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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NEXUS PHARMACEUTICALS, LLC, Plaintiff, vs. SABA ILAC SANAYI VE TICARET A.S., Defendant.	Civil Action No.

COMPLAINT

Nexus Pharmaceuticals, LLC ("Nexus"), by its undersigned attorneys, for its complaint against Defendant Saba Ilac Sanayi ve Ticaret A.S. ("Saba" or "Defendant"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, and for a declaratory judgement of patent infringement under 28 U.S.C. §§ 2201 and 2202, that arises out of Saba's submission of Abbreviated New Drug Application ("ANDA") No. 218622 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of EMERPHED® (ephedrine sulfate injection), 50mg/10mL (5mg/mL) single-dose vials prior to the

expiration of U.S. Patent Nos. 11,090,278 ("the '278 patent"), 11,241,400 ("the '400 patent"), 11,478,436 ("the '436 patent"), and 11,426,369 ("the '369 patent"), attached hereto as Exhibit A, Exhibit B, Exhibit C, and Exhibit D, respectively.

PARTIES

2. Nexus is a limited liability company organized and existing under the laws of the State of Illinois, having its principal place of business at 400 Knightsbridge Parkway, Lincolnshire, Illinois.

3. Nexus is the holder of New Drug Application No. 213407 for EMERPHED (ephedrine sulfate injection).

4. Nexus is the owner and assignee of the '278 patent, the '400 patent, the '436 patent, and the '369 patent.

5. Upon information and belief, Saba is a company organized under the laws of Turkey, having a principal place of business at Halkali Merkez Mh., Basin Ekspres Cd. 5/1B, 34303 Kucukcekmece/Istanbul, Turkey.

6. Upon information and belief, Saba is a pharmaceutical company that "exist[s] to offer innovative and diversified [range] of products with a high quality experience enabling healthy life opportunity to be available to everyone on a global scale." *See* https://www.sabailac.com.tr/en/mission-vision (last accessed on August 14, 2025).

7. Upon information and belief, Saba derives substantial revenue from the marketing, manufacture, and/or sale of generic pharmaceutical products in the United States and New Jersey.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. Venue is proper in this district for Saba pursuant to 28 U.S.C. §§ 1391 and 1400(b) at least because, *inter alia*, upon information and belief, Saba is a foreign corporation organized

and existing under the laws of Turkey and may be sued in any judicial district in which it is subject to personal jurisdiction, including in this judicial district.

10. Based on the facts and causes alleged herein, including infringement under 35 U.S.C. § 271(e)(2) by Saba's ANDA and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Saba.

11. This Court has personal jurisdiction over Saba at least because, upon information and belief, Saba directly or indirectly develops, manufactures, markets and/or sells or intends to market and sell generic drugs throughout the United States and in this judicial district.

12. This Court has personal jurisdiction over Saba at least because, *inter alia*, upon information and belief, (1) Saba itself, and/or in concert with its related entities, has filed an ANDA for the purpose of seeking approval to engage in commercial manufacture, use, offer for sale, sale, and/or importation of the Saba ANDA Product in the United States, including the State of New Jersey; and (2) Saba itself, and/or in concert with its related entities, will market, distribute, offer for sale, and/or sell the Saba ANDA Product in the United States, including the State of New Jersey, upon approval of ANDA No. 218622, and Saba will derive substantial revenue from the use or consumption of the Saba ANDA Product in the State of New Jersey.

13. On information and belief, if ANDA No. 218622 is approved, the generic product described in ANDA No. 218622 would, among other things, be marketed, distributed, offered for sale, and/or sold in New Jersey, prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

14. For at least the above reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, it would not be unfair or unreasonable for Saba to litigate this

action in this District, Saba has availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being haled into court in this Judicial District, and Saba is subject to personal jurisdiction in this District.

15. Upon information and belief, Saba is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Saba in the State of New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

16. Upon information and belief, Saba has designated its outside counsel, Shashank Upadhye, Esq. of Upadhye Tang LLP, 109 Symonds Drive, #174, Hinsdale, Illinois, as an agent in the United States authorized to accept service of process for Saba, with respect to Saba's ANDA seeking FDA approval for the Saba ANDA Product.

