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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VALEANT PHARMACEUTICALS INTERNATIONAL, INC., SALIX PHARMACEUTICALS, INC., PROGENICS PHARMACEUTICALS, INC. and WYETH LLC, Plaintiffs, v. PAR STERILE PRODUCTS, LLC, PAR PHARMACEUTICAL, INC., and ENDO INTERNATIONAL PLC, Defendants.	Civil Action No.: _____ *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Valeant Pharmaceuticals International, Inc. ("Valeant"), Salix Pharmaceuticals, Inc. ("Salix"), Progenics Pharmaceuticals, Inc. ("Progenics"), and Wyeth LLC (collectively, "Plaintiffs") by way of Complaint against Defendants Par Sterile Products, LLC, Par Pharmaceutical, Inc., and Endo International plc (collectively, "Par" or "Defendants") allege as follows:

THE PARTIES

1. Plaintiff Valeant is a corporation organized and existing under the laws of Canada. Its United States headquarters are located at 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.

2. Plaintiff Salix is a corporation organized and existing under the laws of California, having its principal place of business at 8510 Colonnade Center Drive, Raleigh, NC 27615. Salix is the registered holder of approved New Drug Application No. 021964, which covers Relistor®.

3. Plaintiff Progenics is a corporation organized and existing under the laws of Delaware, having its principal place of business at One World Trade Center, 47th Floor, New York, NY 10007.

4. Plaintiff Wyeth LLC, formerly Wyeth, is a Delaware LLC, having places of business at 235 East 42nd Street, New York, NY 10017, and One Giralda Farms, Madison, NJ 07940.

5. Upon information and belief, Defendant Par Sterile Products, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a regular and established place of business at Morris Corporate Center 2, One Upper Pond Road, Parsippany, NJ 07054. Par Sterile Products, LLC is a wholly-owned subsidiary, directly or indirectly, of Par Pharmaceutical, Inc. and Endo International plc.

6. Upon information and belief, Defendant Par Pharmaceutical, Inc., is a corporation organized and existing under the laws of the State of New York, having a place of business at One Ram Ridge Road, Chestnut Ridge, NY, 10977. Par Pharmaceutical, Inc. is a wholly-owned subsidiary, directly or indirectly, or Endo International plc.

7. Upon information and belief, Defendant Endo International plc is a publicly-traded company organized and existing under the laws of Ireland, having a place of business at First Floor, Minerva House Simmonscourt Road, Ballsbridge, Dublin 4, Ireland.

NATURE OF THE ACTION

8. This is an action for infringement of U.S. Patent Nos. 8,247,425 ("the '425 patent"); 8,420,663 ("the '663 patent"); 8,552,025 ("the '025 patent"); 8,822,490 ("the '490 patent"); 9,180,125 ("the '125 patent"); and 9,669,096 ("the '096 patent") arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Par's filing of an Abbreviated New Drug Application ("ANDA") under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market its generic methylnaltrexone bromide injection, 12 mg/0.6 mL, single use vials ("Par's proposed generic methylnaltrexone vial product").

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

10. Upon information and belief, this Court has jurisdiction over Par Sterile Products, LLC. Upon information and belief, Par Sterile Products, LLC is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Par Sterile Products, LLC directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Par's proposed generic methylnaltrexone vial product. Upon information and belief, Par Sterile Products, LLC is registered to do business in New Jersey, with entity ID No. 0600303655, and has purposefully

conducted and continues to conduct business in this judicial district. Upon information and belief, Par Sterile Products, LLC is registered in the State of New Jersey as a "manufacturer and wholesale[r]" of drugs, with Registration No. 5003561. Upon information and belief, Par Sterile Products, LLC operates and maintains a branch in Parsippany, NJ. Upon information and belief, Par Sterile Products, LLC has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by filing actions in this jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction.

11. Upon information and belief, this Court has jurisdiction over Par Pharmaceutical, Inc. Upon information and belief, Par Pharmaceutical, Inc. is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Par Pharmaceutical, Inc. directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Par's proposed generic methylnaltrexone vial product. Upon information and belief, Par Pharmaceutical, Inc. is registered in the State of New Jersey as a "manufacturer and wholesale[r]" of drugs, with Registration No. 5004032. Upon information and belief, Par Pharmaceutical, Inc. operates and maintains a branch in Woodcliff Lake, NJ. Upon information and belief, Par Pharmaceutical, Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by filing actions in this jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction.

12. Upon information and belief, this Court has jurisdiction over Endo International plc. Upon information and belief, Endo International plc is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Endo International plc directly, or indirectly through its wholly

owned subsidiaries, manufactures, markets, and sells generic drug products, including generic products manufactured by Par Sterile Products, LLC, throughout the United States and in this judicial district, and this judicial district is a likely destination for Par's proposed generic methylnaltrexone vial product. Upon information and belief, Endo International plc purposefully has conducted and continues to conduct business in this judicial district.

