MIDLIGE RICHTER, LLC
645 Martinsville Road
Basking Ridge, New Jersey 07920
(908) 626-0622
James S. Richter

Attorneys for Defendants,
Lupin Inc. and Lupin Pharmaceuticals, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ARS PHARMACEUTICALS OPERATIONS, INC., and AEGIS THERAPEUTICS, LLC, Plaintiffs, v. LUPIN INC. and LUPIN PHARMACEUTICALS, INC., Defendants.	Honorable Julien X. Neals, U.S.D.J. Civil Action No. 25 CV 15123 (JXN)(MAH) **DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendants Lupin Inc. and Lupin Pharmaceuticals, Inc. ("LPI"), (collectively, "Lupin" or "Defendants"), by and through its undersigned counsel, provides the following answers, affirmative defenses and counterclaims to the Complaint for Patent Infringement ("Complaint") (Civ. No. 2:25-cv-15123, D.I. 1) filed by Plaintiffs ARS Pharmaceuticals Operations, Inc. ("ARS") and Aegis Therapeutics, LLC ("Aegis") (collectively "Plaintiffs"). This pleading is based upon Defendants' knowledge as to their own activities, and upon information and belief as to other matters. Pursuant to Fed. R. Civ. P. 8(b)(3), Defendants deny all allegations in the Complaint except those admitted specifically below.

Nature of the Action and Subject Matter

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code and arising under 35 U.S.C. §§ 271 and 281- 283, arising from Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 220047 ("Lupin's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to manufacture, use, import, distribute, offer to sell, and/or sell a generic version of ARS's neffy® (epinephrine nasal spray) drug product prior to the expiration of United States Patent Nos. 10,576,156 ("the '156 patent"); 10,682,414 ("the '414 patent"); 11,173,209 ("the '209 patent"); 11,191,838 ("the '11-838 patent"); 11,717,571 ("the '571 patent"); 11,744,895 ("the '895 patent"); 11,918,655 ("the '655 patent"); and 12,324,838 ("the '12-838 patent") (collectively, the "neffy® Patents").

ANSWER: Defendants admit that the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") lists the '156, '414, '209, '11-838, '571, '895, '655, and the '12-838 patents (together, "the Patents-in-Suit") for NEFFY®. Defendants further admit that Lupin Inc. submitted ANDA No. 220047 ("Lupin's ANDA" or the "Lupin ANDA") to the FDA, listing NEFFY® as the reference product, seeking approval to engage in the commercial manufacture, use, sale, and/or importation of a generic product, "Epinephrine nasal spray," which has a dosage strength of 2 mg/nasal spray ("the ANDA Product" or "Lupin's ANDA Product"), prior to the expiration dates of the Patents-in-Suit that are listed in the Orange Book. Defendants further admit that the Complaint purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, but denies that Plaintiffs are entitled to relief. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in this paragraph and therefore denies the same.

The Parties

2. Plaintiff ARS Pharmaceuticals Operations, Inc. is a corporation organized and existing under the laws of the state of Delaware, with a principal place of business at 11682 El Camino Real, San Diego, California 92130.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in this paragraph and therefore denies the same.

3. Plaintiff Aegis Therapeutics, LLC is a corporation organized and existing under the laws of the state of California, with a principal place of business at 3430 Carmel Mountain Road, San Diego, California, 92121.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in this paragraph and therefore denies the same.

4. On information and belief, Defendant Lupin Inc. is a corporation organized and existing under the laws of the state of Delaware, having a regular and established place of business at 400 Campus Drive, Somerset, New Jersey, 08873.

ANSWER: Defendants admit that Lupin Inc. is a corporation organized and existing under the laws of the state of Delaware. Defendants deny any remaining allegations set forth in this paragraph.

5. On information and belief, Defendant Lupin Ltd. is an Indian corporation having a place of business at B/4 Laxmi Towers, Bandra Kurla Complex Bandra (E), Mumbai, 400 051, India.

ANSWER: This paragraph contains legal conclusions and is directed to an entity who was, at the time of filing, a separate Defendant to this action. The parties stipulated to the dismissal of Lupin Ltd. from this litigation, as ordered by the Court on September 29. 2025. *See* Civ. No. 2:25-CV-15123, D.I. 10. Therefore, no response is required from Defendants.

6. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a regular and established place of business at 400 Campus Drive, Somerset, New Jersey, 08873.

ANSWER: Defendants admit that Lupin Pharmaceuticals, Inc. ("LPI") is a corporation organized and existing under the laws of the State of Delaware. Defendants deny that LPI is a proper party to this action. Lupin denies any remaining allegations in this paragraph.

7. On information and belief, Lupin Inc. and Lupin Pharmaceuticals, Inc. are direct or indirect wholly owned subsidiaries of Lupin Ltd. Upon further information and belief, Lupin Inc. is a wholly owned subsidiary of Nanomi B.V., which is a wholly owned subsidiary of Lupin

Ltd. And upon further information and belief, Lupin Pharmaceuticals, Inc. is 97% owned by Lupin Inc. and 3% by Lupin Ltd.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendants. To the extent a response is required, Defendants admit that all shares of Defendants Lupin Inc. and Lupin Pharmaceuticals, Inc. are indirectly owned by Lupin Ltd. Defendants deny any remaining allegations set forth in this paragraph.

JURISDICTION AND VENUE

8. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit that the Complaint cites the patent laws of the United States generally. Lupin does not contest subject matter jurisdiction for purposes of this action only. Defendants deny any remaining allegations set forth in this paragraph.

9. Venue is proper over Lupin Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc. under 28 U.S.C. §§ 1391 and/or 1400(b).

ANSWER: This paragraph contains legal conclusions to which no response is required. This paragraph also contains allegations regarding an entity that has been dismissed from this action. Defendants deny that Lupin Ltd. is a proper party to this litigation, and that venue is proper in this District as to Lupin Ltd. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this litigation. To the extent a response is required, Defendants do not contest venue in this Court as to the remaining Defendants for the purposes of this action only. Defendants deny any remaining allegations set forth in this paragraph.

10. On information and belief, each of Lupin Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc. derive substantial revenue from interstate and/or international commerce, including substantial revenue from goods developed, made, used and/or consumed in the State of New Jersey and within this judicial district.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendants. To the extent a response is required, Defendants deny the allegations of this paragraph.

11. On information and belief, Defendants list their Somerset, New Jersey Manufacturing and R&D location as "Lupin's first and only commercial manufacturing facility in the United States" and state that its location in Somerset, New Jersey "encompasses all functional areas of pharmaceutical manufacturing including quality control, packaging, production, quality assurance, regulatory affairs, research and development, formulation, and technical services."

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendants. To the extent a response is required, Defendants admit that this paragraph contains selectively edited quotations of Defendants' websites, which are documents that speak for themselves. Defendants deny any remaining allegations set forth in this paragraph.

12. On information and belief, Lupin Inc. and Lupin Pharmaceuticals, Inc. sell generic drugs manufactured and supplied by Lupin Ltd. throughout the United States, including in the State of New Jersey and in this judicial district.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendants. To the extent that a response is required, Lupin admits that it sells products that are the subjects of Abbreviated New Drug Applications, providing high-quality pharmaceuticals which deliver value to patients, customers and the healthcare system throughout the United States, including in the State of New Jersey. Defendants deny any remaining allegations set forth in this paragraph.

13. This Court has personal jurisdiction over Lupin Inc. because Lupin Inc., on information and belief, at least: (1) maintains a regular and established place of business at 400 Campus Drive, Somerset, New Jersey 08873; (2) has purposefully availed itself of the privileges of doing business in the State of New Jersey and in this judicial district, including

directly or indirectly through its wholly owned subsidiary, agent, and/or alter ego Lupin Pharmaceuticals, Inc., which maintains a regular and established place of business in New Jersey; and (3) has and maintains systematic and extensive contacts with the State of New Jersey and this judicial district, including through the manufacture, offer for sale and/or sale of generic pharmaceuticals in New Jersey including through, directly or indirectly, its wholly owned subsidiary, agent, and/or alter ego, Lupin Pharmaceuticals, Inc. At least because of its physical presence in New Jersey and this judicial district, this Court has personal jurisdiction over Lupin Inc.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant Lupin Inc. does not contest personal jurisdiction in this Court for the purposes of this action only. Defendants deny any remaining allegations set forth in this paragraph.

14. This Court has personal jurisdiction over Lupin Ltd. because Lupin Ltd., on information and belief, at least: (1) has purposefully availed itself of the privileges of doing business in the State of New Jersey and in this judicial district, including directly or indirectly through its wholly owned subsidiaries, agents, and/or alter egos, Lupin Inc. and Lupin Pharmaceuticals, Inc., which maintain a regular and established place of business in New Jersey; and (2) has and maintains systematic and extensive contacts with the State of New Jersey and this judicial district, including through the manufacture, offer for sale and/or sale of generic pharmaceuticals in New Jersey including through, directly or indirectly, its wholly owned subsidiaries, agents, and/or alter egos, Lupin Inc. and Lupin Pharmaceuticals, Inc.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendants. To the extent a response is required, Defendants deny the allegations of this paragraph.

15. This Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. because Lupin Pharmaceuticals, Inc., on information and belief, at least: (1) maintains a regular and established place of business at 400 Campus Drive, Somerset, New Jersey 08873; (2) has purposefully availed itself of the privileges of doing business in the State of New Jersey and in this judicial district, including directly or indirectly through its parent, principal and/or alter ego Lupin Inc.; and (3) has and maintains systematic and extensive contacts with the State of New Jersey and this judicial district, including through the manufacture, offer for sale and/or sale of generic pharmaceuticals in New Jersey including through, directly or indirectly, its parent, principal and/or alter ego, Lupin Inc. Also, on information and belief, Lupin Pharmaceuticals, Inc. has registered as an entity the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey, and has registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler. At least because of its

physical presence in New Jersey and this judicial district, this Court has personal jurisdiction over Lupin Pharmaceuticals, Inc.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny that LPI is a proper party to this action. Defendants deny any remaining allegations of this paragraph.

16. On information and belief, Lupin Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc. acted in concert and/or in privity with one another, and/or aided in the development, preparation and submission of Abbreviated New Drug Application No. 220047 ("Lupin's ANDA") and/or notification of certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) ("Lupin's Paragraph IV Certification") giving rise to this civil action.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendants. To the extent a response is required, Defendants deny the allegations of this paragraph.

17. On information and belief, unless enjoined, Lupin will import, make, use, sell and/or offer for sale the generic drug product for which Lupin is seeking approval through submission of Lupin's ANDA ("the Lupin ANDA Product") in the State of New Jersey and in this judicial district.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent that a response is required, Lupin admits that it sells products that are the subjects of Abbreviated New Drug Applications, providing high-quality pharmaceuticals which deliver value to patients, customers and the healthcare system throughout the United States, including in the State of New Jersey. Defendants deny any remaining allegations set forth in this paragraph.

