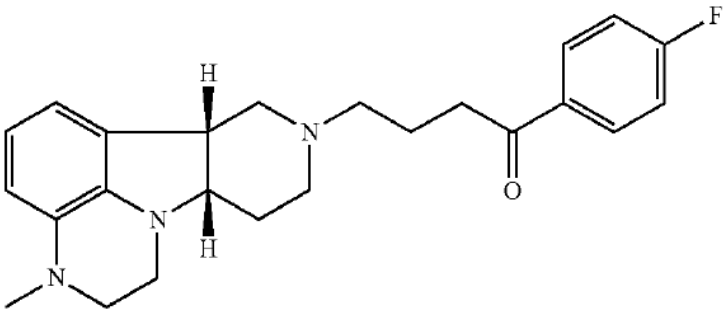
ANSWER: Denied.

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

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

ANSWER: Paragraph 405 contains legal conclusions and allegations to which no answer is required. To the extent that DRL is required to answer, DRL admits that claim 1 of the '348 patent reads as follows:

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



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

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

wherein the capsule comprises the lumateperone mono-tosylate in an amount equivalent to 0.01 to 30 mg or 35 to 45 mg of lumateperone free base.

(The '348 patent at Claim 1). DRL denies any and all remaining allegations of Paragraph 405.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

415. The foregoing actions by DRL 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.

416. Upon information and belief, DRL 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.

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

ANSWER: Denied.

418. Unless DRL 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 XXX—'348 Patent

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

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

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

ANSWER: Denied.

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

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

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

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

ANSWER: Paragraph 423 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the '419 patent, titled "4-((6bR,10aS)-3-METHYL-2,3,6b,9,10,10a-HEXAHYDRO-1H-PYRIDO[3',4':4,5]PYRROLO[1,2,3-de]QUINOXALIN-8(7H)-YL)-1-(4-((6bR,10aS)-3-METHYL-2,3,6b,9,10,10a-HEXAHYDRO-1H-PYRIDO[3'4':4,5]PYRROLO[1,2,3-de]QUINOXALIN-8(7H)-YL)PHENYL)BUTAN-1-ONE FOR TREATING CONDITIONS OF THE CENTRAL NERVOUS SYSTEM AND CARDIAC DISORDERS," issued on or about September 12, 2023. DRL denies that the '419 patent was "duly and legally issued," and any suggestion or implication that the '419 patent is valid or enforceable. DRL also admits that a purported copy of the '419 patent is attached as Exhibit P to the Complaint. DRL denies any and all remaining allegations of Paragraph 423.

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

ANSWER: Paragraph 424 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, the face of the '419 patent lists the purported "Inventors" as Peng Li, Robert E. Davis, and Kimberly Vanover. DRL denies any and all remaining allegations of Paragraph 424.

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

ANSWER: Paragraph 425 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that, according to the electronic records of the USPTO, "INTRA-CELLULAR THERAPIES, INC." is identified as the current assignee of the '419 patent. DRL lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 425, and therefore denies any and all remaining allegations of Paragraph 425.

426. 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 426 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that the Orange Book currently identifies the '419 patent in connection with NDA No. 209500 for CAPLYTA®. DRL denies any and all remaining allegations of Paragraph 426.

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

ANSWER: DRL admits that DRL, by DRL's Notice Letter, properly and timely provided the requisite notice, pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(B)(ii)-(iv) and 21 C.F.R. § 314.95, to Intra-Cellular Therapies, Inc. that DRL submitted DRL's ANDA to FDA seeking approval to market DRL's ANDA Product prior to the expiration of the Asserted Patents. DRL denies any and all remaining allegations of Paragraph 427.

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

ANSWER: Paragraph 428 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL has provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that, in its opinion and to the best of its knowledge, the claims of the '419 patent are invalid and/or will not be infringed by DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 428.

