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And Endo Operations Limited

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ENDO USA, INC. and ENDO OPERATIONS LIMITED, Plaintiffs, v. GLAND PHARMA LIMITED, Defendant.	)	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Endo USA, Inc. ("Endo USA") and Endo Operations Limited ("Endo Operations") (collectively, "Endo" or "Plaintiffs"), by and through their undersigned counsel, hereby allege against Defendant Gland Pharma Limited ("Gland" or "Defendant") as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, arising from Gland's submission of Abbreviated New Drug Application ("ANDA") No. 216963 to the United States Food and Drug Administration ("FDA"), seeking approval to market a generic version of Endo's VASOSTRICT® (vasopressin) 20 units/100ml and 40 units/100ml solution ("Gland's ANDA Products") before the expiration of U.S. Patent Nos. 9,919,026 ("the '026 patent"), 9,925,233 ("the '233 patent"), 9,925,234 ("the

'234 patent"), 9,962,422 ("the '422 patent"), 9,968,649 ("the '649 patent"), 9,974,827 ("the '827 patent"), 9,981,006 ("the '006 patent"), and 10,010,575 ("the '575 patent") (collectively "the Patents-in-Suit").

THE PARTIES

2. Plaintiff Endo USA, Inc. is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 9 Great Valley Parkway, Malvern, PA 19355. Endo USA markets and sells pharmaceutical products, including injectable pharmaceutical products.

3. Plaintiff Endo Operations Limited is a limited liability company organized and existing under the laws of Ireland, having its principal place of business at First Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland.

4. Upon information and belief, Defendant Gland Pharma Limited is a corporation organized and existing under the laws of India, having its principal place of business at Survey No. 143-148, 150 & 151, Near Gandimaisamma "X" Roads, D.P. Pally, Dundigal Gandimaisamma Mandal, Medchal-Malkajgiri District, Hyderabad 500043, Telangana, India.

JURISDICTION AND VENUE

5. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. On information and belief, this Court has personal jurisdiction over Gland under the New Jersey state long arm statute and consistent with due process of law because Gland has extensive contacts with the State of New Jersey and regularly does business in this judicial district.

Further, Gland plans to sell its ANDA Products in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

7. This Court has personal jurisdiction over Gland because Gland has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contact with the State of New Jersey. On information and belief, Gland regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. On information and belief, Gland derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. On information and belief, Gland derives substantial revenue from selling generic pharmaceutical products and/or pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

8. This Court has personal jurisdiction over Gland because, on information and belief, Gland derives substantial revenue from directly or indirectly selling generic pharmaceutical products and/or pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this judicial district.

9. Upon information and belief, Gland is in the business of, among other things, the development, manufacturing, importation, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this judicial district. Gland's website states that Gland Pharma has "a global footprint across 60 countries, including the United States," with a "focus on complex injectables including NCE-1s, First-to-File products and 505(b)(2) filings."[1]

[1] https://glandpharma.com/about (last accessed December 26, 2024).

10. This Court has personal jurisdiction over Gland because, inter alia, Gland has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Endo in New Jersey. Further, on information and belief, following the FDA's approval of the ANDA, Gland will make, use, import, sell, and/or offer for sale its ANDA Products in the United States, including in New Jersey, prior to the expiration of the Patents-in-Suit.

11. On information and belief, this Court also has personal jurisdiction over Gland because it has previously availed itself of the legal protections of the State of New Jersey by, among other things, not contesting jurisdiction in this judicial district, and pursuing counterclaims in this judicial district, including in at least *American Regent, Inc. v. Gland Pharma Limited*, C.A. No. 2:24-cv-07756-BRM-CLW, ECF No. 11 (D.N.J. Aug. 30, 2024); and *Merck Sharp & Dohme LLC v. Gland Pharma Limited*, C.A. No. 2:22-cv-05461-MEF-ESK, ECF No. 12 (D.N.J. Mar. 6, 2023).

12. In the alternative, this Court has personal jurisdiction over Gland because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Endo's claims arise under federal law; (b) Gland is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Gland has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting its ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Gland satisfies due process.

13. On information and belief, venue is proper in this judicial district under 28 U.S.C. § 1391(c)(3) because Gland is a foreign company not residing in any United States judicial district and may be sued in any judicial district.