18. This Court also has personal jurisdiction over Lupin Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc. because they have committed an act of statutory infringement under 35 U.S.C. § 271(e)(2)(A), and intend to make, use, sell offer for sale and/or import the Lupin ANDA Product in the State of New Jersey and in this judicial district, which has caused and will continue to cause foreseeable harm to Plaintiffs in the State of New Jersey and this judicial district.

ANSWER: This paragraph contains legal conclusions to which no response is required, and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendants. To the extent a response is required, Defendants deny that Lupin Ltd. is a proper party to this litigation, and that personal jurisdiction is proper in this District as to Lupin Ltd. Defendants further deny that LPI is a proper party to this litigation. Lupin Inc. does not contest personal jurisdiction in this Court for the purposes of this action only. Defendants further admit that Lupin Inc. filed ANDA No. 220047, with a Paragraph IV certification concerning the Patents-in-Suit, seeking approval to market the Lupin ANDA Product. Defendants deny any remaining allegations set forth in this paragraph.

19. Alternatively, to the extent Lupin Ltd. is not subject to the general jurisdiction of, or specific jurisdiction in, any state, this Court has personal jurisdiction over Lupin Ltd. under Fed. R. Civ. P. 4(k)(2) because Lupin Ltd. is an entity organized and having its principal place of business located outside of the United States and has sufficient contacts with the United States as a whole, including but not limited to the submission of Abbreviated New Drug Applications, including but not limited to Lupin's ANDA and the commercialization of, on information and belief, at least 150 generic drugs in the United States.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendants. To the extent a response is required, Defendants deny that Lupin Ltd. is a proper party to this litigation, and that personal jurisdiction is proper in this District as to Lupin Ltd. Defendants deny any remaining allegations set forth in this paragraph.

20. On information and belief, if Lupin's ANDA is approved, Lupin Ltd. will manufacture, use, sell, offer to sell and/or import into the United States the Lupin ANDA Product, and intends to derive and will derive substantial revenue from the manufacture, use, sale, offer for sale and/or importation into the United States of the Lupin ANDA Product.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendants. To the extent a response is required, Defendants deny that Lupin Ltd.

is a proper party to this litigation, and that personal jurisdiction is proper in this District as to Lupin Ltd. Defendants deny any remaining allegations set forth in this paragraph.

21. On information and belief, Lupin Inc. and Lupin Pharmaceuticals, Inc. operate under the direction and control, and for the benefit, of Lupin Ltd.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendants. To the extent a response is required, Defendants deny that Lupin Ltd. is a proper party to this litigation, and that personal jurisdiction is proper in this District as to Lupin Ltd. Defendants deny that LPI is a proper party to this litigation. Defendants deny any remaining allegations set forth in this paragraph.

22. On information and belief, Lupin Ltd. and its direct or indirect subsidiaries, Lupin Inc. and Lupin Pharmaceuticals, Inc. operate, and publicly hold themselves out as, a single integrated business in the United States as "Lupin."

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendants. To the extent a response is required, Defendants deny that Lupin Ltd. is a proper party to this litigation, and that personal jurisdiction is proper in this District as to Lupin Ltd. Defendants deny that LPI is a proper party to this litigation. Defendants deny any remaining allegations set forth in this paragraph.

23. On information and belief, Lupin Inc., Lupin Ltd, and Lupin Pharmaceuticals, Inc. have not challenged personal jurisdiction, and have asserted counterclaims, when previously sued in this judicial district. *See, e.g.*, *AstraZeneca AB, et al. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 3:09-cv-05404 (JAP)(TJB) (D.N.J.); *Abbott Labs and Laboratories Fournier S.A. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 2:09-cv-01007 (GEB)(MCA) (D.N.J.); *Abbott Labs and Laboratories Fournier S.A. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 2:10-cv-01578 (DMC)(JAD) (D.N.J.); *Janssen Products, L.P., et. al. v. Lupin Limited, et. al.*, Civ. Action No. 2:10-cv-05954 (WHW)(MAS) (D.N.J.); *Novartis Corp., et al. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 2:06-cv-05954 (GEB)(ES) (D.N.J.); *Elan Int'l. Ltd. and Fournier Laboratories Ireland Ltd. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 2:09-cv-01008 (GEB)(MCA) (D.N.J.); *Jazz Pharmaceuticals, Inc., et al. v. Lupin Ltd., et al.*, Civ. Action No. 2:15-cv-06548 (ES)(JAD) (D.N.J.*); Horizon*

Pharma Ireland Limited, et al. v. Lupin Ltd., et al., Civ. Action No. 1:15-cv-06935 (NLH)(AMD) (D.N.J.); *Senju Pharmaceutical Co., Ltd, et al. v. Lupin Ltd., et al.*, Civ. Action No. 1:16-cv-01097 (JBS)(KMW) (D.N.J.); *Bausch Health Ireland Ltd., et al. v. Lupin Ltd.*, et al., 1:20-cv-11039 (RMB)(KMW) (D.N.J.); *Merck Sharp & Dohme BV, et al. v. 12 Lupin Ltd.*, et al., 2:20-cv-02786 (CCC)(MF) (D.N.J.); *Bristol-Myers Squibb Co. v. Lupin Ltd., et al.*, 3:20-cv-07810 (MAS)(TJB) (D.N.J.); *Jazz Pharmaceuticals Ireland Ltd. v. Lupin Ltd., et al.*, Civ. Action No. 2:21-cv-14271 (SRC)(JSA) (D.N.J.); *Jazz Pharmaceuticals Ireland Ltd. v. Lupin Ltd., et al.*, Civ. Action No. 2:22-cv-02773 (SRC)(JSA) (D.N.J.); *Jazz Pharmaceuticals Ireland Ltd. v. Lupin Ltd., et al.*, Civ. Action No. 2:23-cv-00329 (SRC)(JSA) (D.N.J.); and *Jazz Pharmaceuticals Ireland Ltd. v. Lupin Ltd., et al.*, Civ. Action No. 2:24-cv-08786 (SRC)(JSA) (D.N.J.).

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendants. To the extent a response is required, Defendants deny that Lupin Ltd. is a proper party to this litigation, and that personal jurisdiction is proper in this District as to Lupin Ltd. To the extent a response is required, Defendants deny that LPI is a proper party to this action. Lupin Inc. does not contest personal jurisdiction in this Court for the purposes of this action only and states that pleadings in previous actions speak for themselves. Defendants deny any remaining allegations set forth in this paragraph.

THE PATENTS-IN-SUIT

24. The ’156 patent, entitled “Compositions for drug administration,” was duly issued by the United States Patent and Trademark Office (“USPTO”) on March 3, 2020. The ‘156 patent covers the importation, manufacture, use, sale, and/or offer for sale of neffy®. A true and correct copy of the ’156 patent is appended hereto as **Exhibit A**.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that a purported copy of the ’156 patent is attached to the Complaint as Exhibit A. Defendants admit that on its face, the ’156 patent is entitled “Compositions for drug administration.” Defendants deny any remaining allegations set forth in this paragraph.

25. The ’414 patent, entitled “Intranasal epinephrine formulations and methods for the treatment of disease,” was duly issued by the USPTO on June 16, 2020. The ’414 patent covers the importation, manufacture, use, sale, and/or offer for sale of neffy®. A true and correct copy of the ’414 patent is appended hereto as **Exhibit B**.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that a purported copy of the ’414 patent is attached to the Complaint as Exhibit B. Defendants admit that on its face, the ’414 patent is entitled “Intranasal epinephrine formulations and methods for the treatment of disease.” Defendants deny any remaining allegations set forth in this paragraph.

26. The ’209 patent, entitled “Compositions for drug administration,” was duly issued by the USPTO on November 16, 2021. The ‘209 patent covers the importation, manufacture, use, sale, and/or offer for sale of neffy®. A true and correct copy of the ’209 patent is appended hereto as **Exhibit C**.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that a purported copy of the ’209 patent is attached to the Complaint as Exhibit C. Defendants admit that on its face, the ’209 patent is entitled “Compositions for drug administration.” Defendants deny any remaining allegations set forth in this paragraph.

27. The ’11-838 patent, entitled “Intranasal epinephrine formulations and methods for the treatment of disease,” was duly issued by the USPTO on December 7, 2021. The ’11-838 patent covers the importation, manufacture, use, sale, and/or offer for sale of neffy®. A true and correct copy of the ’11-838 patent is appended hereto as **Exhibit D**.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that a purported copy of the ’11-838 patent is attached to the Complaint as Exhibit D. Defendants admit that on its face, the ’11-838 patent is entitled “Intranasal epinephrine formulations and methods for the treatment of disease.” Defendants deny any remaining allegations set forth in this paragraph.

28. The ’571 patent, entitled “Intranasal epinephrine formulations and methods for the treatment of disease,” was duly issued by the USPTO on August 8, 2023. The ’571 patent covers

the importation, manufacture, use, sale, and/or offer for sale of neffy®. A true and correct copy of the '571 patent is appended hereto as **Exhibit E**.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that a purported copy of the '571 patent is attached to the Complaint as Exhibit E. Defendant admits that on its face, the '571 patent is entitled "Intranasal epinephrine formulations and methods for the treatment of disease." Defendants deny any remaining allegations set forth in this paragraph.

29. The '895 patent, entitled "Intranasal epinephrine formulations and methods for the treatment of disease," was duly issued by the USPTO on September 5, 2023. The '895 patent covers the importation, manufacture, use, sale, and/or offer for sale of neffy®. A true and correct copy of the '895 patent is appended hereto as **Exhibit F**.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that a purported copy of the '895 patent is attached to the Complaint as Exhibit F. Defendant admits that on its face, the '895 patent is entitled "Intranasal epinephrine formulations and methods for the treatment of disease." Defendants deny any remaining allegations set forth in this paragraph.

30. The '655 patent, entitled "Intranasal epinephrine formulations and methods for the treatment of disease," was duly issued by the USPTO on March 5, 2024. The '655 patent covers the importation, manufacture, use, sale, and/or offer for sale of neffy®. A true and correct copy of the '655 patent is appended hereto as **Exhibit G**.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that a purported copy of the '655 patent is attached to the Complaint as Exhibit G. Defendant admits that on its face, the '655 patent is entitled "Intranasal epinephrine formulations and methods for the treatment of disease." Defendants deny any remaining allegations set forth in this paragraph.

31. The '12-838 patent, entitled "Intranasal epinephrine formulations and methods for the treatment of disease," was duly issued by the USPTO on June 10, 2025. The '12-838 patent covers the importation, manufacture, use, sale, and/or offer for sale of neffy®. A true and correct copy of the '12-838 patent is appended hereto as **Exhibit H**.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that a purported copy of the '12-838 patent is attached to the Complaint as Exhibit H. Defendant admits that on its face, the '12-838 patent is entitled "Intranasal epinephrine formulations and methods for the treatment of disease." Defendants deny any remaining allegations set forth in this paragraph.