429. According to DRL's Notice Letter, DRL's ANDA Product contains lumateperone.

ANSWER: Paragraph 429 contains legal conclusions to which no answer is required. To the extent that DRL is required to answer, DRL admits that DRL's Notice Letter states that DRL submitted DRL's ANDA to FDA seeking approval for DRL's ANDA Product. DRL denies any and all remaining allegations of Paragraph 429.

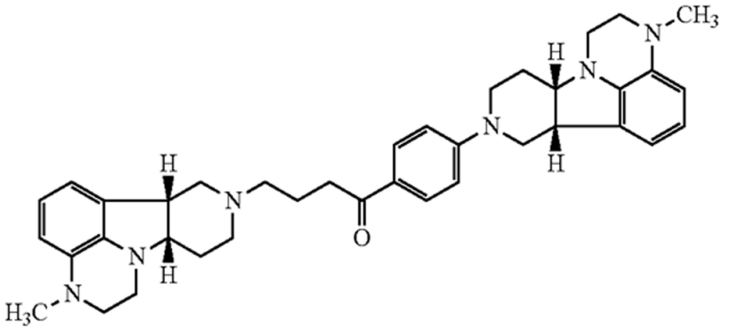
430. Upon information and belief, DRL's ANDA Product and the use of DRL's ANDA Product are covered by one or more claims of the '419 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

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

A compound of Formula I:

Formula I

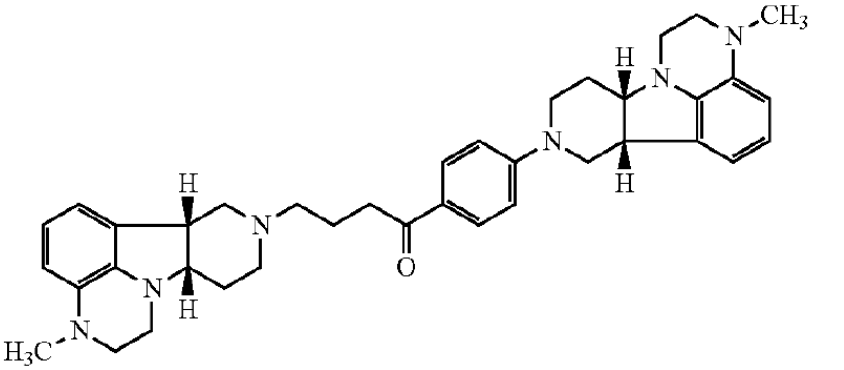


in free base or pharmaceutically acceptable salt form.

ANSWER: Paragraph 431 contains legal conclusions and allegations to which no answer is required. To the extent that DRL is required to answer, DRL admits that claim 1 of the '419 patent reads as follows:

1. A compound of Formula I:

Formula I



in free base or pharmaceutically acceptable salt form.

(The '419 patent at Claim 1). DRL denies any and all remaining allegations of Paragraph 431.

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

441. The foregoing actions by DRL 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.

442. Upon information and belief, DRL 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.

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

ANSWER: Denied.

444. Unless DRL 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 XXXII—'419 Patent

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

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

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

ANSWER: Denied.

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

ANSWER: Denied.

PLAINTIFF'S PRAYER FOR RELIEF

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

SEPARATE DEFENSES

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

FIRST DEFENSE
(Invalidity)

The claims of U.S. Patent Nos. 8,648,077 ("the '077 patent"), 9,168,258 ("the '258 patent"), 9,199,995 ("the '995 patent"), 9,616,061 ("the '061 patent"), 9,956,227 ("the '227 patent"), 10,117,867 ("the '867 patent"), 10,464,938 ("the '938 patent"), 10,695,345 ("the '345 patent"), 10,960,009 ("the '009 patent"), 11,026,951 ("the '951 patent"), 11,052,084 ("the '084 patent"), 11,690,842 ("the '842 patent"), 11,753,419 ("the '419 patent"), 11,806,348 ("the '348 patent"), RE48,825 ("the RE '825 patent"), and RE48,839 ("the RE '839 patent") (collectively, "Asserted Patents") are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including without limitation §§ 101, 102, 103 and/or 112, and/or any judicially-created basis for invalidation or unenforceability.