14. Venue is further proper in this Court because in its November 18, 2024 letter to Endo ("Gland's Notice Letter") Gland designated Windels Marx Lane & Mittendorf, LLP in Madison, New Jersey as its agent in the United States authorized to accept service of process for Gland.

15. Venue is further proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

THE PATENTS-IN-SUIT

16. The '026 patent, entitled "Vasopressin Formulations for Use in Treatment of Hypotension," was issued by the United States Patent and Trademark Office ("the USPTO") on March 20, 2018. The '026 patent names Matthew Kenney, Vinayagam Kannan, Sunil Vandse, and Suketu Sanghvi as inventors. Endo Operations is the assignee of the '026 patent. A true and correct copy of the '026 patent is attached as Exhibit A.

17. The '233 patent, entitled "Vasopressin Formulations for Use in Treatment of Hypotension," was issued by the USPTO on March 27, 2018. The '233 patent names Matthew Kenney, Vinayagam Kannan, Sunil Vandse, and Suketu Sanghvi as inventors. Endo Operations is the assignee of the '233 patent. A true and correct copy of the '233 patent is attached as Exhibit B.

18. The '234 patent, entitled "Vasopressin Formulations for Use in Treatment of Hypotension," was issued by the USPTO on March 27, 2018. The '234 patent names Matthew Kenney, Vinayagam Kannan, Sunil Vandse, and Suketu Sanghvi as inventors. Endo Operations is the assignee of the '234 patent. A true and correct copy of the '234 patent is attached as Exhibit C.

19. The ’422 patent, entitled “Vasopressin Formulations for Use in Treatment of Hypotension,” was issued by the USPTO on May 8, 2018. The ’422 patent names Matthew Kenney, Vinayagam Kannan, Sunil Vandse, and Suketu Sanghvi as inventors. Endo Operations is the assignee of the ’422 patent. A true and correct copy of the ’422 patent is attached as Exhibit D.

20. The ’649 patent, entitled “Vasopressin Formulations for Use in Treatment of Hypotension,” was issued by the USPTO on May 15, 2018. The ’649 patent names Matthew Kenney, Vinayagam Kannan, Sunil Vandse, and Suketu Sanghvi as inventors. Endo Operations is the assignee of the ’649 patent. A true and correct copy of the ’649 patent is attached as Exhibit E.

21. The ’827 patent, entitled “Vasopressin Formulations for Use in Treatment of Hypotension,” was issued by the USPTO on May 22, 2018. The ’827 patent names Matthew Kenney, Vinayagam Kannan, Sunil Vandse, and Suketu Sanghvi as inventors. Endo Operations is the assignee of the ’827 patent. A true and correct copy of the ’827 patent is attached as Exhibit F.

22. The ’006 patent, entitled “Vasopressin Formulations for Use in Treatment of Hypotension,” was issued by the USPTO on May 29, 2018. The ’006 patent names Matthew Kenney, Vinayagam Kannan, Sunil Vandse, and Suketu Sanghvi as inventors. Endo Operations is the assignee of the ’006 patent. A true and correct copy of the ’006 patent is attached as Exhibit G.

23. The ’575 patent, entitled “Vasopressin Formulations for Use in Treatment of Hypotension,” was issued by the USPTO on July 3, 2018. The ’575 patent names Matthew Kenney, Vinayagam Kannan, Sunil Vandse, and Suketu Sanghvi as inventors. Endo Operations is the assignee of the ’575 patent. A true and correct copy of the ’575 patent is attached as Exhibit H.

VASOSTRICT®

24. Vasopressin, the active ingredient in VASOSTRICT®, is a polypeptide hormone that causes contraction of vascular and other smooth muscle cells. VASOSTRICT® is a lifesaving drug often used when the blood pressure of a critical care patient drops precipitously.

25. On September 25, 2012, JHP Pharmaceuticals, LLC ("JHP") submitted New Drug Application ("NDA") No. 204485, under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), seeking FDA approval for a vasopressin injection product to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy shock or septic shock). On April 17, 2014, the FDA approved NDA No. 204485 as the first FDA-approved vasopressin injection product for use in a clinical setting in the United States.

26. On February 20, 2014, Par Pharmaceutical Companies, Inc. acquired JHP. On February 26, 2014, JHP changed its name to Par Sterile Products, LLC ("Par Sterile").

27. After the JHP acquisition, Par Sterile became the holder of NDA No. 204485, including all supplements thereto, for VASOSTRICT®.

