IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC Plaintiffs, v. EAGLE PHARMACEUTICALS INC. Defendant.	Civil Action No. _____

COMPLAINT

Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively "Par"), for their complaint against Eagle Pharmaceuticals, Inc., hereby allege as follows:

PARTIES

1. Plaintiff Par Pharmaceutical, Inc. ("Par Pharmaceutical") is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Pharmaceutical develops, manufactures, and markets pharmaceutical products in the United States.

2. Plaintiff Par Sterile Products, LLC ("Par Sterile Products") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977. Par Sterile Products develops, manufactures, and markets injectable pharmaceutical products, and provides manufacturing services to the biopharmaceutical and pharmaceutical industry.

3. Plaintiff Endo Par Innovation Company ("EPIC") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 1 Ram Ridge Road, Chestnut Ridge, New York 10977.

4. Upon information and belief, defendant Eagle Pharmaceuticals, Inc. ("Eagle") is a corporation organized and existing under the law of Delaware, having its corporate offices and principal place of business at 50 Tice Boulevard, Suite 315, Woodcliff Lake, New Jersey 07677. Eagle is a specialty pharmaceutical company that markets injectable treatments for patients across oncology, critical care, and orphan diseases.

NATURE OF ACTION

5. This is an action for infringement of United States Patent Nos. 9,375,478 ("the '478 Patent"), 9,687,526 ("the '526 Patent"), 9,744,209 ("the '209 Patent"), 9,744,239 ("the '239 Patent"), 9,750,785 ("the '785 Patent"), and 9,937,223 ("the '223 Patent") (collectively, "the Patents-in-Suit"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) (patent infringement).

7. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b) because, *inter alia*, Eagle is incorporated in Delaware, and thus resides in this district.

8. This Court has personal jurisdiction over Eagle because, *inter alia*, Eagle is incorporated in Delaware, and thus resides in this district.

THE DRUG APPROVAL PROCESS

9. A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from the U.S. Food and Drug Administration ("FDA"), typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a). The sponsor of the NDA is required to submit to FDA information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, and FDA then lists the patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." *See* 21 U.S.C. § 355(b)(1) and (c)(2).

10. Alternatively, a company seeking to market a generic version of a previously approved drug is not required to submit a full NDA. Instead, it may file an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. §355(j). The generic drug approval process is considered "abbreviated" because the generic manufacturer may piggyback on the innovator company's data and FDA's prior finding of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the previously approved drug (the "listed drug" or "branded drug").

11. In conjunction with this "abbreviated" application process, Congress has put in place a process for resolving patent disputes relating to generic drugs, pursuant to which an ANDA filer must provide certifications addressing each of the patents listed in the Orange Book for the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12). An ANDA filer may certify, for instance, that it believes a patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4). This is known as a "Paragraph IV Certification."

12. The filer of an ANDA with a Paragraph IV Certification must also provide notice to both the owners of the listed patents and the holder of the NDA for the referenced listed drug. This "Paragraph IV Notice" must include a detailed statement of the factual and legal bases for the applicant's belief that the challenged patent is invalid or not infringed by the proposed generic product. 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95.

13. If the patentee or NDA holder files a patent infringement action within 45 days of receiving a Paragraph IV Notice from an ANDA filer, final approval of the ANDA is subject to a 30-month stay. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3). The 30-month stay is important to the innovator companies because it protects them from the severe financial harm that could otherwise ensue from the FDA granting approval to an infringing product without first providing an opportunity for the infringement case to be resolved. Put another way, the innovator company is assured of a 30-month period during which it may try to enforce its intellectual property rights and resolve any patent dispute before the generic product enters the market. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

FACTUAL BACKGROUND

The Patents-In-Suit

14. On June 28, 2016, the PTO duly and legally issued the '478 Patent, entitled "Vasopressin Formulations For Use In Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '478 Patent is attached as Exhibit A. Par Pharmaceutical owns the '478 Patent.

15. On June 27, 2017, the PTO duly and legally issued the '526 Patent, entitled "Vasopressin Formulations For Use In Treatment Of Hypotension," to Par Pharmaceutical as

assignee. A true and correct copy of the '526 Patent is attached as Exhibit B. Par Pharmaceutical owns the '526 Patent.