SECOND DEFENSE
(Non-Infringement)

The manufacture, use, sale, offer for sale or importation of the proposed lumateperone capsules, 10.5 mg, 21 mg, and 42 mg, that are the subject of DRL's ANDA No. 219229, does not and would not infringe, either directly or indirectly, any valid and/or enforceable claim of the Asserted Patents, either literally or under the doctrine of equivalents.

THIRD DEFENSE
(No Inducement)

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

FOURTH DEFENSE
(No Contributory Infringement)

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

FIFTH DEFENSE
(No Subject Matter Jurisdiction)

The Court lacks subject matter jurisdiction over this action solely for the claims against Dr. Reddy's Inc.

SIXTH DEFENSE
(Safe Harbor)

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

SEVENTH DEFENSE
(No Exceptional Case)

The Complaint fails to state a claim for exceptional case.

EIGHTH DEFENSE
(Failure to State a Claim)

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

NINTH DEFENSE
(Additional Defenses)

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

COUNTERCLAIMS

Defendants/Counterclaim-Plaintiffs Dr. Reddy's Laboratories Inc. ("Dr. Reddy's Inc.") and Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's Ltd.") (collectively, "DRL"), for their Counterclaims against Plaintiff/Counterclaim-Defendant Intra-Cellular Therapies, Inc. ("Plaintiff/Counterclaim-Defendant," "Intra-Cellular Therapies," or "ITCI"), allege as follows:

The Parties

1. Dr. Reddy's Laboratories Inc. is an entity organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540.

2. Dr. Reddy's Laboratories Ltd. is an entity organized and existing under the laws of India, with a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, 500034, India, which is in the state of Telangana.

3. On information and belief and according to the Complaint (D.I. 1 ¶ 4), Intra-Cellular Therapies, Inc. is a corporation organized and existing under the laws of Delaware and having a place of business at 430 East 29th Street, Suite 900, New York, NY 10016.

Jurisdiction and Venue

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

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

6. This Court has personal jurisdiction over Plaintiff/Counterclaim-Defendant because it has availed itself of the rights and privileges, and subjected itself to the jurisdiction of

this forum by suing DRL in this District, and, on information and belief, because Plaintiff/Counterclaim-Defendant conducts substantial business in, and has regular systemic contact with, this District.

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

Background

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

9. On or about October 27, 2015, the USPTO issued U.S. Patent No. 9,168,258 ("the '258 patent").

10. On or about April 11, 2017, the USPTO issued U.S. Patent No. 9,616,061 ("the '061 patent").

11. On or about November 6, 2018, the USPTO issued U.S. Patent No. 10,117,867 ("the '867 patent").

12. On or about February 11, 2014, the USPTO issued U.S. Patent No. 8,648,077 ("the '077 patent").

13. On or about December 1, 2015, the USPTO issued U.S. Patent No. 9,199,995 ("the '995 patent").

14. On or about November 23, 2021, the USPTO issued U.S. Patent No. RE48,825 ("the RE '825 patent").

15. On or about November 5, 2019, the USPTO issued U.S. Patent No. 10,464,938 ("the '938 patent").

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

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

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

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

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

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

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

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

24. Plaintiff/Counterclaim-Defendant purports and claims to own the '077 patent, the '258 patent, the '995 patent, the '061 patent, the '227 patent, the '867 patent, the '938 patent, the '345 patent, the '009 patent, the '951 patent, the '084 patent, the '842 patent, the '419 patent, the '348 patent, the RE '825 patent and the RE '839 patent (collectively, "Asserted Patents") (D.I. 1 ¶¶ 35, 61, 87, 113, 139, 165, 191, 217, 243, 269, 295, 321, 347, 373, 399, 425).

