IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEURELIS, INC., *Plaintiff/Counterclaim Defendant*, v. PADAGIS LLC, PADAGIS US LLC and PADAGIS ISRAEL PHARMACEUTICALS LTD., *Defendants/Counterclaim Plaintiffs*.	C.A. No. 1:25-cv-01228-MN

PADAGIS' ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT

Defendants Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC (collectively, "Padagis") submit this Answer and Counterclaims in response to the Complaint for Patent Infringement of Plaintiff Neurelis, Inc. ("Neurelis" or "Plaintiff"). Padagis denies all allegations in Plaintiff's Complaint except those expressly admitted below. This pleading is based upon Padagis' knowledge of its own activities, and upon information and belief as to the activities of others.

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 12,324,852 (the "'852 patent") and 12,337,061 (the "'061 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 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 (the "Padagis ANDA Product").

[1] Two prior, related cases entitled *Neurelis, Inc. v. Padagis LLC*, C.A. No. 1:24-cv-00562-MN (the "Padagis I Action") and *Neurelis, Inc. v. Padagis LLC, et. al.*, C.A. No. 1:25-cv-00821-MN (the "Padagis II Action") were filed in this Court on May 8, 2024 and July 2, 2025, respectively. The Padagis I Action alleges infringement of U.S. Patent Nos. 11,241,414 (the "'414 patent"),

ANSWER: Padagis admits that the Complaint purports to state an action against Padagis for alleged infringement of U.S. Patent Nos. 12,324,852 (the "'852 patent") and 12,337,061 (the "'061 patent") (collectively "the Asserted Patents") under the patent laws of the United States, Title 35, United States Code, but Padagis denies the allegations have any merit. Padagis further admits that it filed Abbreviated New Drug Application ("ANDA") No. 219320 (the "Padagis ANDA") seeking regulatory approval to market its proposed generic benzodiazepine drug product (the "Padagis ANDA Product"). Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the Padagis ANDA. Footnote 1 of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Padagis admits the Padagis I and Padagis II Actions were filed on May 8, 2024 and July 2, 2025, respectively, are related to this Complaint, and remain pending. Padagis denies the remaining allegations of this paragraph.

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.

ANSWER: Padagis lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same.

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.

11,793,786 (the "'786 patent"), and 8,895,546 (the "'546 Patent") and the Padagis II Action alleges infringement of U.S. Patent No. 12,268,664 (the "'664 Patent"). Those infringement claims remain pending against Padagis and are not repeated herein. Pursuant to L.R. 3.1, the Civil Cover Sheet accompanying this Complaint indicates that the Padagis I and II Actions are Related Actions.

ANSWER: Padagis admits that Padagis Israel Pharmaceuticals Ltd. is a company organized and existing under the laws of Israel with a place of business at 1 Rakefet Street, Shoham, Israel 608500.

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.

ANSWER: Padagis admits that Padagis LLC is a limited liability company organized and existing under the laws of the State of Delaware with a place of business at 1251 Lincoln Road, Allegan, Michigan 49010-9706.

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.

ANSWER: Padagis admits that Padagis US LLC is a limited liability company organized and existing under the laws of the State of Delaware with a place of business at 1251 Lincoln Road, Allegan, Michigan 49010-9706.

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

ANSWER: Padagis admits that Padagis Israel and Padagis US are wholly-owned subsidiaries of Padagis LLC.

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

ANSWER: Padagis admits that Padagis Israel and Padagis US are wholly-owned subsidiaries of Padagis LLC. Padagis denies the remaining allegations of 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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis denies the allegations of 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.

ANSWER: Padagis admits that Padagis Israel Pharmaceuticals Ltd. prepared and submitted the Padagis ANDA. The remaining allegations of this paragraph state legal conclusions to which no response is required. To the extent a response is required, Padagis denies the allegations of this paragraph.

JURISDICTION

10. 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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis admits that this Court has subject-matter jurisdiction only over claims asserted against it under 35 U.S.C. § 271(e)(2)(A). Padagis denies that this Court has subject-matter jurisdiction over any other asserted claims. Padagis denies any remaining allegations of this paragraph.