13. Upon information and belief, Par Sterile Products, LLC, Par Pharmaceutical, Inc., and Endo International plc hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling and distributing generic products in the United States.

14. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

THE PATENTS IN SUIT

15. The U.S. Patent and Trademark Office ("PTO") issued the '425 patent on August 21, 2012. The '425 patent claims, *inter alia*, prefilled syringes comprising liquid compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the '425 patent and have the right to sue for infringement thereof. A copy of the '425 patent is attached as Exhibit A.

16. The PTO issued the '663 patent on April 16, 2013. The '663 patent claims, *inter alia*, methods of using compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the '663 patent and have the right to sue for infringement thereof. A copy of the '663 patent is attached as Exhibit B.

17. The PTO issued the '025 patent on October 8, 2013. The '025 patent claims, *inter alia*, pharmaceutical preparations of methylnaltrexone. Plaintiffs hold all substantial rights in the

'025 patent and have the right to sue for infringement thereof. A copy of the '025 patent is attached as Exhibit C.

18. The PTO issued the '490 patent on September 2, 2014. The '490 patent claims, *inter alia*, packaged compositions comprising liquid compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the '490 patent and have the right to sue for infringement thereof. A copy of the '490 patent is attached as Exhibit D.

19. The PTO issued the '125 patent on November 10, 2015. The '125 patent claims, *inter alia*, compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the '125 patent and have the right to sue for infringement thereof. A copy of the '125 patent is attached as Exhibit E.

20. The PTO issued the '096 patent on June 6, 2017. The '096 patent claims, *inter alia*, pharmaceutical preparations of methylnaltrexone. Plaintiffs hold all substantial rights in the '096 patent and have the right to sue for infringement thereof. A copy of the '096 patent is attached as Exhibit F.

21. Salix is the holder of New Drug Application ("NDA") No. 021964 for Relistor®. In conjunction with NDA No. 021964, the '025 patent, the '425 patent, the '663 patent, the '490 patent, the '125 patent, and the '096 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

22. Methylnaltrexone bromide for subcutaneous injection, 12 mg/0.6 mL vials and 8 mg/0.4 mL and 12 mg/0.6 mL prefilled syringes, are sold in the United States under the trademark Relistor®.

PAR'S INFRINGING ANDA SUBMISSION

23. Upon information and belief, Par filed or caused to be filed with the FDA ANDA No. 209682, under section 505(j) of the Act and 21 U.S.C. § 355(j).

24. Upon information and belief, Par's ANDA No. 209682 seeks FDA approval to sell in the United States Par's proposed generic methylnaltrexone vial product, intended to be a generic version of Relistor®.

25. Salix, Progenics and Wyeth LLC received a letter from "Par Pharmaceutical (an endo international company)" "on behalf of Par Sterile Products, LLC" dated July 14, 2017, purporting to be a Notice of Certification for ANDA No. 209682 ("Par's notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 C.F.R. § 314.95. Par's notice letter was addressed to Salix at Bridgewater, NJ.

26. Par's notice letter alleges that Par has submitted to the FDA ANDA No. 209682 seeking FDA approval to sell Par's proposed generic methylnaltrexone vial product, intended to be a generic version of Relistor®.

27. Par's notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defenses, does not allege non-infringement of at least claims 1-23 of the '025 patent, claims 3-4, 14, and 27-32 of the '425 patent, claims 4-6, 20-21, and 37-46 of the '490 patent, claims 1-20 of the '125 patent, and claims 1-39 of the '096 patent.

28. Upon information and belief, ANDA No. 209682 seeks approval of Par's proposed generic methylnaltrexone vial product that is the same, or substantially the same, as Relistor®.

29. Upon information and belief, Par Sterile Products, LLC's actions related to ANDA No. 209682 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Par Pharmaceutical, Inc. and Endo International plc.

COUNT I AGAINST PAR

Infringement of the '425 Patent Under § 271(e)(2)

30. Paragraphs 1-29 are incorporated herein as set forth above.

31. Under 35 U.S.C. § 271(e)(2), Par has infringed at least one claim of the '425 patent by submitting, or causing to be submitted to the FDA, ANDA No. 209682 seeking approval for the commercial marketing of Par's proposed generic methylnaltrexone vial product before the expiration date of the '425 patent.

32. Upon information and belief, Par's proposed generic methylnaltrexone vial product will, if approved and marketed, infringe at least one claim of the '425 patent.

33. Upon information and belief, Par will, through the manufacture, use, import, offer for sale, and/or sale of Par's proposed generic methylnaltrexone vial product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '425 patent.