28. Par Sterile submitted a supplemental NDA, including for approval of 40 units/100 mL and 20 units/100 mL presentations of VASOSTRICT® ("VASOSTRICT® Premixed Products"), which the FDA approved on April 15, 2020 and April 21, 2021, respectively.

29. According to the FDA-approved prescribing information, VASOSTRICT® is indicated "to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines."

30. Par Pharmaceutical Inc. ("Par Pharmaceutical") and Par Sterile have transferred their respective businesses related to vasopressin, including their business related to NDA No. 204485, to Endo USA.

31. Endo Operations is the holder of NDA No. 204485, including all supplements thereto, for VASOSTRICT®.

32. Endo Operations has appointed Endo USA as its exclusive distributor for VASOSTRICT® in the United States.

33. The Patents-in-Suit are listed in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

34. As indicated in the Orange Book, the expiration date for the Patents-in-Suit is January 30, 2035.

GLAND'S ANDA AND NOTICE LETTER

35. Upon information and belief, Gland submitted ANDA No. 216963 to the FDA, which included a certification with respect to the Patent-in-Suit under Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) ("Paragraph IV Certification"), seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of vasopressin in dextrose injection, 20 units/100ml and 40 units/100ml solution for intravenous use ("Gland's ANDA Products") before the expiration of the Patents-in-Suit.

36. No earlier than November 18, 2024, Gland sent written notice of its Paragraph IV Certification to Endo ("Gland's Notice Letter"). Gland's Notice Letter alleged that the claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, or offer for sale in the United States or importation into the United States of Gland's ANDA Products.

37. Upon information and belief, following FDA approval of Gland's ANDA, Gland will make, use, sell, or offer to sell Gland's ANDA Products throughout the United States, or import such products into the United States.

38. Gland's submission of its ANDA to the FDA, and any commercial manufacture, use, offer to sell, sale, and/or importation of Gland's ANDA Products, has infringed and will infringe the Patents-in-Suit, as detailed below.

39. In the Notice Letter, Gland offered confidential access to portions of its ANDA which contained unreasonable restrictions that differ materially from restrictions found under protective orders.

40. Under 21 U.S.C. § 355(j)(5)(c)(i)(III), an "offer of confidential access shall contain such restrictions . . . on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

41. Endo attempted to negotiate with Gland to obtain relevant information from Gland's ANDA and offered modifications to Gland's offer of confidential access that are consistent with 21 U.S.C. § 355(j)(5)(c)(i)(III). To date, Endo has not received a substantive response from Gland.

COUNT I
(Infringement of the '026 Patent)

42. Endo incorporates each of the preceding paragraphs as if fully set forth herein.

43. Gland, by submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Gland's ANDA Products, prior to the expiration of the Patents-in-Suit on January 30, 2035.

44. Gland's ANDA has been pending before the FDA since at least November 18, 2024, the date that Gland sent the Gland Notice Letter to Endo.

45. The submission of Gland's ANDA to the FDA, which seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Gland's ANDA Products before the expiration of the '026 patent, constitutes infringement by Gland of one or more claims of the '026 patent under 35 U.S.C. § 271(e)(2)(A).

46. Unless enjoined by this Court, upon FDA approval of Gland's ANDA, Gland will infringe one or more claims of the '026 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Gland's ANDA Products into the United States. On information and belief, upon FDA approval of Gland's ANDA, Gland will intentionally encourage acts of direct infringement with knowledge of the '026 patent and knowledge that its acts are encouraging infringement.

47. Unless enjoined by this Court, upon FDA approval of Gland's ANDA, Gland will contributorily infringe one or more claims of the '026 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Gland's ANDA Products into the United States. On information and belief, Gland has had and continues to have knowledge that Gland's ANDA Products are especially adapted for a use that infringes one or more claims of the '026 patent and that there is no substantial non-infringing use for Gland's ANDA Products.

48. Endo will be substantially and irreparably damaged and harmed if Gland's infringement of the '026 patent is not enjoined.

49. Endo does not have an adequate remedy at law.

50. Gland's infringement of the '026 patent would be willful, wanton, and deliberate.

51. There is a justiciable controversy between the parties as to the infringement of the '026 patent.

COUNT II
(Infringement of the '233 Patent)

52. Endo incorporates each of the preceding paragraphs as if fully set forth herein.

53. Gland, by submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Gland's ANDA Products, prior to the expiration of the Patents-in-Suit on January 30, 2035.

