IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEURELIS, INC., *Plaintiffs*, v. PADAGIS LLC, PADAGIS US LLC, AND PADAGIS ISRAEL PHARMACEUTICALS LTD., LUPIN INC., LUPIN LTD., AND LUPIN PHARMACEUTICALS, INC., *Defendants*.	Civil Action No. 25-cv-821-MN

LUPIN DEFENDANTS' ANSWER TO THE COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants Lupin Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") by and through the undersigned attorneys, answer the Complaint of Neurelis, Inc. ("Neurelis" or "Plaintiff") as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Lupin denies all allegations in Plaintiff's Complaint except those specifically admitted below.

COMPLAINT FOR PATENT INFRINGEMENT

1. This is an action for infringement of U.S. Patent Nos. 11,241,414 (the "'414 patent"), 11,793,786 (the "'786 patent"), and 12,268,664 (the "'664 patent") (collectively "the Asserted Patents") under the patent laws of the United States, Title 35, United States Code, that arises out of Padagis's submission of Abbreviated New Drug Application ("ANDA") No. 219320 and Lupin's submission of ANDA No. 220394 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell and/or import generic versions of VALTOCO® (diazepam nasal spray), prior to the expiration of the Asserted Patents.[1] Padagis's ANDA No. 219320 covers a diazepam nasal spray, 10 mg/spray

[1] A prior, related case entitled "*Neurelis, Inc. v. Padagis LLC*, C.A. No. 1:24-cv-00562MN" (the "Padagis I Action") was filed in this Court on May 8, 2024. The Padagis I Action alleges infringement of the '414 patent, the '786 patent and U.S. Patent No. 8,895,546 (the "'546 Patent") against Padagis. Those claims remain pending and are not repeated herein. Pursuant to L.R. 3.1,

(the Padagis ANDA Product"). Lupin's ANDA No. 220394 covers a diazepam nasal spray, 5 mg/spray, 7.5 mg/spray, and 10 mg/spray (the "Lupin ANDA Products"),

RESPONSE: Lupin admits that Plaintiff's Complaint against Lupin is for infringement of U.S. Patent Nos. 11,241,414 (the "'414 patent"), 11,793,786 (the "'786 patent"), and 12,268,664 (the "'664 patent") (collectively "the Asserted Patents") arising under the patent laws of the United States, but denies that Plaintiff is entitled to any such relief. Lupin further admits that Lupin Inc. submitted Abbreviated New Drug Application ("ANDA") No. 220394 ("the Lupin ANDA" or "Lupin's ANDA") seeking U.S. Food and Drug Administration ("FDA") approval for a proposed generic diazepam nasal spray (5 mg/spray, 7.5 mg/spray, and 10 mg/spray) ("Lupin's ANDA Product"), prior to the expiration of the Asserted Patents. Lupin denies any remaining allegations in this paragraph, including those in footnote 1.

THE PARTIES

2. Neurelis is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3430 Carmel Mountain Road, Suite 300, San Diego, California 92121.

RESPONSE: On information and belief, Lupin admits that Plaintiff Neurelis is a company organized and existing under the laws of the State of Delaware. Lupin lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies those allegations.

3. On information and belief, Defendant Padagis Israel Pharmaceuticals Ltd. ("Padagis Israel") is a company organized and existing under the laws of Israel with a principal place of business at 1 Rakefet Street, Shoham, Israel 6085000.

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the Civil Cover Sheet accompanying this Complaint indicates that the Padagis I Action is a Related Action.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

4. On information and belief, Defendant Padagis LLC is a limited liability company organized and existing under the laws of the State of Delaware with a principal place of business at 1251 Lincoln Road, Allegan, Michigan 49010-9706.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

5. On information and belief, Defendant Padagis US LLC ("Padagis US") is a limited liability company organized and existing under the laws of the State of Delaware with a principal place of business at 1251 Lincoln Road, Allegan, Michigan 49010-9706.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

6. On information and belief, Padagis Israel and Padagis US are wholly-owned subsidiaries of Padagis LLC.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

7. On information and belief, Padagis LLC directs the operations, management, and activities of Padagis Israel and Padagis US in the United States.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

8. On information and belief, Padagis LLC, Padagis US, and Padagis Israel are agents of each other and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to

development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to Padagis's ANDA Product.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

9. On information and belief, Padagis participated in, assisted, and cooperated in the acts complained of herein, and acted in concert to prepare and submit ANDA No. 219320 ("the Padagis ANDA") to the FDA for the manufacture, importation, marketing, and sale of the drug that is the subject of the Padagis ANDA if it is approved.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

10. On information and belief, Lupin Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at Harborplace Tower, 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202.

RESPONSE: Lupin admits that Lupin Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 5801 Pelican Bay Boulevard Suite 500 Naples, FL 34108. Lupin denies any remaining allegations in this paragraph.

11. On information and belief, Defendant Lupin Limited is a corporation organized and existing under the laws of the Republic of India, with a principal place of business at 3rd Floor, Kalpataru Inspire, Off Western Expressway Highway, Santacruz (East), Mumbai 400 055, India.

RESPONSE: Lupin admits that Lupin Ltd. is an Indian corporation having a place of business at 3rd Floor, Kalpataru Inspire, Off Western Expressway Highway, Santacruz (East), Mumbai 400 055, India. Lupin denies that Lupin Ltd. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

12. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at Harborplace Tower, 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202.

RESPONSE: Lupin admits that Lupin Pharmaceuticals, Inc., is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 5801 Pelican Bay Blvd., Suite 500, Naples, FL 34108-2734. Lupin denies that Lupin Pharmaceuticals, Inc., is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

13. On information and belief, Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary of Lupin Limited.

RESPONSE: Lupin admits that Lupin Pharmaceuticals, Inc., is indirectly a wholly owned subsidiary of Lupin Ltd. Lupin denies that Lupin Pharmaceuticals, Inc. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

14. On information and belief, Lupin Limited directs the operations, management, and activities of Lupin Pharmaceuticals, Inc. in the United States.