BACKGROUND

17. EMERPHED® is sold and marketed under New Drug Application No. 213407, which was approved by the FDA on April 21, 2020.

18. EMERPHED® is the first and only FDA-approved ready to use ephedrine injection and is supplied, among other presentations, as a single-use 10mL vial containing 50mg ephedrine sulfate.

19. Ephedrine, the active ingredient in EMERPHED®, is an alpha- and beta-adrenergic agonist and a norepinephrine-releasing agent. EMERPHED® is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

20. EMERPHED® and/or the use of EMERPHED® according to its FDA-approved prescribing information is a commercial embodiment of the '278 patent, the '400 patent, the '436 patent, and the '369 patent.

21. The '278 patent, entitled "Compositions comprising ephedrine or an ephedrine salt and methods of making and using same" was duly and legally issued on August 17, 2021.

22. The ’278 patent has been listed in connection with EMERPHED® in the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the “Orange Book.”

23. As indicated in the Orange Book, the patent expiration date for the ’278 patent is May 16, 2040.

24. The ’400 patent, entitled “Compositions comprising ephedrine or an ephedrine salt and methods of making and using same” was duly and legally issued on February 8, 2022.

25. As indicated in the Orange Book, the patent expiration date for the ’400 patent is May 16, 2040.

26. The ’436 patent, entitled “Compositions comprising ephedrine or an ephedrine salt and methods of making and using same” was duly and legally issued on October 25, 2022.

27. The ’436 patent has been listed in connection with EMERPHED® in the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the “Orange Book.”

28. As indicated in the Orange Book, the patent expiration date for the ’436 patent is May 16, 2040.

29. The ’369 patent, entitled “Compositions Comprising Ephedrine or and Ephedrine Salt and Methods of Making and Using Same” was duly and legally issued on August 30, 2022.

30. The ’369 patent expires on May 16, 2040.

31. Upon information and belief, Saba prepared ANDA No. 218622.

32. By letter dated July 14, 2025 (“the Notice Letter”), Saba notified Nexus pursuant to the Federal Food, Drug, and Cosmetic Act (“FDCA”) that Saba had submitted to the FDA ANDA No. 218622, seeking approval from the FDA to engage in the commercial manufacture, use and/or

sale of a generic Ephedrine Sulfate Injection USP, 50mg/10mL (5 mg/mL) single-dose vials ("Saba's ANDA Product") prior to the expiration of the '278 patent, the '400 patent, and the '436 patent.

33. Upon information and belief, Saba submitted ANDA No. 218622 to the FDA, which contained a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA ("Paragraph IV Certification") asserting that the '278 patent, the '400 patent, and the '436 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Saba's ANDA Product, or alternatively, that these patents are invalid.

34. Upon information and belief, Saba's ANDA Product is a drug product that is a generic version of EMERPHED® (ephedrine sulfate injection), 50mg/10ml (5 mg/mL), as its reference listed drug, containing the same or equivalent ingredients in the same or equivalent amounts.

35. In the Notice Letter, Saba disclosed that the active ingredient of Saba's ANDA product is ephedrine sulfate.

36. Upon information and belief, Saba's ANDA product is a ready-to-use pre-mixed composition to be stored at the same or equivalent conditions as EMERPHED®.

37. Upon information and belief, Saba's ANDA product contains ephedrine sulfate, sodium chloride, and water in the same or equivalent amounts as EMERPHED®. Upon information and belief, Saba's ANDA product does not contain a preservative.

38. Upon information and belief, Saba's ANDA product will feature the same or equivalent chemical properties as EMERPHED®.

39. Upon information and belief, Saba's ANDA product will be manufactured using the same or equivalent methods as EMERPHED®.

40. Upon information and belief, Saba's ANDA product will use the same or an equivalent container to EMERPHED®.

41. Upon information and belief, Saba's ANDA product will be sterilized in the same or an equivalent method to EMERPHED®.