16. On August 29, 2017, the PTO duly and legally issued the '209 Patent, entitled "Vasopressin Formulations For Use In Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '209 Patent is attached as Exhibit C. Par Pharmaceutical owns the '209 Patent.

17. On August 29, 2017, the United States Patent and Trademark Office ("PTO") duly and legally issued the '239 Patent, entitled "Vasopressin Formulations For Use In Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '239 Patent is attached as Exhibit D. Par Pharmaceutical owns the '239 patent.

18. On September 5, 2017, the PTO duly and legally issued the '785 Patent, entitled "Vasopressin Formulations For Use In Treatment Of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '785 Patent is attached as Exhibit E. Par Pharmaceutical owns the '785 Patent.

19. On April 10, 2018, the PTO duly and legally issued the '223 Patent, entitled "Vasopressin Formulations For Use In Treatment of Hypotension," to Par Pharmaceutical as assignee. A true and correct copy of the '223 Patent is attached as Exhibit F. Par Pharmaceutical owns the '223 Patent.

20. EPIC is the exclusive licensee of the Patents-In-Suit.

VASOSTRICT®

21. Vasopressin, the active ingredient in VASOSTRICT® (described below), 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.

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

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

24. Par Sterile Products submitted supplemental NDAs including supplemental NDA Nos. 204485/S-003 and 204485/S-004 for the current formulations of VASOSTRICT®—20 units/mL in 1 mL vials and 200 units/10 mL in 10 mL multi-dose vials. On March 18, 2016, the FDA approved NDA No. 204485/S-003 for the 20 units/mL in 1 mL vial formulation of VASOSTRICT®. On December 17, 2016, the FDA approved NDA No. 204485/S-004 for the 200 units/10 mL in 10mL vial formulation of VASOSTRICT®.

25. Par Sterile Products is the holder of NDA 204485, including all supplements thereto, for VASOSTRICT®.

26. Par timely submitted information regarding the Patents-in-Suit for listing in the "Orange Book" with respect to VASOSTRICT®, pursuant to 21 U.S.C. § 355(b)(1) and (c)(2). The FDA thereafter listed the Patents-in-Suit in the Orange Book, pursuant to 21 C.F.R. § 314.53(e).

27. VASOSTRICT® is FDA-approved as indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. Par markets and sells its VASOSTRICT® products to hospitals, both directly and via group purchasing organizations and wholesalers. VASOSTRICT® has enjoyed tremendous commercial success, with 2017 annual sales of $400 million.

Eagle's Infringing Generic Vasopressin Injection Product

28. Upon information and belief, on or before March 23, 2018, Eagle submitted ANDA No. 211538 (the "Eagle ANDA") pursuant to 35 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of a proposed generic Vasopressin Injection USP, 20 units/1 mL (20 units/mL), referencing Par's VASOSTRICT® products as the reference listed drug (the "Proposed ANDA Product"). The dosage form of the Proposed ANDA Product is a multiple dose injection solution.

29. On or about April 16, 2018, Eagle sent Par Sterile Products and Par Pharmaceutical a notice stating that Eagle had submitted its ANDA seeking approval to manufacture, use, or sell the Proposed ANDA Product prior to expiration of the '239, '478, '526, '785, and '209 Patents (the "First Paragraph IV Notice"). On or about May 18, 2018, Eagle sent Par Sterile Products and Par Pharmaceutical a notice stating that Eagle had submitted its ANDA seeking approval to manufacture, use, or sell the Proposed ANDA Product prior to expiration of the '223 Patent (the "Second Paragraph IV Notice").

30. The First and Second Paragraph IV Notices advised that the Eagle ANDA includes Paragraph IV Certifications stating that it is Eagle's opinion that the Patents-in-Suit are invalid and not infringed by the Proposed ANDA Product. Eagle's Paragraph IV Notices

included an Offer of Confidential Access to the Eagle ANDA pursuant to 21 U.S.C. § 355(j)(5)(C).

31. On May 14, 2018, Par requested confidential access to Eagle's ANDA pursuant to the terms of Eagle's Offer of Confidential Access. Eagle produced heavily redacted copies of portions of the Eagle ANDA on May 23, 2018.