COUNT II AGAINST PAR

Declaratory Judgment of Infringement of the '425 Patent

34. Paragraphs 1-33 are incorporated herein as set for the above.

35. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

36. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

37. Par has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Par's proposed generic methylnaltrexone vial product before the expiration of the '425 patent, including Par's filing of ANDA No. 209682.

38. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Par's proposed generic methylnaltrexone vial product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '425 patent.

39. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Par's proposed generic methylnaltrexone vial product will constitute infringement of at least one claim of the '425 patent.

COUNT III AGAINST PAR

Infringement of the '663 Patent Under § 271(e)(2)

40. Paragraphs 1-39 are incorporated herein as set forth above.

41. Under 35 U.S.C. § 271(e)(2), Par has infringed at least one claim of the '663 patent by submitting, or causing to be submitted to the FDA, ANDA No. 209682 seeking approval for the commercial marketing of Par's proposed generic methylnaltrexone vial product before the expiration date of the '663 patent.

42. Upon information and belief, Par's proposed generic methylnaltrexone vial product will, if approved and marketed, infringe at least one claim of the '663 patent.

43. Upon information and belief, Par will, through the manufacture, use, import, offer for sale, and/or sale of Par's proposed generic methylnaltrexone vial product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '663 patent.

COUNT IV AGAINST PAR

Declaratory Judgment of Infringement of the '663 Patent

44. Paragraphs 1-43 are incorporated herein as set for the above.

45. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

46. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

47. Par has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Par's proposed generic methylnaltrexone vial product before the expiration of the '663 patent, including Par's filing of ANDA No. 209682.

48. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Par's proposed generic methylnaltrexone vial product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '663 patent.

49. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Par's proposed generic

methylnaltrexone vial product will constitute infringement of at least one claim of the '663 patent.

COUNT V AGAINST PAR

Infringement of the '025 Patent Under § 271(e)(2)

50. Paragraphs 1-49 are incorporated herein as set forth above.

51. Under 35 U.S.C. § 271(e)(2), Par has infringed at least one claim of the '025 patent by submitting, or causing to be submitted to the FDA, ANDA No. 209682 seeking approval for the commercial marketing of Par's proposed generic methylnaltrexone vial product before the expiration date of the '025 patent.

52. Upon information and belief, Par's proposed generic methylnaltrexone vial product will, if approved and marketed, infringe at least one claim of the '025 patent.

53. Upon information and belief, Par will, through the manufacture, use, import, offer for sale, and/or sale of Par's proposed generic methylnaltrexone vial product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '025 patent.

COUNT VI AGAINST PAR

Declaratory Judgment of Infringement of the '025 Patent

54. Paragraphs 1-53 are incorporated herein as set for the above.

55. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

56. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

57. Par has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Par's proposed generic methylnaltrexone vial product before the expiration of the '025 patent, including Par's filing of ANDA No. 209682.

58. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Par's proposed generic methylnaltrexone vial product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '025 patent.

59. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Par's proposed generic methylnaltrexone vial product will constitute infringement of at least one claim of the '025 patent.

COUNT VII AGAINST PAR

Infringement of the '490 Patent Under § 271(e)(2)

60. Paragraphs 1-59 are incorporated herein as set forth above.

61. Under 35 U.S.C. § 271(e)(2), Par has infringed at least one claim of the '490 patent by submitting, or causing to be submitted to the FDA, ANDA No. 209682 seeking approval for the commercial marketing of Par's proposed generic methylnaltrexone vial product before the expiration date of the '490 patent.

62. Upon information and belief, Par's proposed generic methylnaltrexone vial product will, if approved and marketed, infringe at least one claim of the '490 patent.

63. Upon information and belief, Par will, through the manufacture, use, import, offer for sale, and/or sale of Par's proposed generic methylnaltrexone vial product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '490 patent.

COUNT VIII AGAINST PAR

Declaratory Judgment of Infringement of the '490 Patent

64. Paragraphs 1-63 are incorporated herein as set for the above.

65. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

66. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

67. Par has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Par's proposed generic methylnaltrexone vial product before the expiration of the '490 patent, including Par's filing of ANDA No. 209682.

68. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Par's proposed generic methylnaltrexone vial product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '490 patent.

69. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Par's proposed generic methylnaltrexone vial product will constitute infringement of at least one claim of the '490 patent.

COUNT IX AGAINST PAR

Infringement of the '125 Patent Under § 271(e)(2)

70. Paragraphs 1-69 are incorporated herein as set forth above.

71. Under 35 U.S.C. § 271(e)(2), Par has infringed at least one claim of the '125 patent by submitting, or causing to be submitted to the FDA, ANDA No. 209682 seeking approval for the commercial marketing of Par's proposed generic methylnaltrexone vial product before the expiration date of the '125 patent.

72. Upon information and belief, Par's proposed generic methylnaltrexone vial product will, if approved and marketed, infringe at least one claim of the '125 patent.