32. Aegis has been and is the owner by assignment of the neffy® Patents. ARS holds a license to the neffy® Patents from Aegis.

ANSWER: Defendants admit that Aegis is listed as the "Assignee" on the face of each of the Patents-in-Suit. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in this paragraph and therefore deny the same.

The NEFFY® Drug Product

33. New Drug Application No. 214697 (the "neffy® NDA") is held by ARS, pursuant to which ARS sells a drug product under the trade name neffy® (epinephrine nasal spray) under its license to the neffy® Patents.

ANSWER: Defendants admit that public FDA records list ARS as the holder of NDA No. 214697 for NEFFY®. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in this paragraph and therefore deny the same.

34. neffy® is approved for use in the emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients 4 years of age and older who weigh 15 kg or greater. The claims of the Patents-in-Suit cover, inter alia, pharmaceutical compositions and nasal spray devices comprising epinephrine formulations and methods of use and administration of those drug products.

ANSWER: This paragraph contains legal conclusions to which no response is required. Defendants admit that the FDA-approved label for the NEFFY® 2 mg/spray product listed as the reference product in Lupin's ANDA is "indicated for emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kg or greater." Defendants deny any remaining allegations set forth in this paragraph.

35. The neffy® patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") pursuant to, inter alia, 21 U.S.C. 355(b)(1) and 21 CFR § 314.53.

ANSWER: Admitted.

36. The labeling for neffy® instructs health care providers and patients to administer neffy® in accordance with at least some of the methods claimed in the Patents-in-Suit

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent that a response is required from Defendants, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations set forth in this paragraph and therefore deny the same.

Lupin's ANDA

37. On information and belief, Lupin submitted Lupin's ANDA with the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of a 2 mg/spray epinephrine nasal spray.

ANSWER: Admitted.

38. By filing its ANDA, on information and belief, Lupin intends to engage, and there is at least the substantial likelihood that Lupin will engage, in the commercial importation, use, offer for sale and/or sale, or inducement of the use thereof or contribution thereto, of the Lupin ANDA Product immediately or imminently upon receiving FDA approval of Lupin's ANDA. On information and belief, following FDA approval of its ANDA, Lupin plans to import, make, use, sell, or offer to sell the Lupin ANDA Product throughout the United States including in the State of New Jersey and in this judicial district.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent that a response is required from Defendants, denied.

39. On information and belief, by filing its ANDA, Lupin has represented to the FDA that the Lupin ANDA Product is bioequivalent to neffy®.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Lupin Inc. submitted Lupin's ANDA to the FDA seeking approval for Lupin's ANDA Product. Lupin denies any remaining allegations

in this paragraph.

40. On information and belief, Lupin's ANDA contained written certifications to the FDA pursuant to U.S.C. § 355(j)(2)(A)(vii)(IV) ("Lupin's Paragraph IV Certifications"), alleging that the claims of the neffy® Patents are invalid and/or will not be infringed by the importation, manufacture, use, sale or offer for sale of the Lupin ANDA Product.

ANSWER: Admitted.

41. Pursuant to Section 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act, by letter dated August 8, 2025, Lupin informed ARS and Aegis that Lupin had filed the Lupin Paragraph IV Certifications with the FDA under 21 U.S.C. § 355(j)(2)(B)(i)-(iv) and 21 C.F.R.§ 314.95(c)(1) (the "Lupin Notice Letter").

ANSWER: Admitted.

42. The Lupin Notice Letter, purporting to be Lupin's Notification of Certification pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c)(6), stated that "we advise you that the patents alleged to be invalid, unenforceable, and/or not infringed are [the neffy® Patents]." The Lupin Notice Letter also purported to contain a "detailed statement of the factual and legal bases for Lupin's opinion that, to the best of Lupin's knowledge . . . [the neffy® Patents] are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the drug product described in Lupin's ANDA or sale of the drug product described in Lupin's ANDA."

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent that a response is required from Defendants, Defendants admit that this paragraph contains selectively edited excerpts of Lupin's Notification of Certification pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c)(6), which is a document that speaks for itself. Defendants deny any remaining allegations set forth in this paragraph.

43. Plaintiff ARS Pharmaceuticals Operations, Inc., holder of the neffy® NDA, received the Lupin Notice Letter not earlier than on or about August 13, 2025. Plaintiff Aegis Therapeutics, LLC, owner of record of the neffy® Patents, received the Lupin Notice Letter not earlier than on or about August 11, 2025.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations set forth in this paragraph and therefore deny the same.

44. Lupin's filing of its ANDA for the purpose of obtaining FDA approval to engage in the commercial importation, manufacture, use, offer for sale and/or sale (or the inducement

thereof or contribution thereto) of the drug product that is the subject of Lupin's ANDA prior to the expiration of the neffy® Patents is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent that a response is required from Defendants, denied.

Count I
(Infringement of U.S. Patent No. 10,576,156)

45. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

ANSWER: To the extent an answer to this paragraph is required, Defendants incorporate by reference their answers to the foregoing paragraphs as if fully set forth herein.

46. By submission of its ANDA, Lupin intends to obtain approval to commercially manufacture, use, import, offer for sale, and/or sell, alleged generic equivalents of Plaintiffs' neffy® drug product prior to the expiration date of the '156 patent.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations of this paragraph.

47. Lupin's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of the Lupin ANDA Product prior to the expiration of the '156 patent, constitutes an act of infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit that they mailed ARS and Aegis the Lupin Notice Letter, which speaks for itself. Defendants deny any remaining allegations set forth in this paragraph.

48. There is a justiciable controversy between the parties as to the infringement of the '156 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Plaintiffs have filed suit accusing Lupin of infringement of the '156 patent. Lupin denies any remaining allegations in this

paragraph.

49. Lupin's manufacture, use, importation, offer for sale, sale, and/or importation of its proposed ANDA Product will, on information and belief, directly infringe or induce infringement of at least one claim of the '156 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

50. Unless Lupin is enjoined from infringing the '156 patent, Plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

Count II
(Infringement of U.S. Patent No. 10,683,414)

51. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

ANSWER: To the extent an answer to this paragraph is required, Defendants incorporate by reference their answers to the foregoing paragraphs as if fully set forth herein.

52. By submission of its ANDA, Lupin intends to obtain approval to commercially manufacture, use, import, offer for sale, and/or sell, alleged generic equivalents of Plaintiffs' neffy® drug product prior to the expiration date of the '414 patent.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations of this paragraph.

53. Lupin's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of the Lupin ANDA Product prior to the expiration of the '414 patent, constitutes an act of infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit that they mailed ARS and Aegis the Lupin Notice Letter, which speaks for itself. Defendants deny any remaining allegations set forth in this paragraph.

54. There is a justiciable controversy between the parties as to the infringement of the '414 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Plaintiffs have filed suit accusing Lupin of infringement of the '414 patent. Lupin denies any remaining allegations in this paragraph.

55. Lupin's manufacture, use, importation, offer for sale, sale, and/or importation of its proposed ANDA Product will, on information and belief, directly infringe or induce infringement of at least one claim of the '414 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

56. Unless enjoined, Lupin's importation, manufacture, use, offer for sale, and/or sale of its proposed ANDA Product, on information and belief, will induce and/or contribute to the infringement of at least one claim of the '414 patent.

ANSWER: Denied.

57. Unless Lupin is enjoined from infringing the '414 patent, Plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

Count III
(Infringement of U.S. Patent No. 11,173,209)

58. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

ANSWER: To the extent an answer to this paragraph is required, Defendants incorporate by reference their answers to the foregoing paragraphs as if fully set forth herein.

59. By submission of its ANDA, Lupin intends to obtain approval to commercially manufacture, use, import, offer for sale, and/or sell, alleged generic equivalents of Plaintiffs' neffy® drug product prior to the expiration date of the '209 patent.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations of this paragraph.

60. Lupin's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of the Lupin ANDA Product prior to the expiration of the '209 patent, constitutes an act of infringement of

one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit that they mailed ARS and Aegis the Lupin Notice Letter, which speaks for itself. Defendants deny any remaining allegations set forth in this paragraph.

61. There is a justiciable controversy between the parties as to the infringement of the '209 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Plaintiffs have filed suit accusing Lupin of infringement of the '209 patent. Lupin denies any remaining allegations in this paragraph.

62. Lupin's manufacture, use, importation, offer for sale, sale, and/or importation of its proposed ANDA Product will, on information and belief, directly infringe or induce infringement of at least one claim of the '209 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

63. Unless enjoined, Lupin's importation, manufacture, use, offer for sale, and/or sale of its proposed ANDA Product will, on information and belief, induce and/or contribute to the infringement of at least one claim of the '209 patent.

ANSWER: Denied.

64. Unless Lupin is enjoined from infringing the '209 patent, Plaintiffs will suffer substantial and irrep-arable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

Count IV
(Infringement of U.S. Patent No. 11,191,838)

65. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

ANSWER: To the extent an answer to this paragraph is required, Defendants incorporate

by reference their answers to the foregoing paragraphs as if fully set forth herein.

66. By submission of its ANDA, Lupin intends to obtain approval to commercially manufacture, use, import, offer for sale, and/or sell, alleged generic equivalents of Plaintiffs' neffy® drug product prior to the expiration date of the '11-838 patent.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations of this paragraph.

67. Lupin's submission of its ANDA to obtain approval to engage in the commercial manu-facture, use, sale, or offer for sale in, or importation into, the United States of the Lupin ANDA Product prior to the expiration of the '11-838 patent, constitutes an act of infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit that they mailed ARS and Aegis the Lupin Notice Letter, which speaks for itself. Defendants deny any remaining allegations set forth in this paragraph.

68. There is a justiciable controversy between the parties as to the infringement of the '11-838 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Plaintiffs have filed suit accusing Lupin of infringement of the '11-838 patent. Lupin denies any remaining allegations in this paragraph.

69. Lupin's manufacture, use, importation, offer for sale, sale, and/or importation of its proposed ANDA Product will, on information and belief, directly infringe or induce infringement of at least one claim of the '11-838 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

70. Unless enjoined, Lupin's importation, manufacture, use, offer for sale, and/or sale of its proposed ANDA Product, on information and belief, will induce and/or contribute to the infringement of at least one claim of the '11-838 patent.

ANSWER: Denied.

71. Unless Lupin is enjoined from infringing the '11-838 patent, Plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

Count V
(Infringement of U.S. Patent No. 11,717,571)

72. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

ANSWER: To the extent an answer to this paragraph is required, Defendants incorporate by reference their answers to the foregoing paragraphs as if fully set forth herein.

73. By submission of its ANDA, Lupin intends to obtain approval to commercially manufacture, use, import, offer for sale, and/or sell, alleged generic equivalents of Plaintiffs' neffy® drug product prior to the expiration date of the '571 patent.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations of this paragraph.