32. Par objected to Eagle's improper and incomplete production, advising Eagle that Par could not conduct a full and complete infringement analysis based on the incomplete and heavily redacted portions of the ANDA that Eagle had produced.

33. Par requested that Eagle produce a complete and unredacted version of its ANDA, and thereafter explained the reasons why the unproduced, additional portions of Eagle's ANDA were relevant to its evaluation of the full extent of Eagle's infringement and why Eagle's improper withholding of the majority of is ANDA, including for example its batch records, stability and other testing data, and other CMC information, had hampered that evaluation.

34. Eagle refused to make a further production and has continued to withhold substantial portions of its ANDA from Par.

35. By failing to produce all of its ANDA, and heavily redacting the portions of the ANDA that it did produce, Eagle has withheld critical information relevant to the design, operation and characteristics of the Proposed ANDA Product and thereby thwarted Par's ability to conduct a full and complete investigation of the full extent to which the Proposed ANDA Product infringes the Patents-In-Suit and Eagle's representations in its Paragraph IV Notices about the nature and characteristics of its Proposed ANDA Product.

36. Because Eagle's Proposed ANDA Product has not been approved by FDA and is not yet commercially available, Par is not aware of any means for obtaining additional

information concerning the design, operation and characteristics of the Proposed ANDA Product other than obtaining it directly from Eagle pursuant to the Eagle's Offer of Confidential Access to its ANDA.

37. Nevertheless, even based on the limited and incomplete information produced by Eagle, and upon information and belief, it is apparent that the Proposed ANDA Product infringes one or more of the Patents-in-Suit, as detailed below. In the absence of a full and complete copy of Eagle's ANDA and such other information as may be needed to ascertain the full extent to which Eagle has infringed and will infringe the Patents-in-Suit, Par resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm its belief and to present to the Court evidence that Eagle infringes one or more claims of each of the Patents-in-Suit.

COUNT I:
INFRINGEMENT OF THE '239 PATENT

38. Par incorporates each of the preceding paragraphs as if fully set forth herein.

39. Upon information and belief, and subject to Par's ongoing investigation and discovery efforts, Eagle's submission of its ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed ANDA Product prior to the expiration of the '239 Patent, constitutes infringement of the '239 Patent under 35 U.S.C. § 271(e)(2)(A).

40. Upon information and belief, and subject to Par's ongoing investigation and discovery efforts, any commercial manufacture, use, offer for sale, sale, and/or importation of into the United States of the Proposed ANDA Product before expiration of the '239 patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '239 Patent under 35 U.S.C. §§ 271(a)-(c).

41. In particular, and among other things, the commercial manufacture, use, offer for sale, sale, and/or importation of into the United States of the Proposed ANDA Product would lead to such infringement of at least claim 1 of the '239 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
> a) providing a pharmaceutical composition for intravenous administration consisting of, in a unit dosage form:
> i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
> ii) optionally chlorobutanol;
> iii) acetic acid, acetate, or a combination thereof;
> iv) 0-2% vasopressin degradation products; and
> v) water;
> b) diluting the unit dosage form in a diluent to provide a concentration from about 0.1 units/mL to about 1 unit/mL of vasopressin or the pharmaceutically-acceptable salt thereof; and
> c) administering the diluted unit dosage form to the human by intravenous administration; wherein:
> the unit dosage form has a pH of 3.5 to 4.1;
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and
> the human is hypotensive.

42. Upon information and belief, and subject to Par's ongoing investigation and discovery efforts, if the Proposed ANDA Product is administered as intended, doctors, nurses and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Eagle would actively and intentionally induce such infringement.

43. Any launch by Eagle of its Proposed ANDA Product before expiration of the '239 Patent would cause Par to suffer immediate and irreparable harm.

44. Upon information and belief, Eagle was aware of the existence of the '239 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product will lead to infringement of the '239 Patent.

45. Eagle's infringement of the '239 Patent is willful.

COUNT II:
INFRINGEMENT OF THE '223 PATENT

46. Par incorporates each of the preceding paragraphs as if fully set forth herein.

47. Upon information and belief, and subject to Par's ongoing investigation and discovery efforts, Eagle's submission of its ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed ANDA Product prior to the expiration of the '223 Patent, constitutes infringement of the '223 Patent under 35 U.S.C. § 271(e)(2)(A).