RESPONSE: Lupin admits that Lupin Pharmaceuticals, Inc., is indirectly a wholly owned subsidiary of Lupin Ltd. Lupin denies that Lupin Ltd. and Lupin Pharmaceuticals, Inc., are proper parties to this action. Lupin denies any remaining allegations in this paragraph.

15. On information and belief, Lupin Inc., Lupin Limited, and Lupin Pharmaceuticals, Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to Lupin's ANDA Product.

RESPONSE: This paragraph contains conclusions of law for which no response is required. Lupin denies that Lupin Ltd. and Lupin Pharmaceuticals, Inc., are proper parties to this action. Lupin denies any remaining allegations in this paragraph.

16. On information and belief, Lupin participated in, assisted, and cooperated in the acts complained of herein, and acted in concert to prepare and submit ANDA No. 220394 ("the Lupin ANDA") to the FDA for the manufacture, importation, marketing, and sale of the drug that is the subject of the Lupin ANDA if it is approved.

RESPONSE: Lupin admits that Lupin Ltd. is in the business of developing, preparing, and manufacturing generic drugs. Lupin further admits that Lupin Pharmaceuticals, Inc., sells and

distributes generic drugs throughout the United States. Lupin further admits that Lupin Inc. prepared and submitted the Lupin ANDA to the FDA. Lupin denies that Lupin Ltd. and Lupin Pharmaceuticals, Inc., are proper parties to this action. Lupin denies any remaining allegations in this paragraph.

JURISDICTION

17. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 1391, 1400(b), 2201, and 2202.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that this action cites the patent laws of the United States generally. Lupin does not contest that this Court has jurisdiction over the subject matter of this action against Lupin Inc. for the purposes of the Asserted Patents in this action only. Lupin denies any remaining allegations in this paragraph.

18. This Court has personal jurisdiction over Padagis LLC because, among other things, it has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipated being hailed into court here. On information and belief, Padagis LLC is a limited liability company formed under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Padagis LLC develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transactions business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business within the State of Delaware.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

19. This Court has personal jurisdiction over Padagis US because, among other things, it has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipated being hailed into court here. On information and belief, Padagis US is a limited liability company formed under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief,

Padagis US develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the state of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business within the State of Delaware.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

20. Padagis Israel is subject to personal jurisdiction in Delaware because, among other things, Padagis Israel, itself and through itself and through its affiliates Padagis LLC and Padagis US, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being hailed into court here. On information and belief Padagis Israel, itself and through its affiliates Padagis LLC and Padagis US, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the state of Delaware, and/or has engaged in systemic and continuous business contacts within the State of Delaware.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

21. Padagis 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, including in an action within this judicial district. *See, e.g., Hikma Pharms. USA Inc. v. Padagis Israel Pharms. Ltd*., C.A. 1:23-cv-00654-GBW-SRF, Docket No. 11 at 38-39, Counterclaims ¶ 42 (Aug. 14, 2023). This Court has personal jurisdiction over Padagis because Padagis LLC, Padagis US, and Padagis Israel previously submitted to the jurisdiction of this Court. *See id*., D.I. 11 at 7, Answer to ¶ 11 (Aug. 14, 2023). Further, Padagis Israel availed itself of this Court by asserting counterclaims under the patent laws of the United States. *See id*., D.I. 11 at 32-56 (Counterclaims).

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

22. Alternatively, if Padagis Israel's connections with Delaware, including its connections with Padagis LLC and Padagis US, are found to be insufficient to confer personal jurisdiction then, on information and belief, exercising jurisdiction over Padagis Israel is proper

because: (a) Plaintiff's claims arise under federal law; (b) Padagis Israel is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Padagis Israel has sufficient contacts with the United States as a whole, including but not limited to manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Padagis Israel satisfies due process. Federal Rule of Civil Procedure 4(k)(2).

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

23. This Court has personal jurisdiction over Lupin Inc. because, among other things, it has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipated being hailed into court here. On information and belief, Lupin Inc is a corporation formed under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Lupin Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transactions business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business within the State of Delaware.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Lupin Inc. is a corporation organized and existing under the laws of the State of Delaware. Lupin further admits that Lupin Inc. prepared and submitted the Lupin ANDA to the FDA. Lupin does not contest that this Court has personal jurisdiction over Lupin Inc. for purposes of this action only. Lupin denies any remaining allegations in this paragraph.

24. This Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. because, among other things, it has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipated being hailed into court here. On information and belief, Lupin Pharmaceuticals, Inc. is a corporation formed under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Lupin Pharmaceuticals, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transactions business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business within the State of Delaware.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Lupin Pharmaceuticals, Inc., is a corporation organized and existing under the laws of the State of Delaware. Lupin further admits that Lupin Pharmaceuticals, Inc., sells and distributes generic drugs throughout the United States. Lupin denies that Lupin Pharmaceuticals, Inc., is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

25. Lupin Limited is subject to personal jurisdiction in Delaware because, among other things, Lupin Limited, itself and through itself and through its affiliate Lupin Pharmaceuticals, Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being hailed into court here. On information and belief Lupin Limited, itself and through its affiliate Lupin Pharmaceuticals, Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the state of Delaware, and/or has engaged in systemic and continuous business contacts within the State of Delaware.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Lupin Ltd. is an Indian corporation that is in the business of developing, preparing, and manufacturing generic drugs. Lupin denies that Lupin Ltd. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

26. Lupin Inc. 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, including in an action within this judicial district. *See, e.g., Neurocrine Biosciences, Inc., v. Lupin Limited et al*., C.A. No. 1:22-cv-01061-MN, D.I. 6 at 5, (Sep. 9, 2022). This Court has personal jurisdiction over Lupin Inc. because Lupin Inc. previously submitted to the jurisdiction of this Court. *See, e.g., Galderma Laboratories L.P. et al v. Lupin Inc. et al*., C.A. No. 1:21-cv-0710-SB, D.I. 10 at 12, (Feb. 7, 2022). Further, Lupin Limited availed itself of this Court by asserting counterclaims under the patent laws of the United States. *See id*., D.I. 10 at 12-19 (Counterclaims).