74. Lupin's submission of its ANDA to obtain approval to engage in the commercial manu-facture, use, sale, or offer for sale in, or importation into, the United States of the Lupin's ANDA Product prior to the expiration of the '571 patent, constitutes an act of infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit that they mailed ARS and Aegis the Lupin Notice Letter, which speaks for itself. Defendants deny any remaining allegations set forth in this paragraph.

75. There is a justiciable controversy between the parties as to the infringement of the '571 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Plaintiffs have filed suit accusing Lupin of infringement of the '571 patent. Lupin denies any remaining allegations in this paragraph.

76. Lupin's manufacture, use, importation, offer for sale, sale, and/or importation of its proposed ANDA Product will, on information and belief, directly infringe or induce infringement of at least one claim of the '571 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

77. Unless enjoined, Lupin's importation, manufacture, use, offer for sale, and/or sale of its proposed ANDA Product will, on information and belief, induce and/or contribute to the infringement of at least one claim of the '571 patent.

ANSWER: Denied.

78. Unless Lupin is enjoined from infringing the '571 patent, Plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

Count VI
(Infringement of U.S. Patent No. 11,744,895)

79. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

ANSWER: To the extent an answer to this paragraph is required, Defendants incorporate by reference their answers to the foregoing paragraphs as if fully set forth herein.

80. By submission of its ANDA, Lupin intends to obtain approval to commercially manufacture, use, import, offer for sale, and/or sell, alleged generic equivalents of Plaintiffs' neffy® drug product prior to the expiration date of the '895 patent.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations of this paragraph.

81. Lupin's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of the Lupin ANDA Product prior to the expiration of the '895 patent, constitutes an act of infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit that they mailed ARS and Aegis the Lupin Notice Letter, which speaks for itself. Defendants deny any remaining allegations set forth in this

paragraph.

82. There is a justiciable controversy between the parties as to the infringement of the '895 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Plaintiffs have filed suit accusing Lupin of infringement of the '895 patent. Lupin denies any remaining allegations in this paragraph.

83. Lupin's manufacture, use, importation, offer for sale, sale, and/or importation of its proposed ANDA Product will, on information and belief, directly infringe or induce infringement of at least one claim of the '895 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

84. Unless enjoined, Lupin's importation, manufacture, use, offer for sale, and/or sale of its proposed ANDA Product will, on information and belief, induce and/or contribute to the infringement of at least one claim of the '895 patent.

ANSWER: Denied.

85. Unless Lupin is enjoined from infringing the '895 patent, Plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

Count VII
(Infringement of U.S. Patent No. 11,918,655)

86. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

ANSWER: To the extent an answer to this paragraph is required, Defendants incorporate by reference their answers to the foregoing paragraphs as if fully set forth herein.

87. By submission of its ANDA, Lupin intends to obtain approval to commercially manufacture, use, import, offer for sale, and/or sell, alleged generic equivalents of Plaintiffs' neffy® drug product prior to the expiration date of the '655 patent.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations of this paragraph.

88. Lupin's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of the Lupin ANDA Product prior to the expiration of the '655 patent, constitutes an act of infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit that they mailed ARS and Aegis the Lupin Notice Letter, which speaks for itself. Defendants deny any remaining allegations set forth in this paragraph.

89. There is a justiciable controversy between the parties as to the infringement of the '655 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Plaintiffs have filed suit accusing Lupin of infringement of the '655 patent. Lupin denies any remaining allegations in this paragraph.

90. Lupin's manufacture, use, importation, offer for sale, sale, and/or importation of its proposed ANDA Product will, on information and belief, directly infringe or induce infringement of at least one claim of the '655 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

91. Unless enjoined, Lupin's importation, manufacture, use, offer for sale, and/or sale of its proposed ANDA Product will, on information and belief, induce and/or contribute to the infringement of at least one claim of the '655 patent.

ANSWER: Denied.

92. Unless Lupin is enjoined from infringing the '655 patent, Plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

Count VIII
(Infringement of U.S. Patent No. 12,324,838)

93. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

ANSWER: To the extent an answer to this paragraph is required, Defendants incorporate by reference their answers to the foregoing paragraphs as if fully set forth herein.

94. By submission of its ANDA, Lupin intends to obtain approval to commercially manufacture, use, import, offer for sale, and/or sell, alleged generic equivalents of Plaintiffs' neffy® drug product prior to the expiration date of the '12-838 patent.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations of this paragraph.

95. Lupin's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of the Lupin ANDA Product prior to the expiration of the '12-838 patent, constitutes an act of infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit that they mailed ARS and Aegis the Lupin Notice Letter, which speaks for itself. Defendants deny any remaining allegations set forth in this paragraph.

96. There is a justiciable controversy between the parties as to the infringement of the '12-838 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Defendants admit that Plaintiffs have filed suit accusing Lupin of infringement of the '12-838 patent. Lupin denies any remaining allegations in this paragraph.

97. Lupin's manufacture, use, importation, offer for sale, sale, and/or importation of its proposed ANDA Product will, on information and belief, directly infringe or induce infringement of at least one claim of the '12-838 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

98. Unless Lupin is enjoined from infringing the '12-838 patent, Plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

RESPONSE TO PRAYER FOR RELIEF

The remainder of the Complaint recites a prayer for relief for which no response is required. To the extent a response is required, Defendants deny that Plaintiffs are entitled to any relief.

AFFIRMATIVE DEFENSES

Defendants assert the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Defendants request that judgment be entered in its favor, dismissing the Complaint with prejudice, awarding Defendants attorneys' fees and costs incurred in this litigation under 35 U.S.C. § 285, and granting further relief as the Court may deem just and proper. Defendants do not assume the burden of proof on any such defenses, except as required by applicable law with respect to the particular defense asserted. Defendants reserve the right to assert other defenses and/or to otherwise supplement or amend this Answer upon discovery of facts or evidence rendering such action appropriate in accordance with the Federal Rules of Civil Procedure and Local Civil Rules of the U.S. District Court for the District of New Jersey.

FIRST AFFIRMATIVE DEFENSE

Each purported claim in the Complaint, in whole or in part, is barred for failure to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The claims of the Patents-in-Suit are invalid for failure to comply with the statutory

provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

THIRD AFFIRMATIVE DEFENSE

Plaintiffs are barred from asserting the claims of the Patents-in-Suit in whole or in part, either literally or by application of the doctrine of equivalents, by the doctrines of prosecution history estoppel, judicial estoppel, unclean hands, and/or other equitable doctrines.

FOURTH AFFIRMATIVE DEFENSE

The claims of the Patents-in-Suit are unenforceable as a result of inequitable conduct during prosecution before the U.S. Patent & Trademark Office, as particularly explained and alleged in the counterclaims below.

FIFTH AFFIRMATIVE DEFENSE

Defendants do not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the Patents-in-Suit. If the products that are the subject of ANDA No. 220047 were marketed, Defendants would not infringe any valid and enforceable claim of the Patents-in-Suit.

SIXTH AFFIRMATIVE DEFENSE

Defendants have not, do not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patents-in-Suit. If the products that are the subject of ANDA No. 220047 were marketed, Defendants would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patents-in-Suit.

SEVENTH AFFIRMATIVE DEFENSE

Defendant's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

EIGHTH AFFIRMATIVE DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

LUPIN INC.'S COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Lupin Inc. ("Lupin" or "Counterclaim Plaintiff/Defendant") bring the following Counterclaims against ARS Pharmaceuticals Operations, Inc. ("ARS") and Aegis Therapeutics, LLC ("Aegis") (collectively "Counterclaim Defendants/Plaintiffs") for a declaratory judgment that United States Patent Nos. 10,576,156 ("the '156 Patent"); 10,682,414 ("the '414 Patent"); 11,173,209 ("the '209 Patent"); 11,191,838 ("the '11-838 Patent"); 11,717,571 ("the '571 Patent"); 11,744,895 ("the '895 Patent"); 11,918,655 ("the '655 Patent"); and 12,324,838 ("the '12-838 Patent") (collectively, the "Patents-in-Suit") are invalid, unenforceable, and/or not infringed by the manufacture, use, sale, offer for sale, or importation of the epinephrine nasal spray, 2 mg/nasal spray ("Lupin's ANDA Product") that is the subject of Abbreviated New Drug Application ("ANDA") No. 220047 ("Lupin's ANDA").

THE PARTIES

1. On information and belief and as it pled in its Complaint, ARS is a corporation organized and existing under the laws of the state of Delaware, with a principal place of business

at 11682 El Camino Real, San Diego, California 92130.

2. On information and belief and as it pled in its Complaint, Aegis is a corporation organized and existing under the laws of the state of California, with a principal place of business at 3430 Carmel Mountain Road, San Diego, California, 92121.

3. Lupin Inc. is a corporation organized and existing under the laws of the State of Delaware, having a regular and established place of business at 5801 Pelican Bay Boulevard, Suite 500, Naples, Florida 34108.

JURISDICTION AND VENUE

4. 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 pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, based on an actual controversy between the parties arising under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq*.

5. This Court has personal jurisdiction over Counterclaim Defendants/Plaintiffs on the basis of, *inter alia*, its contacts with New Jersey relating to the subject matter of this action, including having filed the Complaint in the underlying suit.

6. Venue is proper under 28 U.S.C. §§ 1391 and 1400 and as a result of Counterclaim Defendants/Plaintiffs' filing of the Complaint in the underlying suit.

7. There is an actual justiciable controversy between the parties concerning non-infringement, invalidity, and unenforceability of the Patents-in-Suit.

BACKGROUND

8. This is an action based upon an actual controversy between the parties concerning the invalidity, unenforceability, and/or non-infringement of the Patents-in-Suit.

9. Counterclaim Defendants/Plaintiffs have alleged that the submission of Lupin's ANDA infringes, will infringe, will induce infringement, or will contribute to infringement of one or more claims of the Patents-in-Suit.

10. Upon information and belief, ARS holds approved New Drug Application ("NDA") No. 214697 for NEFFY® (epinephrine, 2 mg/nasal spray).

11. 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).

12. 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).

13. On information and belief, Counterclaim Defendants/Plaintiffs caused the Patents-in-Suit to be listed in the Orange Book as patents that claim a pharmaceutical composition comprising and/or a method of using a drug encompassed by NDA No. 214697, NEFFY®, which is held by ARS.

14. On information and belief, the '156 Patent, entitled "Composition for Drug Administration," issued on March 3, 2020.

15. On information and belief, the '414 Patent, entitled "Intranasal Epinephrine Formulations and Methods the Treatment of Diseases," issued on June 16, 2020.

16. On information and belief, the '209 patent, entitled "Composition for Drug Administration," issued on November 16, 2021.

17. On information and belief, the '11-838 Patent, entitled "Intranasal Epinephrine Formulations and Methods the Treatment of Diseases," issued on December 7, 2021.