11. 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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest this Court exercising personal

jurisdiction over it for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

12. 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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest this Court exercising personal jurisdiction over it for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

13. 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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest this Court exercising personal jurisdiction over it for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

14. 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). Still further, all three Padagis entities have submitted to the jurisdiction of this Court in the two Related Actions. *See, supra* n. 1 (Padagis I & II Actions).

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis admits that it has consented to personal jurisdiction in this Court for the limited purposes of those actions and has filed counterclaims in this Court. Padagis does not contest this Court exercising personal jurisdiction over it for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

15. 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).

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest this Court exercising personal jurisdiction over it for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

VENUE

16. 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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest venue for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

17. 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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest venue for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

18. 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).

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis does not contest venue for purposes of this action only. Padagis denies any remaining allegations of this paragraph.

19. Further, Padagis has not contested venue in this district before this Court in the two Related Actions. *See, supra* n. 1 (Padagis I & II Actions).

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, admits it did not contest venue in this district for purposes of the Related Actions only. Padagis denies any remaining allegations of this paragraph.

VALTOCO® AND THE PATENTS-IN-SUIT

20. 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.

ANSWER: Padagis lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies the same.

21. 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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis lacks knowledge or information sufficient to form a belief as to the truth of the allegations concerning ownership of New Drug Application ("NDA")

No. 211635, and therefore denies the same. Padagis admits that the FDA's website indicates that Neurelis is the holder of NDA No. 211635, 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. Padagis denies any remaining allegations of this paragraph.

22. Neurelis is the owner of the '852 patent, titled "Administration of Benzodiazepine Compositions." The '852 patent was duly and legally issued on June 10, 2025. The '852 patent claims priority to provisional applications filed June 14, 2011, and December 13, 2011. A true and correct copy of the '852 patent is attached hereto as Exhibit A.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis admits that a copy of what purports to be the '852 patent is attached to the Complaint as Exhibit A. Padagis states that the '852 patent speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the patent. Padagis denies any remaining allegations of this paragraph.

23. The '852 patent discloses and claims, among other things, a method of treating bouts of intermittent and stereotypic episodes of increased seizure activity in an epilepsy patient that is distinguishable from other seizures suffered by the patient by administering 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 dodecyl maltoside.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis states that the '852 patent speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the patent. Padagis denies any remaining allegations of this paragraph.

24. Neurelis is the owner of the '061 patent, titled "Administration of Benzodiazepine Compositions." The '061 patent was duly and legally issued on June 24, 2025. The '061 patent claims priority to provisional applications filed June 14, 2011, and December 13, 2011. A true and correct copy of the '061 patent is attached hereto as Exhibit B.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis admits that a copy of what purports to be the ’061 patent is attached to the Complaint as Exhibit B. Padagis states that the ’061 patent speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the patent. Padagis denies any remaining allegations of this paragraph.

25. The ’061 patent discloses and claims, among other things, a method of treating bouts of intermittent and stereotypic episodes of increased seizure activity in an epilepsy patient that is distinguishable from other seizures suffered by the patient by administering a pharmaceutical solution for nasal administration consisting of 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, ethanol, and dodecyl maltoside.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis states that the ’061 patent speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the patent. Padagis denies any remaining allegations of this paragraph.

26. Pursuant to 21 U.S.C. § 355(b)(1), Neurelis previously submitted information concerning the ’852 and ’061 patents to the FDA in connection with NDA No. N211635, identifying each as a patent covering VALTOCO. The ’852 and ’061 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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis admits that the Asserted Patents are listed in the Orange Book for VALTOCO®. Padagis denies any remaining allegations of this paragraph.

27. The Orange Book lists the expiration date for the ’852 patent as October 16, 2032 and June 13, 2032, for the ’061 patent.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis admits that the Orange Book ostensibly lists an expiration

date for the ’852 patent as October 16, 2032 and an expiration date for the ’061 patent as June 13, 2032. Padagis denies any remaining allegations of this paragraph.

PADAGIS’S ANDA NO. 219320 AND NOTICE LETTERS

28. 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.