RESPONSE: Lupin admits that Lupin Inc. has not contested jurisdiction in this District in one or more prior cases arising from the filing of ANDAs and that it filed counterclaims in one

or more of those cases. Lupin does not contest that this Court has personal jurisdiction over Lupin Inc. for purposes of this action only. Lupin denies any remaining allegations in this paragraph.

27. Lupin Limited 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, including in an action within this judicial district. *See, e.g., Vertex Pharmaceuticals, Inc., v. Lupin Limited*., C.A. No. 1:25-cv-00450-RGA, D.I. 9 at 32, Counterclaims ¶ 37 (May 2, 2025). This Court has personal jurisdiction over Lupin Limited because Lupin Limited previously submitted to the jurisdiction of this Court. *See id*., D.I. 9 at 7, Answer to ¶¶ 23-24 (May 2, 2025). Further, Lupin Limited availed itself of this Court by asserting counterclaims under the patent laws of the United States. *See id*., D.I. 9 at 34-36 (Counterclaims).

RESPONSE: Lupin admits that Lupin Ltd. has not contested jurisdiction in this District in one or more prior cases arising from the filing of ANDAs and that it filed counterclaims in one or more of those cases. Lupin denies that Lupin Ltd. is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

28. Lupin Pharmaceuticals, Inc. 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, including in an action within this judicial district. *See, e.g., Vertex Pharmaceuticals, Inc., v. Lupin Limited*., C.A. No. 1:25-cv-00450-RGA, D.I. 9 at 32, Counterclaims ¶ 37 (May 2, 2025). This Court has personal jurisdiction over Pharmaceuticals, Inc. because Lupin Pharmaceuticals, Inc. previously submitted to the jurisdiction of this Court. *See id*., D.I. 9 at 7, Answer to ¶¶ 23-24 (May 2, 2025). Further, Lupin Pharmaceuticals, Inc. availed itself of this Court by asserting counterclaims under the patent laws of the United States. *See id*., D.I. 9 at 34-36 (Counterclaims).

RESPONSE: Lupin admits that Lupin Pharmaceuticals, Inc., has not contested jurisdiction in this District in one or more prior cases arising from the filing of ANDAs and that it filed counterclaims in one or more of those cases. Lupin denies that Lupin Pharmaceuticals, Inc., is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

29. Alternatively, if Lupin Limited's connections with Delaware, including its connection with Lupin Pharmaceuticals, Inc., are found to be insufficient to confer personal jurisdiction then, on information and belief, exercising jurisdiction over Lupin Limited is proper because: (a) Plaintiff's claims arise under federal law; (b) Lupin Limited is a foreign defendant

not subject to general personal jurisdiction in the courts of any state; and (c) Lupin Limited has sufficient contacts with the United States as a whole, including but not limited to manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Lupin Limited satisfies due process. Federal Rule of Civil Procedure 4(k)(2).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied. Lupin denies that Lupin Ltd. is a proper party to this action.

VENUE

30. Venue is proper in this district as to Padagis LLC pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, Padagis LLC is a limited liability company organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

31. Venue is proper in this district as to Padagis US pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, Padagis US is a limited liability company organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

32. Venue is proper in this district as to Padagis Israel because, *inter alia*, Padagis Israel is a company organized and existing under the laws of Israel, and as a nonresident Defendant, may be sued in this judicial district pursuant to 28 U.S.C. § 1391(c)(3).

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

33. Venue is proper in this district as to Lupin Inc. pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, Lupin Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin does not contest that venue is proper as to Lupin Inc. for the purposes of this action only. Lupin denies any remaining allegations in this paragraph.

34. Venue is proper in this district as to Lupin Pharmaceuticals, Inc. pursuant to 28 U.S.C. § 1400(b) because, *inter alia*, Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied. Lupin denies that Lupin Ltd. and Lupin Pharmaceuticals, Inc., are proper parties to this action.

35. Venue is proper in this district as to Lupin Limited because, *inter alia*, Lupin Limited is a company organized and existing under the laws of India, and as a nonresident Defendant, may be sued in this judicial district pursuant to 28 U.S.C. § 1391(c)(3).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied. Lupin denies that Lupin Ltd. and Lupin Pharmaceuticals, Inc., are proper parties to this action.

VALTOCO® AND THE PATENTS-IN-SUIT

36. Neurelis was founded in 2007 to develop, license, and commercialize novel drug product candidates that target the broader central nervous system ("CNS") with application in the fields of epilepsy and psychiatry.

RESPONSE: Lupin lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies those allegations.

37. Neurelis holds approved New Drug Application ("NDA") No. N211635, pursuant to which the FDA granted approval for the commercial manufacture, marketing, sale, and use of VALTOCO (diazepam nasal spray) (5 mg, 7.5 mg, or 10 mg of diazepam per 0.1 ml). VALTOCO is a prescription nasal spray rescue medicine used in the treatment of specific seizure activity in patients with epilepsy 2 years of age and older. Specifically, VALTOCO is indicated for the short-term treatment of "seizure clusters," or intermittent, stereotypic episodes of frequent seizure activity (*i.e.*, acute repetitive seizures) that are distinct from a patient's usual seizure pattern.