18. On information and belief, the '571 Patent, entitled "Intranasal Epinephrine Formulations and Methods the Treatment of Diseases," issued on August 8, 2023.

19. On information and belief, the '895 Patent, entitled "Intranasal Epinephrine Formulations and Methods the Treatment of Diseases," issued on September 5, 2023.

20. On information and belief, the '655 Patent, entitled "Intranasal Epinephrine Formulations and Methods the Treatment of Diseases," issued on March 5, 2024.

21. On information and belief, the '12-838 patent, entitled "Intranasal Epinephrine Formulations and Methods the Treatment of Diseases," issued on June 10, 2025.

22. On information and belief, based upon the United States Patent Office's assignment database and according to Counterclaim Defendants/Plaintiffs' allegations in their Complaint, Aegis is the assignee of the each of the Patents-in-Suit.

23. Counterclaim Plaintiff/Defendant Lupin Inc. submitted Lupin's ANDA to the FDA, listing NEFFY® as the reference product, seeking approval to engage in the commercial manufacture, use, sale, and/or importation of a generic product, "Epinephrine nasal spray," which has a dosage strength of 2 mg/nasal spray, prior to the expiration dates of the Patents-in-Suit that are listed in the Orange Book.

24. Pursuant to 21 U.S.C. § 355(j)(2)(B), Counterclaim Plaintiff/Defendant Lupin Inc. notified Counterclaim Defendants/Plaintiffs by letter dated August 8, 2025 (the "Lupin Notice Letter") that Counterclaim Plaintiff/Defendant Lupin Inc. had submitted Paragraph IV Certifications with its ANDA for the Patents-in-Suit. The Lupin Notice Letter, which is incorporated herein by reference, contained a detailed statement of the factual and legal bases for

Lupin Inc.'s Paragraph IV Certifications that the claims of the Patents-in-Suit are invalid, not infringed, and/or unenforceable.

25. According to their Complaint, Counterclaim Defendant/Plaintiff Aegis received the Lupin Notice Letter no later than August 11, 2025, and Counterclaim Defendant/Plaintiff ARS received the Lupin Notice Letter no later than August 13, 2025.

26. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) and 21 C.F.R. § 314.95(c)(8), Lupin Inc. offered Counterclaim Defendants/Plaintiffs confidential access to information from Lupin's ANDA No. 220047 for the purpose of determining whether an infringement action under 21 U.S.C. § 355(j)(5)(B)(iii) could be brought against Lupin Inc. relating to Lupin's ANDA Product.

27. On August 29, 2025, Counterclaim Defendants/Plaintiffs filed the instant lawsuit alleging infringement of the Patents-in-Suit.

28. As a consequence of the foregoing, there is an actual and justiciable controversy between Lupin, on the one hand, and Counterclaim Defendants/Plaintiffs, on the other hand, as to whether the claims of the Patents-in-Suit are invalid and/or unenforceable, and whether the products and/or activities described in Defendant's ANDA No. 220047 infringe, induce infringement, or contribute to the infringement of any valid and enforceable claim of the Patents-in-Suit.

COUNT I
(Declaratory Judgment of Unenforceability of the '156 Patent)

29. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 28 of its Counterclaims as though fully set forth herein.

30. Aegis alleges ownership of the '156 Patent and has brought claims against Defendant, alleging infringement of the '156 Patent.

31. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '156 Patent.

32. The '156 Patent is unenforceable due to inequitable conduct committed by Matthew J. Hierholzer, a patent attorney at the firm DLA Piper LLP (US) who represented Plaintiff/Counterclaim Defendant Aegis during the prosecution of the '156 Patent. As an experienced patent attorney and member of the bar of the United States Patent and Trademark Office ("USPTO"), registration number 53,021, Mr. Hierholzer was aware that he was subject to a duty of candor and good faith in his dealings with the USPTO.

33. As described in more detail below, Mr. Hierholzer made knowing, material misrepresentations regarding the state of the art in a sworn response to a substantive rejection of the then-pending claims of the '156 Patent. Based on Mr. Hierholzer's decade of experience with prosecuting numerous prior art patents related to research conducted by Aegis's then-CEO and sole named inventor of the '156 Patent, Edward T. Maggio, all of which contained disclosures that contradicted the arguments Mr. Hierholzer advanced to secure the issuance of the '156 Patent's claims, the single most reasonable inference to be drawn is that Mr. Hierholzer made these sworn statements with the specific intent to deceive the USPTO. Thus, the '156 Patent is unenforceable.

I. Mr. Hierholzer Was Subject to a Duty of Candor and Good Faith in His Prosecution Communications with the USPTO.

34. Mr. Hierholzer had a duty under USPTO rules to conduct himself with the utmost candor and good faith in all dealings with the Examiner during prosecution of the '156 Patent. *See* 37 C.F.R. § 1.56(a) ("Rule 56") ("[N]o patent will be granted on an application in connection

with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct."). The USPTO's Manual of Patent Examining Procedure ("MPEP") further explains Rule 56's "Duty of Disclosure, Candor, and Good Faith." *See* MPEP § 2001 ("The language of 37 C.F.R. 1.56 . . . emphasizes that there is a duty of candor and good faith which is broader than the duty to disclose material information. … Specifically, the duty of candor and good faith, and by extension the duty to disclose, applies to positions taken by applicants or parties involving the claimed subject matter.")

35. As a registered member of the USPTO bar, Mr. Hierholzer was aware of this duty when he made the statements detailed below.

II. Mr. Hierholzer Materially Misrepresented the State of the Art with the Specific Intent to Mislead the Examiner and Overcome the Rejection of the '156 Patent Claims.

36. United States Patent Application No. 15/890,131 ("the '131 Application"), which issued as the '156 Patent, was filed on February 6, 2018. As originally filed, the '131 Application claimed priority to an earlier Maggio patent, United States Patent No. 9,895,444 ("the '444 Patent"), originally filed on December 18, 2013. (Complaint Ex. A, '156 Patent at Cover Sheet.)

37. The '131 Application received a number of office actions raising various rejections and objections to the patentability of its claims. Notably, the Examiner rejected Aegis's priority claim to the '444 Patent's 2013 filing date in the first office action, determining, and repeating in every subsequent office action, that the '156 Patent's claims were entitled to a priority date no earlier than the '131 Application's February 6, 2018 filing date. That 2018 date is the critical date by which all issues of patentability were argued during the remainder of the '156 Patent's prosecution. (*See* Ex. 1, '156 File History Excerpts, Aug. 9, 2019 Office Action at 2-3.)

38. On August 9, 2019, the Examiner issued a Final Rejection of the '131 Application's pending claims. Despite Mr. Hierholzer's arguments attempting to distinguish them, the Examiner

maintained his previous rejection of all claims as obvious over two references, United States Patent Application Publication No. 2010/209,357 ("Levitt") in view of U.S. Patent No. 5,369,095 ("Kee"). (*See id.* at 4-8.)

39. On September 16, 2019, Mr. Hierholzer attended a telephonic interview with the Examiner to argue for the patentability of the pending claims. Although arguments to distinguish the teachings of Levitt and Kee were discussed, no agreement was reached. However, Mr. Hierholzer and the Examiner did discuss the possibility of overcoming the rejection if Aegis could move the specific concentrations of the permeation enhancer, dodecyl maltoside, from a dependent claim into the independent claim and identify some unexpected results related to the claimed concentration of dodecyl maltoside. (*See* Ex. 1, '156 File History Excerpts, Sept. 20, 2019 Applicant Initiated Interview Summary at 2.)

40. On September 26, 2019, Mr. Hierholzer filed a response to the August 9, 2019 Final Rejection, in which, as discussed during the interview, dependent claim 34, directed to a formulation with a percentage of between about 0.05% and 0.5% dodecyl maltoside, was cancelled and its concentration limitation added to an amended independent claim 16. (*See* Ex. 1, '156 File History Excerpts, Sept. 26, 2019 Claim Amendments at 2.) Mr. Hierholzer also filed a declaration from ARS CEO Richard Lowenthal (a co-inventor on the '414 Patent and related Patents-in-Suit) arguing that testing conducted by a contractor during the development of NEFFY® showed an "unexpected technical effect of using 0.05%–0.5% dodecyl maltoside" relative to a composition containing a different alkyl glycoside penetration enhancer, octyl maltoside. (*See* Ex. 1, '156 File History Excerpts, Sept. 26, 2019 Lowenthal Declaration at 2.)

41. At the same time, Mr. Hierholzer filed arguments in response to the August 9, 2019 Final Rejection. In those arguments, Mr. Hierholzer repeated his arguments attempting to

distinguish Levitt and Kee, but also added, relying on the claim amendments and the Lowenthal declaration, Mr. Hierholzer then made the following new argument:

> Applicant further submits that **the claimed composition provided superior therapeutic results** that are not even contemplated in Levitt or Kee. In particular, the Examiner refers to Table XIX of the present application, which summarizes superior improvement in Cmax as a result of using 0.05%-0.5% dodecyl maltoside in an intranasal composition (all ≥1.5), as compared to octyl maltoside at the same 0.05%-0.5% concentration range (all ≤1.5). Applicant notes that **such unexpected results achieved by using dodecyl maltoside over octyl maltoside** at the same 0.05%-0.5% concentration range applies to all three active agents listed in Table XIX (reproduced below), i.e. sumatriptan, naratriptan, and rizatriptan.

(*See* Ex. 1, '156 File History Excerpts, Sept. 26, 2019 Applicant Remarks at 12 (emphasis added).)

42. This statement, that the fact of dodecyl maltoside producing superior permeation enhancement relative to octyl maltoside constituted "unexpected results" as of the February 6, 2018 priority date of the '131 Application's claims, is false. On information and belief, Mr. Hierholzer knew the falsity of this statement when it was made, and he made this false statement with the specific intent to mislead the Examiner regarding the state of the relevant art as of the claims' 2018 priority date in order to secure allowance of the claims.

43. There can be no doubt that Mr. Hierholzer was aware that there was nothing new or unexpected in 2018 about the superiority of dodecyl maltoside (an organic compound consisting of a maltose molecule bonded to a "tail" consisting of a chain of twelve carbon atoms) versus octyl maltoside (a similar compound in which maltose is bonded with an eight-carbon tail) as a permeation enhancer. The specification of the '444 Patent, which Mr. Hierholzer himself filed in 2013, and which was prior art to the '131 Application's claims, contains the exact same "Table XIX" cited in the September 16, 2019 Applicant Remarks as supposedly demonstrating the unexpected superiority of dodecyl maltoside over octyl maltoside. (*See* Ex. 2, '444 Patent at

69:7-37.) As Mr. Hierholzer also had to have been aware, the '444 Patent specification also contained the same language that appears in the '156 Patent specification explicitly stating the known superiority of dodecyl maltoside over octyl maltoside: "These studies show **that alkylmaltosides with longer alkyl chains** (or number of carbon atoms), e.g., **dodecyl- . . . maltosides, are more effective** . . . . The **shorter alkyl chains** (fewer carbon atoms) e.g., . . . **octylmaltoside, produce less absorption enhancing activity**." (*Compare* Complaint Ex. A, '156 Patent at 46:16-24, *with* Ex. 2, '444 Patent at 69:7-37 (emphasis added).)