54. Gland's ANDA has been pending before the FDA since at least November 18, 2024, the date that Gland sent the Gland Notice Letter to Endo.

55. The submission of Gland's ANDA to the FDA, which seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Gland's ANDA Products before the expiration of the '233 patent, constitutes infringement by Gland of one or more claims of the '233 patent under 35 U.S.C. § 271(e)(2)(A).

56. Unless enjoined by this Court, upon FDA approval of Gland's ANDA, Gland will infringe one or more claims of the '233 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Gland's ANDA Products into the United States. On information and belief, upon FDA approval of Gland's ANDA, Gland will intentionally encourage acts of direct infringement with knowledge of the '233 patent and knowledge that its acts are encouraging infringement.

57. Unless enjoined by this Court, upon FDA approval of Gland's ANDA, Gland will contributorily infringe one or more claims of the '233 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Gland's ANDA Products into the United States.

On information and belief, Gland has had and continues to have knowledge that Gland's ANDA Products are especially adapted for a use that infringes one or more claims of the '233 patent and that there is no substantial non-infringing use for Gland's ANDA Products.

58. Endo will be substantially and irreparably damaged and harmed if Gland's infringement of the '233 patent is not enjoined.

59. Endo does not have an adequate remedy at law.

60. Gland's infringement of the '233 patent would be willful, wanton, and deliberate.

61. There is a justiciable controversy between the parties as to the infringement of the '233 patent.

COUNT III
(Infringement of the '234 Patent)

62. Endo incorporates each of the preceding paragraphs as if fully set forth herein.

63. Gland, by submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Gland's ANDA Products, prior to the expiration of the Patents-in-Suit on January 30, 2035.

64. Gland's ANDA has been pending before the FDA since at least November 18, 2024, the date that Gland sent the Gland Notice Letter to Endo.

65. The submission of Gland's ANDA to the FDA, which seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Gland's ANDA Products before the expiration of the '234 patent, constitutes infringement by Gland of one or more claims of the '234 patent under 35 U.S.C. § 271(e)(2)(A).

66. Unless enjoined by this Court, upon FDA approval of Gland's ANDA, Gland will infringe one or more claims of the '234 patent under 35 U.S.C. § 271(b) by making, using, offering

to sell, selling, and/or importing Gland's ANDA Products into the United States. On information and belief, upon FDA approval of Gland's ANDA, Gland will intentionally encourage acts of direct infringement with knowledge of the '234 patent and knowledge that its acts are encouraging infringement.

67. Unless enjoined by this Court, upon FDA approval of Gland's ANDA, Gland will contributorily infringe one or more claims of the '234 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Gland's ANDA Products into the United States. On information and belief, Gland has had and continues to have knowledge that Gland's ANDA Products are especially adapted for a use that infringes one or more claims of the '234 patent and that there is no substantial non-infringing use for Gland's ANDA Products.

68. Endo will be substantially and irreparably damaged and harmed if Gland's infringement of the '234 patent is not enjoined.

69. Endo does not have an adequate remedy at law.

70. Gland's infringement of the '234 patent would be willful, wanton, and deliberate.

71. There is a justiciable controversy between the parties as to the infringement of the '234 patent.

COUNT IV
(Infringement of the '422 Patent)

72. Endo incorporates each of the preceding paragraphs as if fully set forth herein.

73. Gland, by submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Gland's ANDA Products, prior to the expiration of the Patents-in-Suit on January 30, 2035.

74. Gland's ANDA has been pending before the FDA since at least November 18, 2024, the date that Gland sent the Gland Notice Letter to Endo.

75. The submission of Gland's ANDA to the FDA, which seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Gland's ANDA Products before the expiration of the '422 patent, constitutes infringement by Gland of one or more claims of the '422 patent under 35 U.S.C. § 271(e)(2)(A).

76. Unless enjoined by this Court, upon FDA approval of Gland's ANDA, Gland will infringe one or more claims of the '422 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Gland's ANDA Products into the United States. On information and belief, upon FDA approval of Gland's ANDA, Gland will intentionally encourage acts of direct infringement with knowledge of the '422 patent and knowledge that its acts are encouraging infringement.

