Cynthia S. Betz
Mark M. Makhail
McCARTER & ENGLISH, LLP
4 Gateway Center
100 Mulberry Street
Newark, NJ 07102
973-622-4444
cbetz@mccarter.com
mmakhail@mccarter.com

Attorneys for Plaintiffs
ARS Pharmaceuticals Operations, Inc. and
Aegis Therapeutics, LLC

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ARS PHARMACEUTICALS OPERATIONS, INC., and AEGIS THERAPEUTICS, LLC Plaintiffs, v. LUPIN INC., LUPIN LTD., and LUPIN PHARMACEUTICALS, INC. Defendants.	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT**

ARS Pharmaceuticals Operations, Inc. ("ARS") and Aegis Therapeutics, LLC ("Aegis") (collectively "Plaintiffs"), by and through the undersigned attorneys, bring this Complaint against Defendants Lupin Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc. (collectively, "Lupin" or "Defendants"), and allege as follows:

Nature of the Action and Subject Matter Jurisdiction

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").

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.

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.

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.

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.

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.

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.

Jurisdiction and Venue

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

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

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.

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."

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.

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.

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.

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.

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.

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.

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.

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.

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.

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

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."

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.).

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**.

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**.

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**.

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**.

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**.

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**.

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**.

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**.

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

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.

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.

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.

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.

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.

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.

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

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.

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").

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."

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.

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).

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.

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.

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).

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

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).

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

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.

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.

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).

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

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).

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.

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

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.

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.

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).

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

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).

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.

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.

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.

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.

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).

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

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).

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.

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.

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.

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.

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).

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

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).

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.

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

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.

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.

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).

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

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).

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.

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

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.

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.

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).

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

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).

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.

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

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.

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.

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).

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

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).

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.

WHEREFORE, Plaintiffs request the following relief:

(a) a declaratory judgment that Lupin Inc., Lupin Ltd. and Lupin Pharmaceuticals, Inc., have infringed at least one claim of the neffy® Patents by submitting the Lupin ANDA with the Lupin Paragraph IV Certification;

(b) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that the making, using, selling, offering to sell and/or importing of Lupin's ANDA Product will infringe at least one claim of the neffy® Patents;

(c) a declaratory judgment pursuant to 28 U.S.C. § 2201 *et seq*. that the making, using, offering for sale, selling and/or importing of the Lupin ANDA Product will induce the infringement of at least one claim of the neffy® Patents;

(d) a declaratory judgment pursuant to 28 U.S.C. § 2201 *et seq*. that the making, using, offering for sale, selling and/or importing of the Lupin ANDA Product will contribute to the infringement of at least one claim of the neffy® Patents;

(e) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. and an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval for Lupin Inc., Lupin Ltd. and/or Lupin Pharmaceuticals, Inc., to commercially make, use, sell, offer to sell or import its Lupin ANDA Product earlier than the date following the expiration date of the last to expire of the neffy® Patents (as extended, if applicable);

(f) a preliminary and permanent injunction restraining and enjoining against any infringement by Lupin Inc., Lupin Ltd. and/or Lupin Pharmaceuticals, Inc., their officers, agents, attorneys, employees, successors or assigns, or those acting in privity or concert with them, of the neffy® Patents, through the commercial manufacture, use, sale, offer for sale or importation into the United States of Lupin ANDA Product, and/or any inducement of or contribution to the same;

(g) a permanent injunction under 35 U.S.C. § 271(e)(4)(B) enjoining Lupin Inc., Lupin Ltd. and Lupin Pharmaceuticals, Inc., and their officers, agents, servants, employees and attorneys; and any other entities or persons acting in concert or participation with them from practicing any method claimed in the neffy® Patents or from actively inducing or contributing to the infringement of any claim of the neffy® Patents until after expiration of the last to expire of the neffy® Patents (as extended, if applicable);

(h) Attorneys' fees in this action under 35 U.S.C. § 285; and

(i) Such further and other relief in favor of Plaintiffs and against defendants as this Court may deem just and proper.

Dated: August 29, 2025

Respectfully submitted,

/s/ *Cynthia S. Betz*

Cynthia S. Betz
Mark M. Makhail
McCARTER & ENGLISH, LLP
4 Gateway Center
100 Mulberry Street
Newark, NJ 07102
973-622-4444
cbetz@mccarter.com
mmakhail@mccarter.com

Counsel for Plaintiffs
ARS Pharmaceuticals Operations, Inc. and Aegis Therapeutics, LLC.

Of Counsel:

Thomas H. Wintner
Adam P. Samansky
Peter J. Cuomo
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C.

One Financial Center
Boston, Massachusetts 02111
(617) 542-6000
twintner@mintz.com
apsamansky@mintz.com
pjcuomo@mintz.com

Nana Liu
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C.
44 Montgomery Street
San Francisco, California 94104
(415) 432-6000
nliu@mintz.com

Counsel for Plaintiff
ARS Pharmaceuticals Operations, Inc.

LOCAL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding, except as provided below. I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

/s/ *Cynthia S. Betz*
Cynthia S. Betz
Mark M. Makhail
McCARTER & ENGLISH, LLP
4 Gateway Center
100 Mulberry Street
Newark, NJ 07102
973-622-4444
cbetz@mccarter.com
mmakhail@mccarter.com

Counsel for Plaintiffs
ARS Pharmaceuticals Operations, Inc. and Aegis Therapeutics, LLC.

Of Counsel:

Thomas H. Wintner
Adam P. Samansky
Peter J. Cuomo
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C.
One Financial Center
Boston, Massachusetts 02111
(617) 542-6000
twintner@mintz.com
apsamansky@mintz.com
pjcuomo@mintz.com

Nana Liu
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C.
44 Montgomery Street
San Francisco, California 94104
(415) 432-6000

nliu@mintz.com

Counsel for Plaintiff
ARS Pharmaceuticals Operations, Inc.