RESPONSE: Lupin admits that the FDA's website indicates that Neurelis is the holder of NDA No. N211635, pursuant to which the FDA granted approval for the commercial manufacture, marketing, sale, and use of VALTOCO®, 5 mg, 7.5 mg, or 10 mg of diazepam per 0.1 ml. Lupin denies any remaining allegations in this paragraph.

38. Neurelis is the owner of the '414 patent, titled "Administration of Benzodiazepine Compositions." The '414 patent was duly and legally issued on February 8, 2022. The '414 patent claims priority to a provisional application filed March 28, 2008. A true and correct copy of the '414 patent is attached hereto as Exhibit A.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Plaintiff purports to attach a copy of the '414 patent to the Complaint as Exhibit A. Lupin further admits that the face of the '414 patent indicates that it issued on February 8, 2022, and is titled "Administration of Benzodiazepine Compositions," but Lupin specifically denies that the patent was duly and legally issued. Lupin further admits that the face of '414 patent lists Neurelis, Inc., as an assignee. Lupin denies any remaining allegations in this paragraph.

39. The '414 patent discloses and claims, among other things, a pharmaceutical solution for nasal administration consisting of a benzodiazepine drug (including diazepam and pharmaceutically acceptable salts thereof), one or more tocopherols or tocotrienols, ethanol and benzyl alcohol, and n-dodecyl beta-D-maltoside.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

40. Neurelis is the owner of the '786 patent, titled "Administration of Benzodiazepine Compositions." The '786 patent was duly and legally issued on October 24, 2023. The '786 patent claims priority to a provisional application filed March 28, 2008. A true and correct copy of the '786 patent is attached hereto as Exhibit B.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Plaintiff purports to attach a copy of the '786 patent to the Complaint as Exhibit B. Lupin further admits that the face of the '786

patent indicates that it issued on October 24, 2023, and is titled "Administration of Benzodiazepine Compositions," but Lupin specifically denies that the patent was duly and legally issued. Lupin further admits that the face of '786 patent lists Neurelis, Inc., as an assignee. Lupin denies any remaining allegations in this paragraph.

41. The '786 patent discloses and claims, among other things, a pharmaceutical solution for nasal administration consisting of a benzodiazepine drug (including diazepam and pharmaceutically acceptable salts thereof), one or more tocopherols or tocotrienols, one or more alcohols, and n-dodecyl beta-D-maltoside.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

42. Neurelis is the owner of the '664 patent, titled "Administration of Benzodiazepine Compositions." The '664 patent was duly and legally issued on April 8, 2025. The '664 patent claims priority to a provisional application filed March 28, 2008. A true and correct copy of the '664 patent is attached hereto as Exhibit C.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Lupin admits that Plaintiff purports to attach a copy of the '664 patent to the Complaint as Exhibit C. Lupin further admits that the face of the '664 patent indicates that it issued on April 8, 2025, and is titled "Administration of Benzodiazepine Compositions," but Lupin specifically denies that the patent was duly and legally issued. Lupin further admits that the face of '664 patent lists Neurelis, Inc., as an assignee. Lupin denies any remaining allegations in this paragraph.

43. The '664 patent discloses and claims, among other things, a pharmaceutical solution for nasal administration consisting of a benzodiazepine drug (including diazepam and pharmaceutically acceptable salts thereof), one or more tocopherols or tocotrienols, one or more alcohols, and dodecyl beta-D-maltoside.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

44. Pursuant to 21 U.S.C. § 355(b)(1), Neurelis previously submitted information concerning the '414, '786, and '664 patents to the FDA in connection with NDA No. N211635,

identifying each as a patent covering VALTOCO. The '414, '786, and '664 patents have been listed (along with other patents) in the FDA publication "Approved Drug Products with Therapeutic Equivalents Evaluations" (commonly known as the "Orange Book") as covering VALTOCO.

RESPONSE: Lupin admits that the Orange Book currently lists, among others, the '414, '786, and '664 patents in connection with NDA No. 211635 for Valtoco. Lupin denies any remaining allegations in this paragraph.

45. The Orange Book lists the expiration date for the Asserted Patents as March 27, 2029.

RESPONSE: Lupin admits that the Orange Book currently lists the Patent Expiration for the '414, '786, and '664 patents as March 27, 2029. Lupin denies any remaining allegations in this paragraph.

PADAGIS'S ANDA NO. 219320 AND NOTICE LETTERS

46. Padagis first notified Neurelis by letter dated March 26, 2024 (the "First Padagis Notice Letter") that it had submitted ANDA No. 219320 (the "Padagis ANDA") to the FDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use or sell a generic version of VALTOCO (diazepam nasal spray), 10 mg diazepam/spray (the "Padagis ANDA Product") prior to the expiration of the '546, '414 and '786 patents. The First Padagis Notice Letter informed Neurelis that Padagis's ANDA contained a "Paragraph IV Certification" alleging that the claims of the '546, '414 and '786 patents are invalid, not enforceable, and/or not infringed by the Padagis ANDA Product.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

47. The First Padagis Notice Letter was sent on behalf of Padagis Israel, executed by the Vice President of Legal Affairs at Padagis US (Landon R. Clark), and provided Padagis US as an agent authorized to accept service of process.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

48. In response to the First Padagis Notice Letter, Neurelis commenced the Padagis I Action within forty-five (45) days of Neurelis's receipt of the First Padagis Notice Letter. Accordingly, Neurelis is entitled to a 30-month stay of FDA approval pursuant to 21 U.S.C. §§ 355(j)(5)(B)(iii) and 355(j)(5)(F)(ii).