44. When the Examiner rejected Aegis's priority claim to the '444 Patent's 2013 filing date, the '444 Patent, as well as its April 17, 2014 publication as United States Patent Application Publication No. 2014/107,145 (which contained both Table XIX and the specification language quoted above), became prior art to the claims of the '156 Patent. On information and belief, Mr. Hierholzer was aware of this fact, and yet he still argued that the disclosures that had been in the prior art for at least nearly half a decade constituted unexpected results supporting patentability of the '156 Patent's claims as of their 2018 priority date.

45. However, on information and belief, Mr. Hierholzer was also aware that the language in the specification quoted above was actually much older than the filing of the 2013 application for the '444 Patent. The '444 Patent claimed priority through eight non-provisional patent applications beginning with United States Patent Application No. 11/127,786, filed in May 11, 2005, and five provisional applications dating back to the filing of United States Provisional Patent Application No. 60/604,296 on August. 25, 2004, all naming Edward Maggio as the sole inventor. Provisional Application No. 60/637,284, filed on December 17, 2004, contained the following disclosure: "Based on these studies it appears that **alkylmaltosides with longer alkyl chains, i.e., dodecyl- . . . maltosides . . . are more effective** as absorption enhancers **than those**

with shorter alkyl chains which produce less, e.g., decyl maltoside, **or no, e.g., octylmaltoside, activity**." (Ex. 3, U.S. Prov. Pat. App. No. 60/637,284 at [0052] (emphasis added).) With minor variations in wording, substantially this same disclosure appears in each subsequent application in the '444 Patent's family, as well as in the '156 Patent and its continuation, the '209 Patent.

46. On information and belief, Mr. Hierholzer was aware of these disclosures in the '444 Patent family specification. He signed the filing documents for the '444 Patent's application and all office action responses and information disclosure statements during its prosecution, (*see* Ex. 4, '444 Patent File History Excerpt, Transmittal of New Application dated Dec. 18, 2013), as well as for two other applications in its family dating back to October 18, 2010, (*see* Ex. 5, Transmittal Of New Application dated July 26, 2011; Ex. 6, Transmittal Of New Application dated October 18, 2010). In fact, Mr. Hierholzer signed and/or prepared documents in the prosecution of this patent family dating back to at least February 24, 2009 when he signed an information disclosure statement in the prosecution of Application No. 11/193,825, which had been filed on July 29, 2005. (*See* Ex. 7, Information Disclosure Statement dated February 24, 2009.)

47. Beyond his knowledge that the specifications of other prior art Maggio patents contradicted his assertion of unexpected results, on information and belief, Mr. Hierholzer was also aware of another key piece of prior art during the prosecution of the '156 Patent that contradicted his claims of unexpected results, and which was withheld from the Examiner during prosecution. On May 1, 2014, Dr. Maggio published a paper in the Journal of Excipients and Food Chemicals entitled "Absorption Enhancing Excipients in Systemic Nasal Drug Delivery." (Ex. 8, ET Maggio, *Absorption Enhancing Excipients in Systemic Nasal Drug Delivery*, 5 J. EXCIPIENTS AND FOOD CHEM. 100 (2014) ("Maggio 2014").) In the Maggio 2014 article, as in the earlier

patent disclosures, Dr. Maggio wrote that "shorter chained alkylsaccharides . . . were ineffective, or minimally effective" in increasing nasal absorption, while "[l]onger chain alkylsaccharides such as dodecyl maltoside . . . were very potent absorption enhancers, even at concentrations as low as 0.03-0.06%. No other absorption enhancing agents tested to date have been as effective at such low concentrations." (*Id.* at 105.) This disclosure in the prior art Maggio 2014 article further demonstrates that there was nothing "unexpected" about dodecyl maltoside having superior absorption-enhancing qualities to octyl maltoside as of the 2018 priority date of the '156 Patent claims.

48. On information and belief, Mr. Hierholzer was aware of the Maggio 2014 reference, and its contradiction of his unexpected results argument, when he filed the September 26, 2019 Applicant Remarks.

49. In any event, Mr. Hierholzer was definitely aware of its existence prior to the issuance of the '156 Patent. The '156 Patent issued on March 3, 2020. However, on January 31, 2020, Mr. Hierholzer signed and filed an information disclosure statement in the prosecution of the related '209 Patent disclosing, for the first time in the prosecution of this family, the Maggio 2014 reference. (*See* Ex. 9, '209 Patent File History Excerpt, Jan. 31, 2020 Information Disclosure Statement at No. 18 (Maggio 2014), and Transmittal Letter at 2 (Mr. Hierholzer's signature).)

50. Under the USPTO rules, an attorney's Rule 56 duty to disclose information material to patentability does not end at the issuance of a notice of allowance, but rather "extends until a patent is granted on that application." (MPEP § 2001.04.) On information and belief, Mr. Hierholzer knew of this duty to disclose the Maggio 2014 reference, which he also knew contradicted his argument for patentability based on alleged unexpected results, and chose not to disclose that reference.

51. There can also be no question that both the disclosures of the prior-art Maggio patents in the '444 Patent family and the Maggio 2014 article were material to patentability of the '156 Patent claims. Rule 56 states that information is material to patentability if "(2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability." (37 C.F.R. § 1.56(b)(2).) Because both the disclosures of the prior art Maggio patents in the '444 Patent family and the Maggio 2014 article refute or, at the very least, are inconsistent with Mr. Hierholzer's argument for patentability based on alleged unexpected results, they were material to patentability under Rule 56 and Mr. Hierholzer breached his duty under that rule to disclose that information to the Examiner.

52. Further evidence of the materiality of this information is found in the Examiner's written reasons for allowance of the claims. In his notice of allowance dated January 14, 2020, the Examiner expressly rejected Mr. Hierholzer's arguments seeking to distinguish the Levitt and Kee references, but specifically cited Mr. Hierholzer's arguments based on the Lowenthal Declaration as supporting patentability, stating that the superiority of dodecyl maltoside versus octyl maltoside as a penetration enhancer "constitue[d] unexpected results." (*See* Ex. 1, '156 File History Excerpts, Jan. 14, 2020 Notice of Allowance at 3-6.) This demonstrates that Mr. Hierholzer's knowingly false argument constituted the sole basis for allowance of the '156 Patent claims.

53. Based on Mr. Hierholzer's demonstrated knowledge of material information that contradicted his argument for patentability based on alleged unexpected results dating back at least 14 years prior to the priority date of the '156 Patent claims, and his withholding of the Maggio 2014 reference from the Examiner prior to issuance of the '156 Patent, the only

reasonable inference to be drawn is that Mr. Hierholzer undertook these actions and made what he knew to be a false argument about the state of the art as of the February 6, 2018 priority date and what was "unexpected results" as of that date with the specific intent to mislead the examiner in order to secure allowance of the '156 Patent Claims.

54. Lupin is entitled to a declaration that all claims of the '156 Patent are unenforceable because of Mr. Hierholzer's inequitable conduct during its prosecution.

55. This case is an exceptional one, and Lupin is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II
(Declaratory Judgment of Non-Infringement of the '156 Patent)

56. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 55 of its Counterclaims as though fully set forth herein.

57. Aegis alleges ownership of the '156 Patent and has brought claims against Defendant, alleging infringement of the '156 Patent.

58. The manufacture, use, or sale of Lupin's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '156 Patent, and the submission of Lupin's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '156 Patent.

59. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product infringes, has infringed,

and/or will infringe a valid and enforceable claim of the '156 Patent.

60. Lupin has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '156 Patent and is not liable for such infringement.

61. Lupin is entitled to a declaration that the manufacture, use, or sale of Lupin's ANDA Product would not infringe any valid or enforceable claim of the '156 Patent.

COUNT III
(Declaratory Judgment of Invalidity and/or Unenforceability of the '156 Patent)

62. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 61 of its Counterclaims as though fully set forth herein.

63. Aegis alleges ownership of the '156 Patent and has brought claims against Defendant, alleging infringement of the '156 Patent.

64. One or more claims of the '156 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

65. The '156 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.

66. The alleged invention of the '156 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 '156 Patent is not 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 '156 Patent and would have had a reasonable expectation of success in doing so.

67. The subject matter claimed in the '156 Patent fails to comply with 35 U.S.C. § 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 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.

68. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '156 Patent.

69. Lupin is entitled to a declaration that all claims of the '156 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT IV
(Declaratory Judgment of Unenforceability of the '209 Patent)

70. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 69 of its Counterclaims as though fully set forth herein.

71. Aegis alleges ownership of the '209 Patent and has brought claims against Defendant, alleging infringement of the '209 Patent.

72. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '209 Patent.

73. As set forth in detail in Count I above, the ’156 Patent was secured by inequitable conduct during its prosecution by Matthew J. Hierholzer, a patent attorney for Counterclaim Defendant/Plaintiff Aegis. The ’156 Patent is therefore unenforceable due to Mr. Hierholzer’s inequitable conduct.

74. The ’209 Patent claims priority to the ’156 Patent as a continuation of that patent, and the claims of the ’209 Patent recite methods of using the pharmaceutical compositions claimed in the ’156 Patent. There is therefore an immediate and necessary relation between the claims of the ’209 Patent and the ’156 Patent claims secured through Mr. Hierholzer’s inequitable conduct.

75. Pursuant to the judicially created doctrine of infectious unenforceability, Lupin is entitled to a judgment declaring that all claims of the ’209 Patent are unenforceable due to Mr. Hierholzer’s inequitable conduct during prosecution of the ’156 Patent.

76. This case is an exceptional one, and Lupin is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT V
(Declaratory Judgment of Non-Infringement of the ’209 Patent)

77. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 76 of its Counterclaims as though fully set forth herein.

78. Aegis alleges ownership of the ’209 Patent and has brought claims against Defendant, alleging infringement of the ’209 Patent.

79. The manufacture, use, or sale of Lupin’s ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the ’209 Patent, and the submission of Lupin’s

ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '209 Patent.

80. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '209 Patent.

81. Lupin has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '209 Patent and is not liable for such infringement.

82. Lupin is entitled to a declaration that the manufacture, use, or sale of Lupin's ANDA Product would not infringe any valid or enforceable claim of the '209 Patent.

COUNT VI
(Declaratory Judgment of Invalidity and/or Unenforceability of the '209 Patent)

83. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 82 of its Counterclaims as though fully set forth herein.

84. Aegis alleges ownership of the '209 Patent and has brought claims against Defendant, alleging infringement of the '209 Patent.

85. One or more claims of the '209 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

86. The '209 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.

87. The alleged invention of the ’209 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 ’209 Patent is not 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 ’209 Patent and would have had a reasonable expectation of success in doing so.