25. On or about March 28, 2024, Plaintiff/Counterclaim-Defendant sued DRL in this District alleging that the proposed lumateperone capsules, 10.5 mg, 21 mg, and 42 mg, that are the subject of DRL's Abbreviated New Drug Application No. 219229 ("DRL's ANDA Product"), will infringe the Asserted Patents under 35 U.S.C. § 271(e)(2).

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

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

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

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

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

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

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

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

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

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

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

COUNT III
(Declaratory Judgment of Non-Infringement of the '258 Patent)

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

36. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of DRL's ANDA Product would infringe any valid and/or enforceable claim of the '258 patent.

37. DRL's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '258 patent.

38. DRL is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of DRL's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '258 patent.

COUNT IV
(Declaratory Judgment of Invalidity of the '258 Patent)

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

40. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '258 patent.

41. One or more claims of the '258 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

42. DRL is entitled to a judicial declaration that the claims of the '258 patent are invalid.

COUNT V
(Declaratory Judgment of Non-Infringement of the '061 Patent)

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

44. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of DRL's ANDA Product would infringe any valid and/or enforceable claim of the '061 patent.

45. DRL's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '061 patent.

46. DRL is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of DRL's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '061 patent.

COUNT VI
(Declaratory Judgment of Invalidity of the '061 Patent)

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

48. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '061 patent.

49. One or more claims of the '061 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

50. DRL is entitled to a judicial declaration that the claims of the '061 patent are invalid.

COUNT VII
(Declaratory Judgment of Non-Infringement of the '867 Patent)

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

52. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of DRL's ANDA Product would infringe any valid and/or enforceable claim of the '867 patent.

53. DRL's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '867 patent.

54. DRL is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of DRL's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '867 patent.

COUNT VIII
(Declaratory Judgment of Invalidity of the '867 Patent)

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

56. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '867 patent.

57. One or more claims of the '867 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

58. DRL is entitled to a judicial declaration that the claims of the '867 patent are invalid.

COUNT IX
(Declaratory Judgment of Non-Infringement of the '077 Patent)

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

60. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of DRL's ANDA Product would infringe any valid and/or enforceable claim of the '077 patent.

61. DRL's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '077 patent.

62. DRL is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of DRL's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '077 patent.

COUNT X
(Declaratory Judgment of Invalidity of the '077 Patent)

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

64. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '077 patent.

65. One or more claims of the '077 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

66. DRL is entitled to a judicial declaration that the claims of the '077 patent are invalid.

COUNT XI
(Declaratory Judgment of Non-Infringement of the '995 Patent)

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

68. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of DRL's ANDA Product would infringe any valid and/or enforceable claim of the '995 patent.

69. DRL's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '995 patent.

70. DRL is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of DRL's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '995 patent.

COUNT XII
(Declaratory Judgment of Invalidity of the '995 Patent)

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

72. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '995 patent.

73. One or more claims of the '995 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

74. DRL is entitled to a judicial declaration that the claims of the '995 patent are invalid.

COUNT XIII
(Declaratory Judgment of Non-Infringement of the RE '825 Patent)

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

76. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of DRL's ANDA Product would infringe any valid and/or enforceable claim of the RE '825 patent.

77. DRL's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the RE '825 patent.

78. DRL is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of DRL's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the RE '825 patent.

COUNT XIV
(Declaratory Judgment of Invalidity of the RE '825 Patent)

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

80. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the RE '825 patent.

81. One or more claims of the RE '825 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

82. DRL is entitled to a judicial declaration that the claims of the RE '825 patent are invalid.

COUNT XV
(Declaratory Judgment of Non-Infringement of the '938 Patent)

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

84. There is an actual, substantial, and continuing justiciable case or controversy regarding whether the manufacture, use, offer for sale, sale or importation of DRL's ANDA Product would infringe any valid and/or enforceable claim of the '938 patent.