ANSWER: Padagis admits that it sent written notice of Paragraph IV Certifications dated March 26, 2024 (the “First Padagis Notice Letter”) to Neurelis. Padagis admits that it submitted the Padagis ANDA to the FDA seeking regulatory approval to market the Padagis ANDA Product as described therein. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the Padagis ANDA. Padagis denies any remaining allegations of this paragraph.

29. 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.

ANSWER: Admitted.

30. 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)(i).

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis admits that Padagis sent the First Padagis Notice Letter on March 26, 2024, and that Neurelis filed the Padagis I Action on May 8, 2024. Padagis denies any remaining allegations of this paragraph.

31. 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.

ANSWER: Padagis admits that it sent written notice of a Paragraph IV Certification dated May 21, 2025 (the "Second Padagis Notice Letter") to Neurelis. Padagis admits that it filed the Padagis ANDA seeking regulatory approval to market the Padagis ANDA Product as described therein. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the Padagis ANDA. Padagis denies any remaining allegations of this paragraph.

32. 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.

ANSWER: Admitted.

33. Padagis notified Neurelis by letter dated September 2, 2025 (the "Third 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 '852 patent and the '061 patent. The Third Padagis Notice Letter informed Neurelis that Padagis's ANDA contained a "Paragraph IV Certification" alleging that the claims of the '852 and '061 patents are invalid, not enforceable, and/or not infringed by the Padagis ANDA Product.

ANSWER: Padagis admits that it sent written notice of Paragraph IV Certifications dated September 2, 2025 (the "Third Padagis Notice Letter") to Neurelis. Padagis admits that it filed the Padagis ANDA seeking regulatory approval to market the Padagis ANDA Product as described therein. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the Padagis ANDA. Padagis denies any remaining allegations of this paragraph.

34. The Third Padagis Notice Letter was sent on behalf of Padagis Israel, executed by the Litigation and IP Counsel at Padagis US (Andrew Spitzer), and provided Padagis US as an agent authorized to accept service of process.

ANSWER: Admitted.

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

ANSWER: Admitted.

COUNT I
INFRINGEMENT OF THE '852 PATENT

36. Neurelis re-alleges paragraphs 1-35 as if fully set forth herein.

ANSWER: Padagis repeats and incorporates by reference its responses to the foregoing paragraphs as if fully stated herein.

37. 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 '852 patent. By submitting the Padagis ANDA, Padagis has infringed claims 1-31 of the '852 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Padagis admits that it submitted the Padagis ANDA to the FDA. Padagis denies the remaining allegations of this paragraph at least because the Third Padagis Notice Letter sets forth why the claims of the Asserted Patents are invalid, and an invalid claim cannot be infringed. Padagis further states that there is no requirement under 21 U.S.C. § 355(j) or any related regulations requiring an ANDA applicant to set forth each and every reason why a patent listed in the Orange Book may be invalid, unenforceable, or not infringed. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the Padagis ANDA. Padagis denies any remaining allegations of this paragraph.

38. Claim 1 of the '852 patent provides:

> 1. A method of treating bouts of intermittent and stereotypic episodes of increased seizure activity in an epilepsy patient that is distinguishable from other seizures suffered by the patient comprising:
>
> administering a single spray of 100 μL to one nasal mucosal membrane of the patient of a pharmaceutical solution consisting of:
>
> 56.47 mg of vitamin E USP +/−5%;
> 10 mg of diazepam
> 0.25 mg of dodecyl maltoside;
> 10.50 mg of benzyl alcohol +/−5%, and a sufficient quantity of ethanol;

> wherein administering the single spray of the pharmaceutical solution to the patient achieves 92.5% to 107.5% of the bioavailability of an equivalent dose of diazepam administered intravenously and is safe and effective in treating the bouts of intermittent and stereotypic episodes of increased seizure activity in the patient; and
>
> wherein administering the single spray of the pharmaceutical solution to the one nasal mucosal membrane of the patient results in a treatment selected from the group consisting of a reduction in the severity of the seizure, a reduction in the probability that the patient will experience a repeat seizure, an increase in the interval between a current seizure and a next seizure in the patient, a reduction in the frequency of seizure in the patient and combinations thereof.

ANSWER: This paragraph states legal conclusions to which no response is required. Padagis further states that the '852 patent speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the '852 patent.