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

49. Padagis notified Neurelis by letter dated May 21, 2025 (the "Second Padagis Notice Letter") that it had submitted the Padagis ANDA to the FDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use or sell the Padagis ANDA Product prior to the expiration of the '664 patent. The Second Padagis Notice Letter informed Neurelis that Padagis's ANDA contained a "Paragraph IV Certification" alleging that the claims of the '664 patent are invalid, not enforceable, and/or not infringed by the Padagis ANDA Product.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

50. The Second Padagis Notice Letter was sent on behalf of Padagis Israel, executed by the Vice President of Legal Affairs at Padagis US (Landon R. Clark), and provided Padagis US as an agent authorized to accept service of process.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

51. On information and belief, Padagis's ANDA has not yet been approved by the FDA.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

LUPIN'S ANDA NO. 220394 AND NOTICE LETTER

52. Lupin notified Neurelis by letter dated May 27, 2025 (the "Lupin Notice Letter") that it had submitted ANDA No. 220394 (the "Lupin ANDA") to the FDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use or sell a generic version of VALTOCO (diazepam nasal spray), 5 mg/spray, 7.5 mg/spray, and 10 mg/spray (the "Lupin ANDA Products") prior to the expiration of the '546, '414, '786, and '664 patents. The Lupin Notice Letter informed Neurelis that Lupin's ANDA contained a "Paragraph IV Certification" alleging that the claims of the '546, '414, '786, and '664 patents are invalid, not enforceable, and/or not infringed by the Lupin ANDA Products.

RESPONSE: Lupin admits that Lupin Inc. sent a notification of certification letter to, among others, Neurelis on or about May 27, 2025. Lupin further admits that the letter provided written notice of Lupin Inc.'s ANDA and Paragraph IV Certifications and included a statement of the factual and legal bases for stating that at least the Asserted Patents are invalid, unenforceable, and/or will not be infringed by Lupin's ANDA Product. Lupin further admits that the letter informed Neurelis that Lupin Inc. seeks approval of Lupin's ANDA Product before the Asserted Patents expire. Lupin denies any remaining allegations in this paragraph.

53. The Lupin Notice Letter was sent on behalf of Lupin Inc., executed by Deepro Mukerjee, and provided Deepro Mukerjee as an agent authorized to accept service of process.

RESPONSE: Lupin admits Lupin Inc.'s notice of certification was sent on behalf of Lupin Inc., signed by outside counsel Deepro R. Mukerjee, and provided the name and address of the agent in the United States authorized to accept service of process for Lupin Inc., limited to commencement of a patent infringement suit based on the notification of certification, as Deepro R. Mukerjee.

54. On information and belief, Padagis's ANDA has not yet been approved by the FDA.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

55. This action is being filed within forty-five (45) days of Neurelis's receipt of the Lupin Notice Letter. Accordingly, Neurelis is entitled to a 30-month stay of FDA approval pursuant to 21 U.S.C. §§ 355(j)(5)(B)(iii) and 355(j)(5)(F)(ii).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

COUNT I
INFRINGEMENT OF THE '664 PATENT AGAINST ALL DEFENDANTS

56. Neurelis re-alleges paragraphs 1-55 as if fully set forth herein.

RESPONSE: Lupin repeats and reincorporates by reference its answers to the preceding paragraphs as if fully set forth herein.

57. Padagis submitted the Padagis ANDA to the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, or sale of Padagis's ANDA Product prior to the expiration of the '664 patent. By submitting the Padagis ANDA, Padagis has infringed claims 1-18 of the '664 patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

58. Lupin submitted the Lupin ANDA to the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, or sale of Lupin's ANDA Products prior to the expiration of the '664 patent. By submitting the Lupin ANDA, Lupin has infringed claims 1-18 of the '664 patent under 35 U.S.C. § 271(e)(2)(A).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

59. Claim 1 of the '664 patent provides:

1. A pharmaceutical composition for intranasal administration comprising:

> about 1 to about 20 mg of diazepam dissolved in about 45% to about 85% (w/w) of one or more natural or synthetic tocopherols or tocotrienols selected from the group consisting of: α-tocopherol, β-tocopherol, γ-tocopherol, δ-tocopherol, α-tocotrienol, β-tocotrienol, γ-tocotrienol, δ-tocotrienol, tocophersolan, any esters thereof and any combinations thereof, and about 25% to about 40% (w/w) of one or more alcohols selected from the group consisting of ethanol, propyl alcohol, butyl alcohol, pentanol, benzyl alcohol, and any combinations thereof, and about 0.01% to about 1% (w/v) of dodecyl β-D-maltoside, wherein the pharmaceutical composition is a solution and contains less than 1% water, wherein the pharmaceutical composition is in a pharmaceutically-acceptable spray formulation.

RESPONSE: Lupin admits the claim 1 of the '664 patent is represented by this paragraph. Lupin denies any remaining allegations in this paragraph.

60. By reason of the Second Padagis Notice Letter and the contents thereof, Neurelis is informed and believes and thereon alleges that Padagis's ANDA and ANDA Product literally or through the doctrine of equivalents infringe the claims of the '664 patent. More specifically, Padagis's ANDA and ANDA Product satisfies at least each of the aforementioned claim limitations exemplified in Claim 1 of the '664 patent and/or their equivalents.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

61. On information and belief, immediately upon the FDA's approval of ANDA No. 219320, Padagis intends to, and will, manufacture, use, sell and/or offer to sell the Padagis ANDA Product throughout the United States, and any such commercial activities will directly infringe the '664 patent under 35 U.S.C. § 271(a), will actively induce infringement of the '664 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '664 patent under 35 U.S.C. § 271(c).