88. The subject matter claimed in the ’209 Patent fails to comply with 35 U.S.C. § 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 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.

89. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin’s ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin’s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the ’209 Patent.

90. Lupin is entitled to a declaration that all claims of the ’209 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT VII
(Declaratory Judgment of Unenforceability of the ’414 Patent)

91. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 90 of its Counterclaims as though fully set forth herein.

92. Aegis alleges ownership of the ’414 patent and has brought claims against Defendant, alleging infringement of the ’414 patent.

93. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin’s ANDA and/or the commercial marketing of Lupin’s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the ’414 patent.

94. As set forth in detail in Count I above, the ’156 Patent was secured by inequitable conduct during its prosecution by Matthew J. Hierholzer, a patent attorney for Counterclaim Defendant/Plaintiff Aegis. The ’156 Patent is therefore unenforceable due to Mr. Hierholzer’s inequitable conduct.

95. Although the ’414 Patent does not claim priority to the ’156 Patent, there is substantial overlap between the subject matter claimed in both patents, as both patents claim formulations comprising epinephrine and dodecyl maltoside as a permeation enhancer, which is the same excipient that Mr. Hierholzer misleadingly argued produced unexpected results during prosecution of the ’156 Patent. There is therefore an immediate and necessary relation between the claims of the ’414 Patent and the ’156 Patent claims secured through Mr. Hierholzer’s inequitable conduct.

96. Pursuant to the judicially created doctrine of infectious unenforceability, Lupin is entitled to a judgment declaring that all claims of the ’414 Patent are unenforceable due to Mr. Hierholzer’s inequitable conduct during prosecution of the ’156 Patent.

97. This case is an exceptional one, and Lupin is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

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

98. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 97 of its Counterclaims as though fully set forth herein.

99. Aegis alleges ownership of the '414 Patent and has brought claims against Defendant, alleging infringement of the '414 Patent.

100. The manufacture, use, or sale of Lupin's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '414 Patent, and the submission of Lupin's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '414 Patent.

101. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '414 Patent.

102. Lupin 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.

103. Lupin is entitled to a declaration that the manufacture, use, or sale of Lupin's ANDA Product would not infringe any valid or enforceable claim of the '414 Patent.

COUNT IX
(Declaratory Judgment of Invalidity and/or Unenforceability of the '414 Patent)

104. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 103 of its Counterclaims as though fully set forth herein.

105. Aegis alleges ownership of the '414 Patent and has brought claims against Defendant, alleging infringement of the '414 Patent.

106. One or more claims of the '414 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

107. Before the effective filing date of the '414 Patent, the invention claimed in one or more of the claims of the '414 Patent was described and/or disclosed in at least the prior art United States Patent Application Publication No. 2016/220,489 ("US489") reference.

108. US489 discloses, either expressly or inherently, all the limitations of one or more claims of the '414 Patent.

109. A person of skill in the art would recognize that every element of one or more claims of the '414 Patent is present in the single US489 prior art reference.

110. As such, the invention claimed in one or more claims of the '414 Patent is anticipated by at least US489 and therefore is invalid under 35 U.S.C. § 102.

111. The '414 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.

112. The alleged invention of the '414 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 '414 Patent is not 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 '414 Patent and would have had a reasonable expectation of success in doing so.

113. The subject matter claimed in the '414 Patent fails to comply with 35 U.S.C. § 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 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.

114. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '414 Patent.

115. Lupin is entitled to a declaration that all claims of the '414 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT X
(Declaratory Judgment of Unenforceability of the '11-838 Patent)

116. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 115 of its Counterclaims as though fully set forth herein.

117. Aegis alleges ownership of the '11-838 Patent and has brought claims against Defendant, alleging infringement of the '11-838 Patent.

118. There is an actual, substantial, continuing, and justiciable controversy between the

parties regarding whether the filing of Lupin's ANDA and/or the commercial marketing of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '11-838 patent.

119. As set forth in detail in Count I above, the '156 Patent was secured by inequitable conduct during its prosecution by Matthew J. Hierholzer, a patent attorney for Counterclaim Defendant/Plaintiff Aegis. The '156 Patent is therefore unenforceable due to Mr. Hierholzer's inequitable conduct.

120. Although the '11-838 Patent does not claim priority to the '156 Patent, there is substantial overlap between the subject matter claimed in both patents, as both patents claim formulations comprising epinephrine and dodecyl maltoside as a permeation enhancer, which is the same excipient that Mr. Hierholzer misleadingly argued produced unexpected results during prosecution of the '156 Patent. There is therefore an immediate and necessary relation between the claims of the '11-838 Patent and the '156 Patent claims secured through Mr. Hierholzer's inequitable conduct.

121. Pursuant to the judicially created doctrine of infectious unenforceability, Lupin is entitled to a judgment declaring that all claims of the '11-838 Patent are unenforceable due to Mr. Hierholzer's inequitable conduct during prosecution of the '156 Patent.

122. This case is an exceptional one, and Lupin is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XI
(Declaratory Judgment of Non-Infringement of the '11-838 Patent)

123. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 122 of its Counterclaims as though fully set forth herein.

124. Aegis alleges ownership of the '11-838 Patent and has brought claims against Defendant, alleging infringement of the '11-838 Patent.

125. The manufacture, use, or sale of Lupin's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '11-838 Patent, and the submission of Lupin's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '11-838 Patent.

126. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '11-838 Patent.

127. Lupin has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '11-838 Patent and is not liable for such infringement.

128. Lupin is entitled to a declaration that the manufacture, use, or sale of Lupin's ANDA Product would not infringe any valid or enforceable claim of the '11-838 Patent.

COUNT XII
(Declaratory Judgment of Invalidity and/or Unenforceability of the '11-838 Patent)

129. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 128 of its Counterclaims as though fully set forth herein.

130. Aegis alleges ownership of the '11-838 Patent and has brought claims against Defendant, alleging infringement of the '11-838 Patent.

131. One or more claims of the ’11-838 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

132. Before the effective filing date of the ’11-838 Patent, the invention claimed in one or more of the claims of the ’11-838 Patent was described and/or disclosed in at least the prior art US489 reference.

133. US489 discloses, either expressly or inherently, all the limitations of one or more claims of the ’11-838 Patent.

134. A person of skill in the art would recognize that every element of one or more claims of the ’11-838 Patent is present in the single US489 prior art reference.

135. As such, the invention claimed in one or more claims of the ’11-838 Patent is anticipated by at least US489 and therefore is invalid under 35 U.S.C. § 102.

136. The ’11-838 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.

137. The alleged invention of the ’11-838 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 ’11-838 Patent is not 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 ’11-838 Patent and would have had a reasonable expectation of success in doing so.

138. The subject matter claimed in the '11-838 Patent fails to comply with 35 U.S.C. § 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 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.

139. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '11-838 Patent.

140. Lupin is entitled to a declaration that all claims of the '11-838 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT XIII
(Declaratory Judgment of Unenforceability of the '571 Patent)

141. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 140 of its Counterclaims as though fully set forth herein.

142. Aegis alleges ownership of the '571 patent and has brought claims against Defendant, alleging infringement of the '571 patent.

143. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the commercial marketing of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '571 Patent.

144. As set forth in detail in Count I above, the '156 Patent was secured by inequitable conduct during its prosecution by Matthew J. Hierholzer, a patent attorney for Counterclaim

Defendant/Plaintiff Aegis. The ’156 Patent is therefore unenforceable due to Mr. Hierholzer’s inequitable conduct.

145. Although the ’571 Patent does not claim priority to the ’156 Patent, there is substantial overlap between the subject matter claimed in both patents, as both patents claim formulations comprising epinephrine and dodecyl maltoside as a permeation enhancer, which is the same excipient that Mr. Hierholzer misleadingly argued produced unexpected results during prosecution of the ’156 Patent. There is therefore an immediate and necessary relation between the claims of the ’571 Patent and the ’156 Patent claims secured through Mr. Hierholzer’s inequitable conduct.

146. Pursuant to the judicially created doctrine of infectious unenforceability, Lupin is entitled to a judgment declaring that all claims of the ’571 Patent are unenforceable due to Mr. Hierholzer’s inequitable conduct during prosecution of the ’156 Patent.

147. This case is an exceptional one, and Lupin is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT XIV
(Declaratory Judgment of Non-Infringement of the ’571 Patent)

148. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 147 of its Counterclaims as though fully set forth herein.

149. Aegis alleges ownership of the ’571 Patent and has brought claims against Defendant, alleging infringement of the ’571 Patent.

150. The manufacture, use, or sale of Lupin’s ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the ’571 Patent, and the submission of Lupin’s

ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '571 Patent.

151. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '571 Patent.

152. Lupin has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '571 Patent and is not liable for such infringement.

153. Lupin is entitled to a declaration that the manufacture, use, or sale of Lupin's ANDA Product would not infringe any valid or enforceable claim of the '571 Patent.

COUNT XV
(Declaratory Judgment of Invalidity and/or Unenforceability of the '571 Patent)

154. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 153 of its Counterclaims as though fully set forth herein.

155. Aegis alleges ownership of the '571 Patent and has brought claims against Defendant, alleging infringement of the '571 Patent.

156. One or more claims of the '571 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

157. Before the effective filing date of the ’571 Patent, the invention claimed in one or more of the claims of the ’571 Patent was described and/or disclosed in at least the prior art US489 reference.

158. US489 discloses, either expressly or inherently, all the limitations of one or more claims of the ’571 Patent.

159. A person of skill in the art would recognize that every element of one or more claims of the ’571 Patent is present in the single US489 prior art reference.

160. As such, the invention claimed in one or more claims of the ’571 Patent is anticipated by at least US489 and therefore is invalid under 35 U.S.C. § 102.

161. The ’571 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.

162. The alleged invention of the ’571 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 ’571 Patent is not 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 ’571 Patent and would have had a reasonable expectation of success in doing so.

163. The subject matter claimed in the ’571 Patent fails to comply with 35 U.S.C. § 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 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.

164. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '571 Patent.

165. Lupin is entitled to a declaration that all claims of the '571 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT XVI
(Declaratory Judgment of Unenforceability of the '895 Patent)

166. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 165 of its Counterclaims as though fully set forth herein.

167. Aegis alleges ownership of the '895 Patent and has brought claims against Defendant, alleging infringement of the '895 Patent.

168. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the commercial marketing of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '895 Patent.

169. As set forth in detail in Count I above, the '156 Patent was secured by inequitable conduct during its prosecution by Matthew J. Hierholzer, a patent attorney for Counterclaim Defendant/Plaintiff Aegis. The '156 Patent is therefore unenforceable due to Mr. Hierholzer's inequitable conduct.