42. Upon information and belief, Saba's ANDA product is to be stored at the same or equivalent conditions as EMERPHED®.

43. Upon information and belief, Saba seeks approval for the Saba ANDA Product to be indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

44. Upon information and belief, the proposed labeling for Saba's ANDA product recommends, instructs, and/or promotes administration of Saba's ANDA product to patients for the treatment of clinically important hypotension occurring in the setting of anesthesia.

45. Upon information and belief, the proposed labeling for Saba's ANDA product recommends, instructs, and/or promotes administration to patients by drawing the composition into a syringe and injecting the composition into a patient using the syringe without dilution.

46. Any final approval of Saba's ANDA shall be effective no earlier than January 15, 2028. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I - INFRINGEMENT OF
U.S. PATENT NO. 11,090,278 UNDER 35 U.S.C. § 271(e)(2)

47. Nexus repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

48. Saba's submission of ANDA No. 218622 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Saba's ANDA

Product prior to the expiration of the '278 patent was an act of infringement of the '278 patent under 35 U.S.C. § 271(e)(2).

49. Upon information and belief, Saba will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Saba's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 218622.

50. Upon information and belief, the use of Saba's ANDA Product in accordance with and as directed by Saba's proposed labeling for that product would infringe one or more claims of the '278 patent, either literally or under the doctrine of equivalents.

51. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Saba's ANDA Product would induce or contribute to infringement of one or more claims of the '278 patent, either literally or under the doctrine of equivalents.

52. Upon information and belief, Saba plans and intends to, and will, actively induce infringement of the '278 patent when ANDA No. 218622 is approved, and plans and intends to, and will, do so after approval.

53. Upon information and belief, Saba knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing one or more claims of the '278 patent, either literally or under the doctrine of equivalents, and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use.

54. Upon information and belief, Saba plans and intends to, and will, contribute to infringement of the '278 patent after approval of ANDA No. 218622.

55. The foregoing actions by Saba constitute and/or will constitute infringement of the '278 patent, active inducement of infringement of the '278 patent, and contribution to the infringement by others of the '278 patent.

56. Upon information and belief, Saba has acted with full knowledge of the '278 patent and without a reasonable basis for believing that it would not be liable for infringing the '278 patent, actively inducing infringement of the '278 patent, and/or contributing to the infringement by others of the '278 patent.

57. This case is "exceptional," and Nexus is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

58. Unless Saba is enjoined from infringing the '278 patent, actively inducing infringement of the '278 patent, and contributing to the infringement by others of the '278 patent, Nexus will suffer irreparable injury. Nexus has no adequate remedy at law.

COUNT II - INFRINGEMENT OF
U.S. PATENT NO. 11,241,400 UNDER 35 U.S.C. § 271(e)(2)

59. Nexus repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

60. Saba's submission of ANDA No. 218622 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Saba's ANDA Product prior to the expiration of the '400 patent was an act of infringement of the '400 patent under 35 U.S.C. § 271(e)(2).

61. Upon information and belief, Saba will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Saba's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 218622.

62. Upon information and belief, the use of Saba's ANDA Product in accordance with and as directed by Saba's proposed labeling for that product would infringe one or more claims of the '400 patent, either literally or under the doctrine of equivalents.

63. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Saba's ANDA Product would induce or contribute to infringement of one or more claims of the '400 patent, either literally or under the doctrine of equivalents.

64. Upon information and belief, Saba plans and intends to, and will, actively induce infringement of the '400 patent when ANDA No. 218622 is approved, and plans and intends to, and will, do so after approval.

65. Upon information and belief, Saba knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing one or more claims of the '400 patent, either literally or under the doctrine of equivalents, and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use.

66. Upon information and belief, Saba plans and intends to, and will, contribute to infringement of the '400 patent after approval of ANDA No. 218622.

67. The foregoing actions by Saba constitute and/or will constitute infringement of the '400 patent, active inducement of infringement of the '400 patent, and contribution to the infringement by others of the '400 patent.