77. Unless enjoined by this Court, upon FDA approval of Gland's ANDA, Gland will contributorily infringe one or more claims of the '422 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Gland's ANDA Products into the United States. On information and belief, Gland has had and continues to have knowledge that Gland's ANDA Products are especially adapted for a use that infringes one or more claims of the '422 patent and that there is no substantial non-infringing use for Gland's ANDA Products.

78. Endo will be substantially and irreparably damaged and harmed if Gland's infringement of the '422 patent is not enjoined.

79. Endo does not have an adequate remedy at law.

80. Gland's infringement of the '422 patent would be willful, wanton, and deliberate.

81. There is a justiciable controversy between the parties as to the infringement of the '422 patent.

COUNT V
(Infringement of the '649 Patent)

82. Endo incorporates each of the preceding paragraphs as if fully set forth herein.

83. Gland, by submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Gland's ANDA Products, prior to the expiration of the Patents-in-Suit on January 30, 2035.

84. Gland's ANDA has been pending before the FDA since at least November 18, 2024, the date that Gland sent the Gland Notice Letter to Endo.

85. The submission of Gland's ANDA to the FDA, which seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Gland's ANDA Products before the expiration of the '649 patent, constitutes infringement by Gland of one or more claims of the '649 patent under 35 U.S.C. § 271(e)(2)(A).

86. Unless enjoined by this Court, upon FDA approval of Gland's ANDA, Gland will infringe one or more claims of the '649 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Gland's ANDA Products into the United States. On information and belief, upon FDA approval of Gland's ANDA, Gland will intentionally encourage acts of direct infringement with knowledge of the '649 patent and knowledge that its acts are encouraging infringement.

87. Unless enjoined by this Court, upon FDA approval of Gland's ANDA, Gland will contributorily infringe one or more claims of the '649 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Gland's ANDA Products into the United States.

On information and belief, Gland has had and continues to have knowledge that Gland's ANDA Products are especially adapted for a use that infringes one or more claims of the '649 patent and that there is no substantial non-infringing use for Gland's ANDA Products.

88. Endo will be substantially and irreparably damaged and harmed if Gland's infringement of the '649 patent is not enjoined.

89. Endo does not have an adequate remedy at law.

90. Gland's infringement of the '649 patent would be willful, wanton, and deliberate.

91. There is a justiciable controversy between the parties as to the infringement of the '649 patent.

COUNT VI
(Infringement of the '827 Patent)

92. Endo incorporates each of the preceding paragraphs as if fully set forth herein.

93. Gland, by submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Gland's ANDA Products, prior to the expiration of the Patents-in-Suit on January 30, 2035.

94. Gland's ANDA has been pending before the FDA since at least November 18, 2024, the date that Gland sent the Gland Notice Letter to Endo.

95. The submission of Gland's ANDA to the FDA, which seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Gland's ANDA Products before the expiration of the '827 patent, constitutes infringement by Gland of one or more claims of the '827 patent under 35 U.S.C. § 271(e)(2)(A).

96. Unless enjoined by this Court, upon FDA approval of Gland's ANDA, Gland will infringe one or more claims of the '827 patent under 35 U.S.C. § 271(b) by making, using, offering

to sell, selling, and/or importing Gland's ANDA Products into the United States. On information and belief, upon FDA approval of Gland's ANDA, Gland will intentionally encourage acts of direct infringement with knowledge of the '827 patent and knowledge that its acts are encouraging infringement.

97. Unless enjoined by this Court, upon FDA approval of Gland's ANDA, Gland will contributorily infringe one or more claims of the '827 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Gland's ANDA Products into the United States. On information and belief, Gland has had and continues to have knowledge that Gland's ANDA Products are especially adapted for a use that infringes one or more claims of the '827 patent and that there is no substantial non-infringing use for Gland's ANDA Products.

98. Endo will be substantially and irreparably damaged and harmed if Gland's infringement of the '827 patent is not enjoined.

99. Endo does not have an adequate remedy at law.

100. Gland's infringement of the '827 patent would be willful, wanton, and deliberate.

101. There is a justiciable controversy between the parties as to the infringement of the '827 patent.

COUNT VII
(Infringement of the '006 Patent)

102. Endo incorporates each of the preceding paragraphs as if fully set forth herein.

103. Gland, by submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Gland's ANDA Products, prior to the expiration of the Patents-in-Suit on January 30, 2035.