39. By reason of the Third 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 '852 patent. More specifically, Padagis's ANDA and ANDA Product satisfies at least each of the claim limitations exemplified in Claim 1 of the '852 patent and/or their equivalents.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis denies the allegations of this paragraph at least because the Third Padagis Notice Letter sets forth why the claims of the Asserted Patents are invalid, and invalid claims cannot be infringed. Padagis further states that there is no requirement under 21 U.S.C. § 355(j) or any related regulations requiring an ANDA applicant to set forth each and every reason why a patent listed in the Orange Book may be invalid, unenforceable, or not infringed. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the Padagis ANDA. Padagis denies any remaining allegations of this paragraph.

40. 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

'852 patent under 35 U.S.C. § 271(a), will actively induce infringement of the '852 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '852 patent under 35 U.S.C. § 271(c).

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis denies the allegations of this paragraph at least because the Third Padagis Notice Letter sets forth why the claims of the Asserted Patents are invalid, and invalid claims cannot be infringed. Padagis further states that there is no requirement under 21 U.S.C. § 355(j) or any related regulations requiring an ANDA applicant to set forth each and every reason why a patent listed in the Orange Book may be invalid, unenforceable, or not infringed. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the Padagis ANDA. Padagis denies any remaining allegations of this paragraph.

41. On information and belief, Padagis has acted with full knowledge of the '852 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 '852 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 '852 patent.

ANSWER: Padagis denies the allegations of this paragraph.

42. As a result of the foregoing, Neurelis will be substantially and irreparably harmed if Defendants' infringement of the '852 patent is not enjoined. Neurelis does not have an adequate remedy at law.

ANSWER: Padagis denies the allegations of this paragraph.

43. 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 '852 patent, or the date of any later expiration or exclusivity to which Neurelis is or becomes entitled.

ANSWER: Padagis denies the allegations of this paragraph.

COUNT II
INFRINGEMENT OF THE '061 PATENT

44. Neurelis re-alleges paragraphs 1-43 as if fully set forth herein.

ANSWER: Padagis repeats and incorporates by reference its responses to the foregoing paragraphs as if fully stated herein.

45. 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 '061 patent. By submitting the Padagis ANDA, Padagis has infringed at least claims 1-62 under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Padagis admits that it submitted the Padagis ANDA to the FDA. Padagis denies the remaining allegations of this paragraph at least because the Third Padagis Notice Letter sets forth why the claims of the Asserted Patents are invalid, and an invalid claim cannot be infringed. Padagis further states that there is no requirement under 21 U.S.C. § 355(j) or any related regulations requiring an ANDA applicant to set forth each and every reason why a patent listed in the Orange Book may be invalid, unenforceable, or not infringed. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the Padagis ANDA. Padagis denies any remaining allegations of this paragraph.

46. Claim 21 of the '061 patent provides:

> 21. A method of treating bouts of intermittent and stereotypic episodes of increased seizure activity in an epilepsy patient that is distinguishable from other seizures suffered by the patient comprising:
>
> administering a single spray of 100 μL +/-5% of a stable pharmaceutical solution to a nostril of the patient, the pharmaceutical solution containing:
>
> 56.47 mg of vitamin E UsP +/-5%;
> 10 mg of diazepam; 0.25 mg of dodecyl maltoside +/-5%;
> 10.50 mg of benzyl alcohol +/-5%; and
> a sufficient quantity of ethanol;
>
> wherein administering the single spray of the pharmaceutical solution achieves 92.5% to 107.5% of the bioavailability of an equivalent dose of diazepam administered intravenously;
>
> wherein administering the single spray of the pharmaceutical solution is safe and effective in treating the bouts of intermittent and stereotypic episodes of increased seizure activity in the patient; and

> wherein administering the single spray of the pharmaceutical solution results in a treatment selected from the group consisting of a reduction in the severity of the seizure, a reduction in the probability that the patient will experience a repeat seizure, an increase in the interval between a current seizure and a next seizure in the patient, a reduction in the frequency of seizure in the patient and combinations thereof.

ANSWER: This paragraph states legal conclusions to which no response is required. Padagis further states that the '061 patent speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the '061 patent.