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

62. On information and belief, Padagis has acted with full knowledge of the '664 patent and its claims and without a reasonable basis for believing that it would not be liable for direct, indirect, induced and/or contributory infringement of the '664 patent. Notwithstanding this knowledge, Padagis has asserted its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Padagis's ANDA Product immediately and

imminently upon approval of the Padagis ANDA. Through such activities, Padagis specifically intends infringement of the '664 patent.

RESPONSE: This paragraph contains allegations specific to one or more Padagis entities, which require no response by Lupin. To the extent a response is required, Lupin denies the allegations in this paragraph.

63. By reason of the Lupin Notice Letter and the contents thereof, Neurelis is informed and believes and thereon alleges that Lupin's ANDA and ANDA Products literally or through the doctrine of equivalents infringe the claims of the '664 patent. More specifically, Lupin's ANDA and ANDA Product satisfies at least each of the aforementioned claim limitations exemplified in Claim 1 of the '664 patent and/or their equivalents.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

64. On information and belief, immediately upon the FDA's approval of ANDA No. 220394, Lupin intends to, and will, manufacture, use, sell and/or offer to sell the Lupin ANDA Products throughout the United States, and any such commercial activities will directly infringe the '664 patent under 35 U.S.C. § 271(a), will actively induce infringement of the '664 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '664 patent under 35 U.S.C. § 271(c).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

65. On information and belief, Lupin has acted with full knowledge of the '664 patent and its claims and without a reasonable basis for believing that it would not be liable for direct, indirect, induced and/or contributory infringement of the '664 patent. Notwithstanding this knowledge, Lupin has asserted its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Lupin's ANDA Products immediately and imminently upon approval of the Lupin ANDA. Through such activities, Lupin specifically intends infringement of the '664 patent.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

66. As a result of the foregoing, Neurelis will be substantially and irreparably harmed if Defendants' infringement of the '664 patent is not enjoined. Neurelis does not have an adequate remedy at law.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

67. As a result of the foregoing, Neurelis is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Defendants' ANDAs be a date which is not earlier than the expiration date of the '664 patent, or the date of any later expiration or exclusivity to which Neurelis is or becomes entitled.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

COUNT II
INFRINGEMENT OF THE '414 PATENT AGAINST THE LUPIN DEFENDANTS

68. Neurelis re-alleges paragraphs 1-67 as if fully set forth herein.

RESPONSE: Lupin repeats and reincorporates by reference its answers to the preceding paragraphs as if fully set forth herein.

69. Lupin submitted the Lupin ANDA to the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, or sale of Lupin's ANDA Products prior to the expiration of the '414 patent. By submitting the Lupin ANDA, Lupin has infringed at least claims 1-3; 5-13; and 15-18 under 35 U.S.C. § 271(e)(2)(A).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

70. Claim 1 of the '414 patent provides:

> 1. A pharmaceutical solution for nasal administration consisting of:
>
> diazepam or a pharmaceutically acceptable salt thereof;
>
> one or more natural or synthetic tocopherols or tocotrienols, or any combinations thereof, in an amount from 30% to 95% (w/w);
>
> ethanol and benzyl alcohol in a combined amount from 10% to 70% (w/w); and
>
> n-dodecyl beta-D-maltoside.

RESPONSE: Lupin admits the claim 1 of the '414 patent is represented by this paragraph. Lupin denies any remaining allegations in this paragraph.

71. By reason of the Lupin Notice Letter and the contents thereof, Neurelis is informed and believes and thereon alleges that the Lupin's ANDA and ANDA Products literally or through the doctrine of equivalents infringe the claims of the '414 patent. More specifically, Lupin's ANDA and ANDA Products satisfy at least each of the aforementioned claim limitations exemplified in Claim 1 of the '414 patent and/or their equivalents.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

72. On information and belief, immediately upon the FDA's approval of ANDA No. 220394, Lupin intends to, and will, manufacture, use, sell and/or offer to sell the Lupin ANDA Products throughout the United States, and any such commercial activities will directly infringe the '414 patent under 35 U.S.C. § 271(a), will actively induce infringement of the '414 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '414 patent under 35 U.S.C. § 271(c).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

73. On information and belief, Lupin has acted with full knowledge of the '414 patent and its claims and without a reasonable basis for believing that it would not be liable for direct, indirect, induced, and/or contributory infringement of the '414 patent. Notwithstanding this knowledge, Lupin has asserted its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Lupin's ANDA Products immediately and imminently upon approval of the Lupin ANDA. Through such activities, Lupin specifically intends infringement of the '414 patent.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

74. As a result of the foregoing, Neurelis will be substantially and irreparably harmed if Lupin's infringement of the '414 patent is not enjoined. Neurelis does not have an adequate remedy at law.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

75. As a result of the foregoing, Neurelis is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Lupin

ANDA be a date which is not earlier than the expiration date of the '414 patent, or the date of any later expiration or exclusivity to which Neurelis is or becomes entitled.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

COUNT III
INFRINGEMENT OF THE '786 PATENT AGAINST THE LUPIN DEFENDANTS

76. Neurelis re-alleges paragraphs 1-75 as if fully set forth herein.

RESPONSE: Lupin repeats and reincorporates by reference its answers to the preceding paragraphs as if fully set forth herein.

77. Lupin submitted the Lupin ANDA to the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, or sale of Lupin's ANDA Products prior to the expiration of the '786 patent. By submitting the Lupin ANDA, Lupin has infringed at least claims 1-3; 5-9; 11-13; and 15-27 under 35 U.S.C. § 271(e)(2)(A).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

78. Claim 1 of the '786 patent provides:

> 1. A pharmaceutical solution for nasal administration consisting of:
>
> a therapeutically effective amount of diazepam or a pharmaceutically acceptable salt thereof;
>
> one or more natural or synthetic tocopherols or tocotrienols selected from the group consisting of α-tocopherol, 3-tocopherol, γ-tocopherol, δ-tocopherol, α-tocotrienol, 3-tocotrienol, γ-tocotrienol, δ-tocotrienol, tocophersolan, any isomers thereof, any esters thereof, and any combinations thereof, in an amount from 30% to 95% (w/w); one or more alcohols in an amount from 10% to 70% (w/w), wherein the one or more alcohols comprises benzyl alcohol; and
>
> n-dodecyl beta-D-maltoside.