68. Upon information and belief, Saba has acted with full knowledge of the '400 patent and without a reasonable basis for believing that it would not be liable for infringing the '400 patent, actively inducing infringement of the '400 patent, and/or contributing to the infringement by others of the '400 patent.

69. This case is "exceptional," and Nexus is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

70. Unless Saba is enjoined from infringing the '400 patent, actively inducing infringement of the '400 patent, and contributing to the infringement by others of the '400 patent, Nexus will suffer irreparable injury. Nexus has no adequate remedy at law.

COUNT III - INFRINGEMENT OF
U.S. PATENT NO. 11,478,436 UNDER 35 U.S.C. § 271(e)(2)

71. Nexus repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

72. Saba's submission of ANDA No. 218622 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Saba's ANDA Product prior to the expiration of the '436 patent was an act of infringement of the '436 patent under 35 U.S.C. § 271(e)(2).

73. Upon information and belief, Saba will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Saba's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 218622.

74. Upon information and belief, the use of Saba's ANDA Product in accordance with and as directed by Saba's proposed labeling for that product would infringe one or more claims of the '436 patent, either literally or under the doctrine of equivalents.

75. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Saba's ANDA Product would induce or contribute to infringement of one or more claims of the '436 patent, either literally or under the doctrine of equivalents.

76. Upon information and belief, Saba plans and intends to, and will, actively induce infringement of the ’436 patent when ANDA No. 218622 is approved, and plans and intends to, and will, do so after approval.

77. Upon information and belief, Saba knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing one or more claims of the ’436 patent, either literally or under the doctrine of equivalents, and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use.

78. Upon information and belief, Saba plans and intends to, and will, contribute to infringement of the ’436 patent after approval of ANDA No. 218622.

79. The foregoing actions by Saba constitute and/or will constitute infringement of the ’436 patent, active inducement of infringement of the ’436 patent, and contribution to the infringement by others of the ’436 patent.

80. Upon information and belief, Saba has acted with full knowledge of the ’436 patent and without a reasonable basis for believing that it would not be liable for infringing the ’436 patent, actively inducing infringement of the ’436 patent, and/or contributing to the infringement by others of the ’436 patent.

81. This case is “exceptional,” and Nexus is entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

82. Unless Saba is enjoined from infringing the ’436 patent, actively inducing infringement of the ’436 patent, and contributing to the infringement by others of the ’436 patent, Nexus will suffer irreparable injury. Nexus has no adequate remedy at law.

COUNT IV - INFRINGEMENT OF
U.S. PATENT NO. 11,426,369 UNDER 35 U.S.C. § 271(e)(2)

83. Nexus repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

84. Saba's submission of ANDA No. 218622 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Saba's ANDA Product prior to the expiration of the '369 patent was an act of infringement of the '369 patent under 35 U.S.C. § 271(e)(2).

85. Upon information and belief, Saba will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Saba's ANDA Product with its proposed labeling upon FDA approval of ANDA No. 218622.

86. Upon information and belief, the manufacture, use in accordance with and as directed by Saba's proposed labeling for that product, sale, offer for sale and/or importation of Saba's ANDA Product would infringe one or more claims of the '369 patent, either literally or under the doctrine of equivalents.

87. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Saba's ANDA Product would induce or contribute to infringement of one or more claims of the '369 patent, either literally or under the doctrine of equivalents.

88. Upon information and belief, Saba plans and intends to, and will, actively induce infringement of the '369 patent when ANDA No. 218622 is approved, and plans and intends to, and will, do so after approval.

89. Upon information and belief, Saba knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing one or more claims of the '369 patent,

either literally or under the doctrine of equivalents, and that its ANDA Product and its proposed labeling are not suitable for substantial non-infringing use.

90. Upon information and belief, Saba plans and intends to, and will, contribute to infringement of the '369 patent after approval of ANDA No. 218622.