47. By reason of the Third 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 '061 patent. More specifically, Padagis's ANDA and ANDA Product satisfies at least each of the claim limitations exemplified in Claim 21 of the '061 patent and/or their equivalents.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis denies the allegations of this paragraph at least because the Third Padagis Notice Letter sets forth why the claims of the Asserted Patents are invalid, and invalid claims cannot be infringed. Padagis further states that there is no requirement under 21 U.S.C. § 355(j) or any related regulations requiring an ANDA applicant to set forth each and every reason why a patent listed in the Orange Book may be invalid, unenforceable, or not infringed. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the Padagis ANDA. Padagis denies any remaining allegations of this paragraph.

48. 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 '061 patent under 35 U.S.C. § 271(a), will actively induce infringement of the '061 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '061 patent under 35 U.S.C. § 271(c).

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Padagis denies the allegations of this paragraph at least because

the Third Padagis Notice Letter sets forth why the claims of the Asserted Patents are invalid, and invalid claims cannot be infringed. Padagis further states that there is no requirement under 21 U.S.C. § 355(j) or any related regulations requiring an ANDA applicant to set forth each and every reason why a patent listed in the Orange Book may be invalid, unenforceable, or not infringed. Padagis further states that the ANDA speaks for itself, and Padagis denies the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the Padagis ANDA. Padagis denies any remaining allegations of this paragraph.

49. On information and belief, Padagis has acted with full knowledge of the '061 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 '061 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 '061 patent.

ANSWER: Padagis denies the allegations of this paragraph.

50. As a result of the foregoing, Neurelis will be substantially and irreparably harmed if Defendants' infringement of the '061 patent is not enjoined. Neurelis does not have an adequate remedy at law.

ANSWER: Padagis denies the allegations of this paragraph.

51. 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 '061 patent, or the date of any later expiration or exclusivity to which Neurelis is or becomes entitled.

ANSWER: Padagis denies the allegations of this paragraph.

RESPONSE TO PRAYER FOR RELIEF

Padagis denies that Plaintiff is entitled to any of the relief set forth in its "Prayer for Relief" in the Complaint, or to any other relief for any remaining allegations set forth in the Complaint.

AFFIRMATIVE DEFENSES

Without any admission as to burden of proof and expressly reserving its right to assert any additional defenses or counterclaims that discovery may reveal, Padagis states the following defenses:

FIRST AFFIRMATIVE DEFENSE

Padagis does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, properly construed claim of the ’852 and ’061 patents directly, indirectly, contributorily, by inducement, or in any other manner.

SECOND AFFIRMATIVE DEFENSE

The claims of the ’852 and ’061 patents are invalid for failure to comply with and/or satisfy one or more of the conditions and requirements of Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, 112, 116, and/or 120 thereof, as well as any other judicially-created bases for invalidity.

THIRD AFFIRMATIVE DEFENSE

On information and belief, by virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the issuance of the ’852 and ’061 patents, Plaintiff is estopped from maintaining that Padagis infringes any valid claim of the ’852 and ’061 patents.

FOURTH AFFIRMATIVE DEFENSE

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

FIFTH AFFIRMATIVE DEFENSE

This Court lacks subject matter jurisdiction over portions of the claims asserted against Padagis, in particular, any infringement claims Plaintiff asserts under 35 U.S.C. § 271(a), (b), and/or (c).

* * *

Padagis expressly reserves the right to supplement and/or amend its Answer to Plaintiff's Complaint, including but not limited to supplementation and/or amendment of its defenses and amplifications of denials, as additional facts and information become known through the course of this case and discovery. Padagis further requests that Plaintiff's complaint be dismissed with prejudice and that Padagis be awarded the costs of this action, its attorneys' fees, and all other relief that this Court deems just and proper.

COUNTERCLAIMS

Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC (collectively, "Padagis"), for its counterclaims against Neurelis, Inc. ("Neurelis" or "Counterclaim-Defendant"), alleges as follows:

1. These counterclaim actions are for declaratory judgment of invalidity, non-infringement, and/or unenforceability of one or more claims of U.S. Patent Nos. 12,324,852 (the "'852 patent") and 12,337,061 (the "'061 patent") (collectively, the "Asserted Patents").