104. Gland's ANDA has been pending before the FDA since at least November 18, 2024, the date that Gland sent the Gland Notice Letter to Endo.

105. The submission of Gland's ANDA to the FDA, which seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Gland's ANDA Products before the expiration of the '006 patent, constitutes infringement by Gland of one or more claims of the '006 patent under 35 U.S.C. § 271(e)(2)(A).

106. Unless enjoined by this Court, upon FDA approval of Gland's ANDA, Gland will infringe one or more claims of the '006 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Gland's ANDA Products into the United States. On information and belief, upon FDA approval of Gland's ANDA, Gland will intentionally encourage acts of direct infringement with knowledge of the '006 patent and knowledge that its acts are encouraging infringement.

107. Unless enjoined by this Court, upon FDA approval of Gland's ANDA, Gland will contributorily infringe one or more claims of the '006 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Gland's ANDA Products into the United States. On information and belief, Gland has had and continues to have knowledge that Gland's ANDA Products are especially adapted for a use that infringes one or more claims of the '006 patent and that there is no substantial non-infringing use for Gland's ANDA Products.

108. Endo will be substantially and irreparably damaged and harmed if Gland's infringement of the '006 patent is not enjoined.

109. Endo does not have an adequate remedy at law.

110. Gland's infringement of the '006 patent would be willful, wanton, and deliberate.

111. There is a justiciable controversy between the parties as to the infringement of the '006 patent.

COUNT VIII
(Infringement of the '575 Patent)

112. Endo incorporates each of the preceding paragraphs as if fully set forth herein.

113. Gland, by submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Gland's ANDA Products, prior to the expiration of the Patents-in-Suit on January 30, 2035.

114. Gland's ANDA has been pending before the FDA since at least November 18, 2024, the date that Gland sent the Gland Notice Letter to Endo.

115. The submission of Gland's ANDA to the FDA, which seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Gland's ANDA Products before the expiration of the '575 patent, constitutes infringement by Gland of one or more claims of the '575 patent under 35 U.S.C. § 271(e)(2)(A).

116. Unless enjoined by this Court, upon FDA approval of Gland's ANDA, Gland will infringe one or more claims of the '575 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Gland's ANDA Products into the United States. On information and belief, upon FDA approval of Gland's ANDA, Gland will intentionally encourage acts of direct infringement with knowledge of the '575 patent and knowledge that its acts are encouraging infringement.

117. Unless enjoined by this Court, upon FDA approval of Gland's ANDA, Gland will contributorily infringe one or more claims of the '575 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Gland's ANDA Products into the United States.

On information and belief, Gland has had and continues to have knowledge that Gland's ANDA Products are especially adapted for a use that infringes one or more claims of the '575 patent and that there is no substantial non-infringing use for Gland's ANDA Products.

118. Endo will be substantially and irreparably damaged and harmed if Gland's infringement of the '575 patent is not enjoined.

119. Endo does not have an adequate remedy at law.

120. Gland's infringement of the '575 patent would be willful, wanton, and deliberate.

121. There is a justiciable controversy between the parties as to the infringement of the '575 patent.

PRAYER FOR RELIEF

WHEREFORE, Endo respectfully requests the following relief:

A. A judgment that Gland has infringed the '026 patent under 35 U.S.C. § 271(e)(2)(A) by submitting or causing to be submitted to the FDA ANDA No. 216963, and a judgment that Gland will directly infringe, contributorily infringe, and/or induce infringement of one or more claims of the '026 patent under 35 U.S.C. §§ 271(b) and/or (c) if Gland commercially manufactures, uses, offers for sale, sells, and/or imports into the United States its ANDA Products before the expiration of the '026 patent;

B. A judgment that Gland has infringed the '233 patent under 35 U.S.C. § 271(e)(2)(A) by submitting or causing to be submitted to the FDA ANDA No. 216963, and a judgment that Gland will directly infringe, contributorily infringe, and/or induce infringement of one or more claims of the '233 patent under 35 U.S.C. §§ 271(b) and/or (c) if Gland commercially manufactures, uses, offers for sale, sells, and/or imports into the United States its ANDA Products before the expiration of the '233 patent;