73. Upon information and belief, Par will, through the manufacture, use, import, offer for sale, and/or sale of Par's proposed generic methylnaltrexone vial product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '125 patent.

COUNT X AGAINST PAR

Declaratory Judgment of Infringement of the '125 Patent

74. Paragraphs 1-73 are incorporated herein as set for the above.

75. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

76. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

77. Par has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Par's proposed generic

methylnaltrexone vial product before the expiration of the ’125 patent, including Par’s filing of ANDA No. 209682.

78. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Par’s proposed generic methylnaltrexone vial product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’125 patent.

79. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Par’s proposed generic methylnaltrexone vial product will constitute infringement of at least one claim of the ’125 patent.

COUNT XI AGAINST PAR

Infringement of the ’096 Patent Under § 271(e)(2)

80. Paragraphs 1-79 are incorporated herein as set forth above.

81. Under 35 U.S.C. § 271(e)(2), Par has infringed at least one claim of the ’096 patent by submitting, or causing to be submitted to the FDA, ANDA No. 209682 seeking approval for the commercial marketing of Par’s proposed generic methylnaltrexone vial product before the expiration date of the ’096 patent.

82. Upon information and belief, Par’s proposed generic methylnaltrexone vial product will, if approved and marketed, infringe at least one claim of the ’096 patent.

83. Upon information and belief, Par will, through the manufacture, use, import, offer for sale, and/or sale of Par’s proposed generic methylnaltrexone vial product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’096 patent.

COUNT XII AGAINST PAR

Declaratory Judgment of Infringement of the '096 Patent

84. Paragraphs 1-83 are incorporated herein as set for the above.

85. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

86. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

87. Par has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Par's proposed generic methylnaltrexone vial product before the expiration of the '096 patent, including Par's filing of ANDA No. 209682.

88. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Par's proposed generic methylnaltrexone vial product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '096 patent.

89. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Par's proposed generic methylnaltrexone vial product will constitute infringement of at least one claim of the '096 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Par on the patent infringement claims sets forth above and respectfully request that this Court:

1. Enter judgment that, under 35 U.S.C. § 271(e)(2), Par has infringed at least one claim of the '425 patent by submitting or causing to be submitted ANDA No. 209682 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Par's proposed generic methylnaltrexone vial product before the expiration of the '425 patent;

2. Enter judgment that, under 35 U.S.C. § 271(e)(2), Par has infringed at least one claim of the '663 patent by submitting or causing to be submitted ANDA No. 209682 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Par's proposed generic methylnaltrexone vial product before the expiration of the '663 patent;

3. Enter judgment that, under 35 U.S.C. § 271(e)(2), Par has infringed at least one claim of the '025 patent by submitting or causing to be submitted ANDA No. 209682 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Par's proposed generic methylnaltrexone vial product before the expiration of the '025 patent;

4. Enter judgment that, under 35 U.S.C. § 271(e)(2), Par has infringed at least one claim of the '490 patent by submitting or causing to be submitted ANDA No. 209682 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the

United States of Par's proposed generic methylnaltrexone vial product before the expiration of the '490 patent;

5. Enter judgment that, under 35 U.S.C. § 271(e)(2), Par has infringed at least one claim of the '125 patent by submitting or causing to be submitted ANDA No. 209682 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Par's proposed generic methylnaltrexone vial product before the expiration of the '125 patent;

6. Enter judgment that, under 35 U.S.C. § 271(e)(2), Par has infringed at least one claim of the '096 patent by submitting or causing to be submitted ANDA No. 209682 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Par's proposed generic methylnaltrexone vial product before the expiration of the '096 patent;

7. Order that the effective date of any approval by the FDA of Par's proposed generic methylnaltrexone vial product be a date that is not earlier than the expiration of the '425 patent, the '663 patent, the '025 patent, the '490 patent, the '125 patent, and the '096 patent or such later date as the Court may determine;

8. Enjoin Par from the commercial manufacture, use, import, offer for sale, and/or sale of Par's proposed generic methylnaltrexone vial product until expiration of the '425 patent, the '663 patent, the '025 patent, the '490 patent, the '125 patent, and the '096 patent or such later date as the Court may determine;

9. Enjoin Par and all persons acting in concert with Par from seeking, obtaining, or maintaining approval of Par's ANDA No. 209682 until expiration of the '425 patent, the '663 patent, the '025 patent, the '490 patent, the '125 patent, and the '096 patent;

10. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees; and

11. Award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: August 25, 2017
Morristown, New Jersey

Respectfully submitted,

s/ Joseph P. LaSala
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Progenics Pharmaceuticals, Inc.

CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify that the foregoing statements made by me are true. I am aware that if any of the statements made by me are willfully false, I am subject to punishment.

Dated: August 25, 2017

s/ Joseph P. LaSala

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