THE PARTIES

2. Padagis Israel Pharmaceuticals Ltd. is a corporation organized and existing under the laws of Israel, having a place of business at 1 Rakefet St., Shoham, 608500, Israel.

3. Padagis US LLC is a limited liability company organized and existing under the laws of Delaware with a place of business at 1251 Lincoln Road, Allegan, Michigan 49010.

4. Padagis LLC is a limited liability company organized and existing under the laws of Delaware with a place of business at 1251 Lincoln Road, Allegan, Michigan 49010.

5. 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.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over these counterclaim actions for declaratory judgment pursuant to 35 U.S.C. § 271(e)(5); 28 U.S.C. §§ 1331, 1338, 2201, and 2202; and/or 21 U.S.C. § 355(j), based on an actual controversy between Padagis and Neurelis arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 et seq.

7. The Court has personal jurisdiction over Neurelis based on the filing of this lawsuit in this jurisdiction and because, on information and belief, they are doing business in this jurisdiction.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c), 28 U.S.C. § 1400(b), 21 U.S.C. § 355(j)(5)(C)(i)(II), and by Neurelis's choice of forum.

9. Neurelis alleged in its Complaint that there is an actual and justiciable controversy between the parties as to the noninfringement and invalidity of the Asserted Patents.

ORANGE BOOK LISTINGS

10. On information and belief, the United States Patent and Trademark Office ("USPTO") issued the '852 patent on June 10, 2025. On information and belief, Neurelis purports to be the assignee of the '852 patent. The '852 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to VALTOCO®.

11. On information and belief, the USPTO issued the '061 patent on June 24, 2025. On information and belief, Neurelis purports to be the assignee of the '061 patent. The '061 patent is listed in the Orange Book with respect to VALTOCO®.

PADAGIS' ABBREVIATED NEW DRUG APPLICATION

12. Padagis filed Abbreviated New Drug Application ("ANDA") No. 219320 (the "Padagis ANDA") seeking regulatory approval to market its proposed generic benzodiazepine drug product (the "Padagis ANDA Product") as described therein. In the ANDA, Padagis certified

under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the claims of the ’852 and ’061 patents are invalid, unenforceable, and/or will not be infringed by the activities described in the Padagis ANDA..

PRESENCE OF CONTROVERSY

13. On information and belief, Counterclaim-Defendant is the holder of New Drug Application (“NDA”) No. N211635 for the benzodiazepine drug product currently marketed under the trade name VALTOCO®.

14. On information and belief, prior to the filing of this action, Counterclaim-Defendant caused the FDA to list the ’851 and ’061 patents in the Orange Book in connection with NDA No. N211635.

15. In a letter dated September 2, 2025 (the “Third Padagis Notice Letter”), Padagis notified Neurelis that the Padagis ANDA included a certification that the ’851 and ’062 patents are invalid, unenforceable, and/or will not be infringed by the activities described in the Padagis ANDA.

16. On October 3, 2025, Counterclaim-Defendant filed a patent infringement action against Padagis alleging infringement of the ’851 and ’062 patents.

17. On information and belief, Counterclaim-Defendant has not caused the FDA to remove the ’852 and ’061 patents from the Orange Book in connection with NDA No. 211635.

18. By maintaining the listing of the ’852 and ’061 patents in the Orange Book, Neurelis represents that a claim of patent infringement of the ’852 and ’061 patents “could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug.” 21 U.S.C. § 355(b)(1)(A)(viii).

19. In light of all the circumstances, there has been and is now an actual, substantial, and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court between Padagis and Counterclaim-Defendant as

to whether the Padagis ANDA Product would infringe any or all claims of the ’852 and ’061 patents and whether the claims of the ’852 and ’061 patents are valid and enforceable.

COUNT I.
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’852 PATENT

20. Padagis repeats and incorporates by reference each of the foregoing paragraphs of its counterclaims.

21. The claims of the ’852 patent are invalid for failure to comply with and/or satisfy one or more of the conditions and requirements of patentability specified in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or 120, and/or based on other judicially-created bases for invalidity.

22. The alleged invention of the ’852 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the patent.

23. The alleged invention of the ’852 patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

24. The ’852 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

25. The alleged invention of the ’852 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’852 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’852 patent and would have had a reasonable expectation of success in doing so.