85. DRL's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '938 patent.

86. DRL is entitled to a judicial declaration that the manufacture, use, offer for sale, sale or importation of DRL's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '938 patent.

COUNT XVI
(Declaratory Judgment of Invalidity of the '938 Patent)

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

88. There is an actual, substantial, and continuing justiciable case or controversy regarding the invalidity of the '938 patent.

89. One or more claims of the '938 patent are invalid for failure to comply with one or more of the requirements set forth in Title 35 of the United States Patent Code, including §§ 101, 102, 103 and/or 112, or under a judicially-created basis for invalidation or unenforceability.

90. DRL is entitled to a judicial declaration that the claims of the '938 patent are invalid.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

106. DRL is entitled to a judicial declaration that the claims of the '009 patent are invalid.

COUNT XXI
(Declaratory Judgment of Non-Infringement of the '951 Patent)

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

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

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

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

COUNT XXII
(Declaratory Judgment of Invalidity of the '951 Patent)

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

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

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

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

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

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

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

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

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

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

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

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

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

122. DRL is entitled to a judicial declaration that the claims of the '345 patent are invalid.

COUNT XXV
(Declaratory Judgment of Non-Infringement of the '084 Patent)

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

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

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

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

COUNT XXVI
(Declaratory Judgment of Invalidity of the '084 Patent)

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

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

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

130. DRL is entitled to a judicial declaration that the claims of the '084 patent are invalid.

COUNT XXVII
(Declaratory Judgment of Non-Infringement of the '842 Patent)

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

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

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

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

COUNT XXVIII
(Declaratory Judgment of Invalidity of the '842 Patent)

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

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

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

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

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

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

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

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

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

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

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

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

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

146. DRL is entitled to a judicial declaration that the claims of the '348 patent are invalid.

COUNT XXXI
(Declaratory Judgment of Non-Infringement of the '419 Patent)

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

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

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

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

COUNT XXXII
(Declaratory Judgment of Invalidity of the '419 Patent)

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

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

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

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

PRAYER FOR RELIEF

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

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

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

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

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

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

MIDLIGE RICHTER LLC
Attorneys for Defendants, Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd.

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

Dated: May 28, 2024

***OF COUNSEL** (Pro Hac Vice Forthcoming)*

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, Defendants/Counterclaim-Plaintiffs Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc., by 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, but it appears, at the time of this certification, that the Asserted Patents in this matter are also the subject of the following actions:

- *Intra-Cellular Therapies, Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 3:24-cv-04264 (D.N.J.)
- *Intra-Cellular Therapies, Inc. v. Alkem Lab'ys Ltd.*, C.A. No. 3:24-cv-04312 (D.N.J.)
- *Intra-Cellular Therapies, Inc. v. Hetero USA Inc.*, C.A. No. 3:24-cv-04317 (D.N.J.)
- *Intra-Cellular Therapies, Inc. v. MSN Lab'ys Pvt. Ltd.*, C.A. No. 3:24-cv-04325 (D.N.J.)
- *Intra-Cellular Therapies, Inc. v. Sandoz Inc.*, C.A. No. 3:24-cv-04327 (D.N.J.)
- *Intra-Cellular Therapies, Inc. v. Zydus Pharms. (USA) Inc.*, C.A. No. 3:24-cv-04330 (D.N.J.)

s/ James S. Richter
James S. Richter

Dated: May 28, 2024

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendants/Counterclaim-Plaintiffs Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories Inc., by their undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

s/ James S. Richter
James S. Richter

Dated: May 28, 2024

CERTIFICATION OF SERVICE

The undersigned attorney certifies that a copy of the foregoing Answer, Affirmative Defenses, and Counterclaims to Plaintiffs' Complaint for Patent Infringement was filed via ECF and served on all counsel of record by electronic mail on May 28, 2024.

s/ James S. Richter
James S. Richter

Dated: May 28, 2024