RESPONSE: Lupin admits the claim 1 of the '786 patent is represented by this paragraph. Lupin denies any remaining allegations in this paragraph.

79. By reason of the Lupin Notice Letter and the contents thereof, Neurelis is informed and believes and thereon alleges that the Lupin's ANDA and ANDA Products literally or through

the doctrine of equivalents infringe the claims of the '786 patent. More specifically, Lupin's ANDA and ANDA Products satisfy at least each of the aforementioned claim limitations exemplified in Claim 1 of the '786 patent and/or their equivalents.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

80. On information and belief, immediately upon the FDA's approval of ANDA No. 220394, Lupin intends to, and will, manufacture, use, sell and/or offer to sell the Lupin ANDA Products throughout the United States, and any such commercial activities will directly infringe the '786 patent under 35 U.S.C. § 271(a), will actively induce infringement of the '786 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '786 patent under 35 U.S.C. § 271(c).

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

81. On information and belief, Lupin has acted with full knowledge of the '786 patent and its claims and without a reasonable basis for believing that it would not be liable for direct, indirect, induced, and/or contributory infringement of the '786 patent. Notwithstanding this knowledge, Lupin has asserted its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Lupin's ANDA Products immediately and imminently upon approval of the Lupin ANDA. Through such activities, Lupin specifically intends infringement of the '786 patent.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

82. As a result of the foregoing, Neurelis will be substantially and irreparably harmed if Lupin's infringement of the '786 patent is not enjoined. Neurelis does not have an adequate remedy at law.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

83. As a result of the foregoing, Neurelis is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Lupin ANDA be a date which is not earlier than the expiration date of the '786 patent, or the date of any later expiration or exclusivity to which Neurelis is or becomes entitled.

RESPONSE: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, denied.

PRAYER FOR RELIEF

Lupin denies that Plaintiff is entitled to any of the relief requested in its Prayer for Relief or to any relief whatsoever, including the relief specifically requested against Lupin.

LUPIN'S AFFIRMATIVE DEFENSES

Further answering the Complaint, Lupin asserts the following defenses in response to the allegations of the Complaint, undertaking the burden of proof only as to those defenses required by law, regardless of how such defenses are denominated below. Lupin reserves the right to amend this Answer with additional defenses as further information is obtained in discovery. Lupin asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted.

FIRST AFFIRMATIVE DEFENSE
(Invalidity)

The Asserted Patents and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially

created requirements for patentability and enforceability and/or in view of the defenses recognized in 35 U.S.C. § 282..

SECOND AFFIRMATIVE DEFENSE
(No Direct Infringement)

Lupin does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the Asserted Patents. If the product that is the subject of Lupin's ANDA were marketed, Lupin would not infringe any valid and enforceable claim of the Asserted Patents.

THIRD AFFIRMATIVE DEFENSE
(No Indirect Infringement)

Lupin has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Asserted Patents (either literally or under the doctrine of equivalents). If the product that is the subject of Lupin's ANDA were marketed, Lupin would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Asserted Patents.

FOURTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim for relief against Lupin.

FIFTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim for relief against Lupin for an exceptional case under 35 U.S.C. § 285.

SIXTH AFFIRMATIVE DEFENSE

Lupin has not willfully infringed any claim of the Asserted Patents.

SEVENTH AFFIRMATIVE DEFENSE

Lupin Pharmaceuticals, Inc. is not a proper party to this action.

EIGHTH AFFIRMATIVE DEFENSE

Lupin Ltd. is not a proper party to this action.

NINTH AFFIRMATIVE DEFENSE

Any additional defenses that discovery may reveal.

WHEREFORE, Lupin respectfully requests that Plaintiff take nothing by way of its Complaint, that judgment be entered in favor of Lupin, and that Lupin be awarded its attorneys' fees and costs and all other just and proper relief.

LUPIN INC.'S COUNTERCLAIMS FOR DECLARATORY JUDGMENT

For its counterclaims against Neurelis, Inc. ("Counterclaim Defendant" or "Neurelis"), Defendant Lupin Inc. ("Counterclaim Plaintiff" or "Lupin Inc.") states as follows:

PARTIES

1. Upon information and belief, Neurelis is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3430 Carmel Mountain Road, Suite 300, San Diego, California 92121.

2. Lupin Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 111 South Calvert Street, 21st Floor, Baltimore, Maryland.

JURISDICTION AND VENUE

3. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

4. This Court has personal jurisdiction over Counterclaim Defendant on the basis of, *inter alia*, its contacts with Delaware relating to the subject matter of this action, including having filed suit.

BACKGROUND

5. Upon information and belief, Neurelis holds approved New Drug Application ("NDA") No. 211635 for Valtoco® (diazepam nasal spray) (5 mg, 7.5 mg, or 10 mg of diazepam per 0.1 ml).

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

7. Upon approval of the NDA, the U.S. Food and Drug Administration ("FDA") publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

8. U.S. Patent No. 11,241,414 (the "'414 patent"), titled "Administration of Benzodiazepine Compositions," issued on February 8, 2022. A copy of the '414 patent is attached to the Complaint as Exhibit A.

9. U.S. Patent No. 11,793,786 (the "'786 patent"), titled "Administration of Benzodiazepine Compositions," issued on October 24, 2023. A copy of the '786 patent is attached to the Complaint as Exhibit B.