26. The subject matter claimed in the ’852 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

27. The ’852 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

28. The claims of the ’852 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

29. An actual and justiciable case or controversy exists between Padagis and Counter-Defendant as to whether the ’852 patent is invalid.

30. Padagis is entitled to and seeks a declaration that the claims of the ’852 patent are invalid.

COUNT II.
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’852 PATENT

31. Padagis repeats and incorporates by reference each of the foregoing paragraphs of its counterclaims.

32. Neurelis has accused Padagis of infringing claims of the ’852 patent in connection with the Padagis ANDA.

33. Padagis denies infringement of any valid, properly construed claim of the ’852 patent, and alleges that the manufacture, use, sale, offer for sale or importation of the Padagis

ANDA Product has not infringed, does not infringe and would not, if manufactured, used, sold, offered for sale or imported, infringe any valid, properly construed claim of the ’852 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

34. There is an actual, substantial, and continuing justiciable case or controversy between Padagis and Neurelis regarding infringement of the ’852 patent in connection with the Padagis ANDA.

35. Padagis is entitled to and seeks a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of the Padagis ANDA Product has not infringed, does not infringe and would not, if manufactured, used, sold, offered for sale or imported, infringe any valid, properly construed claim of the ’852 patent either directly or indirectly.

COUNT III.
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’061 PATENT

36. Padagis repeats and incorporates by reference each of the foregoing paragraphs of its counterclaims.

37. The claims of the ’061 patent are invalid for failure to comply with and/or satisfy one or more of the conditions and requirements of patentability specified in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or 120, and/or based on other judicially-created bases for invalidity.

38. The alleged invention of the ’061 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the patent.

39. The alleged invention of the ’061 patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

40. The ’061 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

41. The alleged invention of the ’061 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’061 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’061 patent and would have had a reasonable expectation of success in doing so.

42. The subject matter claimed in the ’061 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

43. The ’061 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

44. The claims of the ’061 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

45. An actual and justiciable case or controversy exists between Padagis and Neurelis as to whether the ’061 patent is invalid.

46. Padagis is entitled to and seeks a declaration that the claims of the ’061 patent are invalid.

COUNT IV.
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’061 PATENT

47. Padagis repeats and incorporates by reference each of the foregoing paragraphs of its counterclaims.

48. Neurelis has accused Padagis of infringing claims of the ’061 patent in connection with the Padagis ANDA.

49. Padagis denies infringement of any valid, properly construed claim of the ’061 patent, and alleges that the manufacture, use, sale, offer for sale or importation of the Padagis ANDA Product has not infringed, does not infringe and would not, if manufactured, used, sold, offered for sale or imported, infringe any valid, properly construed claim of the ’061 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

50. There is an actual, substantial, and continuing justiciable case or controversy between Padagis and Neurelis regarding infringement of the ’061 patent in connection with the Padagis ANDA.

51. Padagis is entitled to and seeks a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of the Padagis ANDA Product has not infringed, does not infringe and would not, if manufactured, used, sold, offered for sale or imported, infringe any valid, properly construed claim of the ’061 patent either directly or indirectly.

PRAYER FOR RELIEF

WHEREFORE, Padagis prays that the Court enter judgment in its favor and against Neurelis as follows:

a. Dismissing the Complaint with prejudice and denying each request for relief made by Plaintiff therein;

b. Declaring the claims of the ’852 and ’061 patents invalid;

c. Declaring that the filing of the Padagis ANDA or the manufacture, use, sale, offer for sale or importation of the Padagis ANDA Product has not, does not, and would not infringe any valid claim, if any, of the ’852 and ’061 patents, either directly or indirectly, either literally or under the doctrine of equivalents;

d. Granting Padagis judgment in its favor on Plaintiff’s claims;

e. Granting Padagis judgment in its favor on its counterclaims;

f. Awarding Padagis such other and further relief as the Court deems just and proper.

POLSINELLI PC

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CERTIFICATE OF SERVICE

I hereby certify that on November 6, 2025, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused a copy of the foregoing document to be served on November 6, 2025, upon the following in the manner indicated:

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