91. The foregoing actions by Saba constitute and/or will constitute infringement of the '369 patent, active inducement of infringement of the '369 patent, and contribution to the infringement by others of the '369 patent.

92. Upon information and belief, Saba has acted with full knowledge of the '369 patent and without a reasonable basis for believing that it would not be liable for infringing the '369 patent, actively inducing infringement of the '369 patent, and contributing to the infringement by others of the '369 patent.

93. This case is "exceptional," and Nexus is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

94. Unless Saba is enjoined from infringing the '369 patent, actively inducing infringement of the '369 patent, and contributing to the infringement by others of the '369 patent, Nexus will suffer irreparable injury. Nexus has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Nexus requests the following relief:

a. A judgment, pursuant to 35 U.S.C. § 271(e)(2), that Saba has infringed the '278 patent, the '400 patent, '436 patent, and/or the '369 patent by submitting to the FDA ANDA No. 218622 with a paragraph IV certification with respect to the '278 patent, the '400 patent, and '436 patent, for the purpose of obtaining approval for the commercial manufacture, use, and/or sale of Saba's ANDA Product before the expiration of the '278 patent, the '400 patent, the '436 patent, and/or the '369 patent;

b. A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Saba's ANDA Product before the expiration of the '278 patent, the '400 patent, the '436 patent, and/or the '369 patent (including any regulatory extensions), will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '278 patent, the '400 patent, the '436 patent, and/or the '369 patent;

c. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of ANDA No. 218622 shall be no earlier than the date on which the '278 patent, the '400 patent, the '436 patent, and/or the '369 patent expire, inclusive of any extension or additional period of exclusivity;

d. A judgment that the '278 patent, the '400 patent, the '436 patent, and the '369 patent are valid and enforceable;

e. An order pursuant to, *inter alia*, 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval for Saba to make, use, offer for sale, sell, market, distribute, or import Saba's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '278 patent, the '400 patent, the '436 patent, and/or the '369 patent, be no earlier than the expiration date of the '278 patent, the '400 patent, the '436 patent, and/or the '369 patent inclusive of any extension(s) or additional period(s) of exclusivity;

f. An order for preliminary and permanent injunction pursuant to, *inter alia*, 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283 enjoining Saba, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Saba's ANDA Product, or any product the making, using,

offering for sale, sale, marketing, distribution, or importation of which infringes the ’278 patent, the ’400 patent, the ’436 patent, and/or the ’369 patent or the inducement of or the contribution to any of the foregoing, prior to the expiration of the ’278 patent, the ’400 patent, the ’436 patent, and/or the ’369 patent inclusive of any extension or additional period of exclusivity;

g. An award, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, of damages or other monetary relief to compensate Nexus if Saba engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Saba’s ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the ’278 patent, the ’400 patent, the ’436 patent, and/or the ’369 patent or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’278 patent, the ’400 patent, the ’436 patent, and/or the ’369 patent inclusive of any extension(s) and additional period(s) of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(C);

h. A judgment pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284 declaring that Saba’s infringement of the ’278 patent, the ’400 patent, the ’436 patent, and/or the ’369 patent is willful and awarding Nexus enhanced damages if Saba commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Saba’s ANDA, prior to the expiration of the ’278 patent, the ’400 patent, the ’436 patent, and/or the ’369 patent (including any regulatory extensions);

i. A judgment pursuant to 35 U.S.C. § 285 that this case against Saba is an exceptional case and an award of attorneys’ fees and costs; and

j. Such further and other relief as this Court may deem just and proper.

Dated: August 26, 2025

Respectfully submitted,

By: */s/ Michael J. Gesualdo*

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Attorneys for Plaintiff,
NEXUS PHARMACEUTICALS, LLC

Local Civil Rule 11.2 and 40.1 Certifications

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, this matter is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Pursuant to Local Civil Rule 40.1, I hereby certify that, to the best of my knowledge, this matter does not relate to any case already or previously pending in the District of New Jersey.

Dated: August 26, 2025

s/ Michael J. Gesualdo
Michael J. Gesualdo