10. U.S. Patent No. 12,268,664 (the "'664 patent"), titled "Administration of Benzodiazepine Compositions," issued on April 8, 2025. A copy of the '664 patent is attached to the Complaint as Exhibit C.

11. Upon information and belief, Neurelis is the assignee of the '414 patent, '786 patent, and '664 patent (collectively, "the Asserted Patents").

12. Upon information and belief, Neurelis caused the Asserted Patents to be listed in the Orange Book as patents that purportedly cover NDA No. 211635 for Valtoco.

13. Lupin Inc. submitted Abbreviated New Drug Application ("ANDA") No. 220394 to obtain FDA approval of diazepam nasal spray (5 mg/Spray, 7.5 mg/Spray, and 10 mg/Spray) ("Lupin's ANDA Product") prior to the expirations of the Asserted Patents.

14. Lupin Inc.'s ANDA No. 220394 contains "Paragraph IV" certifications under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the Asserted Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Lupin Inc.'s ANDA Product.

15. On July 2, 2025, Counterclaim Defendant filed the instant lawsuit alleging infringement of the Asserted Patents.

COUNT I
(Declaratory Judgment of Non-Infringement of the '414 Patent)

16. Lupin Inc. realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

17. Neurelis alleges ownership of the '414 patent, and Neurelis has brought claims against Lupin Inc. alleging infringement of the '414 patent.

18. The manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin Inc.'s ANDA Product would not infringe any valid or enforceable claim of the '414 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

19. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin Inc.'s ANDA No. 220394 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin Inc.'s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '414 patent.

20. Lupin Inc. has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '414 patent and is not liable for such infringement.

21. Lupin Inc. is entitled to a declaration that the manufacture, use, or sale of its ANDA Product would not infringe any valid or enforceable claim of the '414 patent.

COUNT II
(Declaratory Judgment of Invalidity of the '414 Patent)

22. Lupin Inc. realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

23. Neurelis alleges ownership of the '414 patent, and Neurelis has brought claims against Lupin Inc. alleging infringement of the '414 patent.

24. One of more claims of the '414 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability and/or in view of the defenses recognized in 35 U.S.C. § 282.

25. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin Inc.'s ANDA No. 220394 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin Inc.'s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '414 patent.

26. Lupin Inc. is entitled to a declaration that all claims of the '414 patent are invalid.

COUNT III
(Declaratory Judgment of Non-Infringement of the '786 Patent)

27. Lupin Inc. realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

28. Neurelis alleges ownership of the ’786 patent, and Neurelis has brought claims against Lupin Inc. alleging infringement of the ’786 patent.

29. The manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin Inc.’s ANDA Product would not infringe any valid or enforceable claim of the ’786 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

30. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin Inc.’s ANDA No. 220394 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin Inc.’s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the ’786 patent.

31. Lupin Inc. has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’786 patent and is not liable for such infringement.

32. Lupin Inc. is entitled to a declaration that the manufacture, use, or sale of its ANDA Product would not infringe any valid or enforceable claim of the ’786 patent.

COUNT IV
(Declaratory Judgment of Invalidity of the ’786 Patent)

33. Lupin Inc. realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

34. Neurelis alleges ownership of the ’786 patent, and Neurelis has brought claims against Lupin Inc. alleging infringement of the ’786 patent.

35. One of more claims of the ’786 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability and/or in view of the defenses recognized in 35 U.S.C. § 282.

36. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin Inc.'s ANDA No. 220394 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin Inc.'s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '786 patent.

37. Lupin Inc. is entitled to a declaration that all claims of the '786 patent are invalid.

COUNT V
(Declaratory Judgment of Non-Infringement of the '664 Patent)

38. Lupin Inc. realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

39. Neurelis alleges ownership of the '664 patent, and Neurelis has brought claims against Lupin Inc. alleging infringement of the '664 patent.

40. The manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin Inc.'s ANDA Product would not infringe any valid or enforceable claim of the '664 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

41. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin Inc.'s ANDA No. 220394 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin Inc.'s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '664 patent.

42. Lupin Inc. has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '664 patent and is not liable for such infringement.

43. Lupin Inc. is entitled to a declaration that the manufacture, use, or sale of its ANDA Product would not infringe any valid or enforceable claim of the '664 patent.

COUNT VI
(Declaratory Judgment of Invalidity of the '664 Patent)

44. Lupin Inc. realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

45. Neurelis alleges ownership of the '664 patent, and Neurelis has brought claims against Lupin Inc. alleging infringement of the '664 patent.

46. One of more claims of the '664 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting and/or any other judicially created requirements for patentability and enforceability and/or in view of the defenses recognized in 35 U.S.C. § 282.

47. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin Inc.'s ANDA No. 220394 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin Inc.'s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '664 patent.

48. Lupin Inc. is entitled to a declaration that all claims of the '664 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Lupin Inc. requests judgment in its favor and against Counterclaim Defendant as follows:

a. That the Court order the Complaint dismissed with prejudice and judgment be entered in favor of Lupin Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc.;

b. Declaring that all claims of the Asserted Patents are invalid;

c. Declaring that the filing of Lupin Inc.'s ANDA No. 220394 has not, does not, and will not directly or indirectly infringe (literally or under the doctrine of equivalents) any valid and enforceable claim of the Asserted Patents;

d. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin Inc.'s ANDA Product does not, and would not, if marketed, directly or indirectly infringe (literally or under the doctrine of equivalents) any valid and enforceable claim of the Asserted Patents;

e. Declaring this an exceptional case in favor of Lupin Inc. and awarding its attorneys' fees pursuant to 35 U.S.C. § 285;

f. Awarding costs and expenses; and

g. Awarding any and all such other relief as the Court determines to be just and proper.

Dated: August 1, 2025

/s/ Kenneth L. Dorsney

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