C. A judgment that Gland has infringed the '234 patent under 35 U.S.C. § 271(e)(2)(A) by submitting or causing to be submitted to the FDA ANDA No. 216963, and a judgment that Gland will directly infringe, contributorily infringe, and/or induce infringement of one or more claims of the '234 patent under 35 U.S.C. §§ 271(b) and/or (c) if Gland commercially manufactures, uses, offers for sale, sells, and/or imports into the United States its ANDA Products before the expiration of the '234 patent;

D. A judgment that Gland has infringed the '422 patent under 35 U.S.C. § 271(e)(2)(A) by submitting or causing to be submitted to the FDA ANDA No. 216963, and a judgment that Gland will directly infringe, contributorily infringe, and/or induce infringement of one or more claims of the '422 patent under 35 U.S.C. §§ 271(b) and/or (c) if Gland commercially manufactures, uses, offers for sale, sells, and/or imports into the United States its ANDA Products before the expiration of the '422 patent;

E. A judgment that Gland has infringed the '649 patent under 35 U.S.C. § 271(e)(2)(A) by submitting or causing to be submitted to the FDA ANDA No. 216963, and a judgment that Gland will directly infringe, contributorily infringe, and/or induce infringement of one or more claims of the '649 patent under 35 U.S.C. §§ 271(b) and/or (c) if Gland commercially manufactures, uses, offers for sale, sells, and/or imports into the United States its ANDA Products before the expiration of the '649 patent;

F. A judgment that Gland has infringed the '827 patent under 35 U.S.C. § 271(e)(2)(A) by submitting or causing to be submitted to the FDA ANDA No. 216963, and a judgment that Gland will directly infringe, contributorily infringe, and/or induce infringement of one or more claims of the '827 patent under 35 U.S.C. §§ 271(b) and/or (c) if Gland commercially

manufactures, uses, offers for sale, sells, and/or imports into the United States its ANDA Products before the expiration of the '827 patent;

G. A judgment that Gland has infringed the '006 patent under 35 U.S.C. § 271(e)(2)(A) by submitting or causing to be submitted to the FDA ANDA No. 216963, and a judgment that Gland will directly infringe, contributorily infringe, and/or induce infringement of one or more claims of the '006 patent under 35 U.S.C. §§ 271(b) and/or (c) if Gland commercially manufactures, uses, offers for sale, sells, and/or imports into the United States its ANDA Products before the expiration of the '006 patent;

H. A judgment that Gland has infringed the '575 patent under 35 U.S.C. § 271(e)(2)(A) by submitting or causing to be submitted to the FDA ANDA No. 216963, and a judgment that Gland will directly infringe, contributorily infringe, and/or induce infringement of one or more claims of the '575 patent under 35 U.S.C. §§ 271(b) and/or (c) if Gland commercially manufactures, uses, offers for sale, sells, and/or imports into the United States its ANDA Products before the expiration of the '575 patent;

I. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval by the FDA of Gland's ANDA No. 216963 be a date that is not earlier than the last expiration date of the Patents-in-Suit, including any extensions;

J. Preliminary and permanent injunctions enjoining Gland, its respective officers, agents, servants, employees, and those persons in active concert or participation with any of them, from the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Gland's ANDA Products before the last expiration date of the Patents-in-Suit;

K. An injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Gland, its respective officers, agents, servants, employees, and those persons in active concert or

participation with any of them, from the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Gland's ANDA Products before the last expiration date of the Patents-in-Suit;

L. An order that damages or other monetary relief be awarded to Endo if Gland engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of its ANDA Products before the expiration of the Patents-in-Suit for the full terms thereof (including any extensions), and that such damages or monetary relief be trebled and awarded to Endo with prejudgment interest;

M. A declaration that this is an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

N. Costs and expenses incurred by Endo in this actions; and

O. Such other relief as the Court may deem just and proper.

Dated: December 31, 2024

Respectfully submitted,

s/ Kaan Ekiner

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

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.

s/ Kaan Ekiner
Kaan Ekiner

CERTIFICATION PURSUANT TO L. CIV. R. 201.1(d)

Pursuant to Local Civil Rule 201.1, I hereby certify the above-captioned matter is not subject to compulsory arbitration in that, *inter alia*, the Plaintiff seeks non-monetary injunctive relief and the amount in controversy exceeds the $150,000 threshold of interest and costs and any claim for punitive damages.

s/ Kaan Ekiner
Kaan Ekiner