170. Although the '895 Patent does not claim priority to the '156 Patent, there is substantial overlap between the subject matter claimed in both patents, as both patents claim formulations comprising epinephrine and dodecyl maltoside as a permeation enhancer, which is

the same excipient that Mr. Hierholzer misleadingly argued produced unexpected results during prosecution of the '156 Patent. There is therefore an immediate and necessary relation between the claims of the '895 Patent and the '156 Patent claims secured through Mr. Hierholzer's inequitable conduct.

171. Pursuant to the judicially created doctrine of infectious unenforceability, Lupin is entitled to a judgment declaring that all claims of the '895 Patent are unenforceable due to Mr. Hierholzer's inequitable conduct during prosecution of the '156 Patent.

172. This case is an exceptional one, and Lupin is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XVII
(Declaratory Judgment of Non-Infringement of the '895 Patent)

173. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 172 of its Counterclaims as though fully set forth herein.

174. Aegis alleges ownership of the '895 Patent and has brought claims against Defendant, alleging infringement of the '895 Patent.

175. The manufacture, use, or sale of Lupin's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '895 Patent, and the submission of Lupin's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '895 Patent.

176. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the manufacture, use, offer to sell,

sale, and/or importation into the United States of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '895 Patent.

177. Lupin has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '895 Patent and is not liable for such infringement.

178. Lupin is entitled to a declaration that the manufacture, use, or sale of Lupin's ANDA Product would not infringe any valid or enforceable claim of the '895 Patent.

COUNT XVIII
(Declaratory Judgment of Invalidity and/or Unenforceability of the '895 Patent)

179. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 178 of its Counterclaims as though fully set forth herein.

180. Aegis alleges ownership of the '895 Patent and has brought claims against Defendant, alleging infringement of the '895 Patent.

181. One or more claims of the '895 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

182. Before the effective filing date of the '895 Patent, the invention claimed in one or more of the claims of the '895 Patent was described and/or disclosed in at least the prior art US489 reference.

183. US489 discloses, either expressly or inherently, all the limitations of one or more claims of the '895 Patent.

184. A person of skill in the art would recognize that every element of one or more claims of the '895 Patent is present in the single US489 prior art reference.

185. As such, the invention claimed in one or more claims of the '895 Patent is anticipated by at least US489 and therefore is invalid under 35 U.S.C. § 102.

186. The '895 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.

187. The alleged invention of the '895 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 '895 Patent is not 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 '895 Patent and would have had a reasonable expectation of success in doing so.

188. The subject matter claimed in the '895 Patent fails to comply with 35 U.S.C. § 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 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.

189. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '895 Patent.

190. Lupin is entitled to a declaration that all claims of the ’895 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT XIX
(Declaratory Judgment of Unenforceability of the ’655 Patent)

191. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 190 of its Counterclaims as though fully set forth herein.

192. Aegis alleges ownership of the ’655 patent and has brought claims against Defendant, alleging infringement of the ’655 patent.

193. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin’s ANDA and/or the commercial marketing of Lupin’s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the ’655 Patent.

194. As set forth in detail in Count I above, the ’156 Patent was secured by inequitable conduct during its prosecution by Matthew J. Hierholzer, a patent attorney for Counterclaim Defendant/Plaintiff Aegis. The ’156 Patent is therefore unenforceable due to Mr. Hierholzer’s inequitable conduct.

195. Although the ’655 Patent does not claim priority to the ’156 Patent, there is substantial overlap between the subject matter claimed in both patents, as both patents claim formulations comprising epinephrine and dodecyl maltoside as a permeation enhancer, which is the same excipient that Mr. Hierholzer misleadingly argued produced unexpected results during prosecution of the ’156 Patent. There is therefore an immediate and necessary relation between the claims of the ’655 Patent and the ’156 Patent claims secured through Mr. Hierholzer’s inequitable conduct.

196. Pursuant to the judicially created doctrine of infectious unenforceability, Lupin is entitled to a judgment declaring that all claims of the ’655 Patent are unenforceable due to Mr. Hierholzer’s inequitable conduct during prosecution of the ’156 Patent.

197. This case is an exceptional one, and Lupin is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT XX
(Declaratory Judgment of Non-Infringement of the ’655 Patent)

198. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 197 of its Counterclaims as though fully set forth herein.

199. Aegis alleges ownership of the ’655 Patent and has brought claims against Defendant, alleging infringement of the ’655 Patent.

200. The manufacture, use, or sale of Lupin’s ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the ’655 Patent, and the submission of Lupin’s ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the ’655 Patent.

201. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin’s ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin’s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the ’655 Patent.

202. Lupin has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’655 Patent and is not liable for such

infringement.

203. Lupin is entitled to a declaration that the manufacture, use, or sale of Lupin's ANDA Product would not infringe any valid or enforceable claim of the '655 Patent.

COUNT XXI
(Declaratory Judgment of Invalidity and/or Unenforceability of the '655 Patent)

204. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 203 of its Counterclaims as though fully set forth herein.

205. Aegis alleges ownership of the '655 Patent and has brought claims against Defendant, alleging infringement of the '655 Patent.

206. One or more claims of the '655 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

207. Before the effective filing date of the '655 Patent, the invention claimed in one or more of the claims of the '655 Patent was described and/or disclosed in at least the prior art US489 reference.

208. US489 discloses, either expressly or inherently, all the limitations of one or more claims of the '655 Patent.

209. A person of skill in the art would recognize that every element of one or more claims of the '655 Patent is present in the single US489 prior art reference.

210. As such, the invention claimed in one or more claims of the '655 Patent is anticipated by at least US489 and therefore is invalid under 35 U.S.C. § 102.

211. The ’655 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.

212. The alleged invention of the ’655 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 ’655 Patent is not 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 ’655 Patent and would have had a reasonable expectation of success in doing so.

213. The subject matter claimed in the ’655 Patent fails to comply with 35 U.S.C. § 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 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.

214. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin’s ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin’s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the ’655 Patent.

215. Lupin is entitled to a declaration that all claims of the ’655 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

COUNT XXII
(Declaratory Judgment of Unenforceability of the '12-838 Patent)

216. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 215 of its Counterclaims as though fully set forth herein.

217. Aegis alleges ownership of the '12-838 Patent and has brought claims against Defendant, alleging infringement of the '12-838 Patent.

218. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the commercial marketing of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '12-838 Patent.

219. As set forth in detail in Count I above, the '156 Patent was secured by inequitable conduct during its prosecution by Matthew J. Hierholzer, a patent attorney for Counterclaim Defendant/Plaintiff Aegis. The '156 Patent is therefore unenforceable due to Mr. Hierholzer's inequitable conduct.

220. Although the '12-838 Patent does not claim priority to the '156 Patent, there is substantial overlap between the subject matter claimed in both patents, as both patents claim formulations comprising epinephrine and dodecyl maltoside as a permeation enhancer, which is the same excipient that Mr. Hierholzer misleadingly argued produced unexpected results during prosecution of the '156 Patent. There is therefore an immediate and necessary relation between the claims of the '12-838 Patent and the '156 Patent claims secured through Mr. Hierholzer's inequitable conduct.

221. Pursuant to the judicially created doctrine of infectious unenforceability, Lupin is entitled to a judgment declaring that all claims of the '12-838 Patent are unenforceable due to Mr.

Hierholzer's inequitable conduct during prosecution of the '156 Patent.

222. This case is an exceptional one, and Lupin is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT XXIII
(Declaratory Judgment of Non-Infringement of the '12-838 Patent)

223. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 222 of its Counterclaims as though fully set forth herein.

224. Aegis alleges ownership of the '12-838 Patent and has brought claims against Defendant, alleging infringement of the '12-838 Patent.

225. The manufacture, use, or sale of Lupin's ANDA Product would not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '12-838 Patent, and the submission of Lupin's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and/or enforceable claim of the '12-838 Patent.

226. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '12-838 Patent.

227. Lupin has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '12-838 Patent and is not liable for such infringement.

228. Lupin is entitled to a declaration that the manufacture, use, or sale of Lupin's ANDA Product would not infringe any valid or enforceable claim of the '12-838 Patent.

COUNT XXIV
(Declaratory Judgment of Invalidity and/or Unenforceability of the '12-838 Patent)

229. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 228 of its Counterclaims as though fully set forth herein.

230. Aegis alleges ownership of the '12-838 Patent and has brought claims against Defendant, alleging infringement of the '12-838 Patent.

231. One or more claims of the '12-838 Patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b), and/or one or more of the judicially created requirements for patentability and enforceability of patent.

232. The '12-838 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.

233. The alleged invention of the '12-838 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 '12-838 Patent is not 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 '12-838 Patent and would have had a reasonable expectation of success in doing so.

234. The subject matter claimed in the '12-838 Patent fails to comply with 35 U.S.C. § 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 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.

235. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Lupin's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '12-838 Patent.

236. Lupin is entitled to a declaration that all claims of the '12-838 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Lupin respectfully requests judgment in its favor and against Counterclaim Defendants/Plaintiffs as follows:

a. Declaring that the Court order the Complaint dismissed with prejudice and judgment be entered in favor of Lupin;

b. Declaring that each claim of the Patents-in-Suit is unenforceable due to inequitable conduct;

c. Declaring that all claims of the Patents-in-Suit are invalid;

d. Declaring that the filing of Lupin's ANDA No. 220047 has not infringed, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid and enforceable claim of the Patents-in-Suit;

e. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Lupin's ANDA Product does not, and would not, if marketed, infringe any valid

and enforceable claim of the Patents-in-Suit.

f. Declaring this an exceptional case in favor of Lupin and awarding its attorneys' fees pursuant to 35 U.S.C. § 285 and/or under all applicable statutes and rules in common law that would be appropriate;

g. Awarding costs and expenses under all applicable statutes and rules in common law that would be appropriate; and

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

MIDLIGE RICHTER LLC
Attorneys for Defendants,
Lupin Inc. and Lupin Pharmaceuticals, Inc.

By: *s/ James S. Richter*
James S. Richter
jrichter@midlige-richter.com

Dated: October 16, 2025

OF COUNSEL:

Michael W. Johnson (*pro hac vice* forthcoming)
Heather M. Schneider (*pro hac vice* forthcoming)
Eric L. Saunders (*pro hac vice* forthcoming)
Jason N. Zaccaro (*pro hac vice* forthcoming)
GEMINI LAW LLP
32 W 39th Street
New York, NY 10018
(917) 915-8832
mjohnson@geminilaw.com
hschneider@geminilaw.com
esaunders@geminilaw.com
jzaccaro@geminilaw.com

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rules 11.2, the undersigned counsel for Defendants certifies that, to the best of his knowledge, information and belief, the matter in controversy is not the subject of any other action or proceeding.

s/ James S. Richter
James S. Richter

Dated: October 16, 2025

LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seeks, *inter alia*, injunctive relief.

s/ James S. Richter
James S. Richter

Dated: October 16, 2025

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Defendants Lupin Inc. and Lupin Pharmaceuticals, Inc.'s foregoing Answer, Affirmative Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on October 16, 2025.

s/ James S. Richter
James S. Richter

DATED: October 16, 2025