48. Upon information and belief, and subject to Par's ongoing investigation and discovery efforts, any commercial manufacture, use, offer for sale, sale, and/or importation of into the United States of the Proposed ANDA Product before expiration of the '223 patent will lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '223 Patent under 35 U.S.C. §§ 271(a)-(c).

49. In particular, and among other things, upon information and belief, and subject to Par's ongoing investigation and discovery efforts, the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed ANDA Product into the United States would lead to such infringement of least claim 1 of the '223 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
> a) providing a pharmaceutical composition for intravenous administration comprising:
> i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof;
> ii) acetate buffer; and
> iii) water, wherein the pharmaceutical composition has a pH from about 3.7 to about 3.8;
> wherein the pharmaceutical composition is provided in a container;
> b) puncturing a dispensing region of the container a first time

and drawing from the container a portion of the pharmaceutical composition;

c) intravenously administering the portion of the pharmaceutical composition to the human; wherein:

the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically acceptable salt thereof per minute; wherein:

the human is hypotensive;

d) puncturing the dispensing region of the container a second time and drawing from the container a second portion of the pharmaceutical composition; wherein:

the second time that the dispensing region of the container is punctured occurs at least 48 hours after the first time that the dispensing region of the container is punctured;

e) intravenously administering the second portion of the pharmaceutical composition to the human; wherein:

the administration of the second portion of the pharmaceutical composition provides to the human from about 0.01 units of vasopressin or the pharmaceutically acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically acceptable salt thereof per minute.

50. Upon information and belief, and subject to Par's ongoing investigation and discovery efforts, if the Proposed ANDA Product is administered as intended, doctors, nurses and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Eagle would actively and intentionally induce such infringement.

51. Any launch by Eagle of its ANDA Product before expiration of the '223 Patent would cause Par to suffer immediate and irreparable harm.

52. Upon information and belief, Eagle was aware of the existence of the '223 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product will lead to infringement of the '223 Patent.

53. Eagle's infringement of the '223 Patent is willful.

COUNT III:
INFRINGEMENT OF THE '478 PATENT

54. Par incorporates each of the preceding paragraphs as if fully set forth herein.

55. Upon information and belief, and subject to Par's ongoing investigation and discovery efforts, Eagle's submission of its ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed ANDA Product prior to the expiration of the '478 Patent, constitutes infringement of the '478 Patent under 35 U.S.C. § 271(e)(2)(A).

56. Upon information and belief, and subject to Par's ongoing investigation and discovery efforts, any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product before expiration of the '478 patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '478 Patent under 35 U.S.C. §§ 271(a)-(c).

57. In particular, and among other things, upon information and belief, and subject to Par's ongoing investigation and discovery efforts, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product would lead to such infringement of at least claim 1 of the '478 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human in a unit dosage form, wherein the unit dosage form consists essentially of:
>
> a) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
>
> b) 10 mM acetate buffer; and
>
> c) water; wherein:
>
> the unit dosage form has a pH of 3.8;
>
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and
>
> the human is hypotensive

58. Upon information and belief, and subject to Par's ongoing investigation and discovery efforts, if the Proposed ANDA Product is administered as intended, doctors, nurses and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Eagle would actively and intentionally induce such infringement.

59. Any launch by Eagle of its Proposed ANDA Product before expiration of the '478 Patent would cause Par to suffer immediate and irreparable harm.

60. Upon information and belief, Eagle was aware of the existence of the '478 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product will lead to infringement of the '478 Patent.

61. Eagle's infringement of the '478 Patent is willful.

COUNT IV:
INFRINGEMENT OF THE '526 PATENT

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

63. Upon information and belief, and subject to Par's ongoing investigation and discovery efforts, Eagle's submission of its ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed ANDA Product prior to the expiration of the '526 Patent, constitutes infringement of the '526 Patent under 35 U.S.C. § 271(e)(2)(A).

64. Upon information and belief, and subject to Par's ongoing investigation and discovery efforts, any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product before expiration of the '526 patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '526 Patent under 35 U.S.C. §§ 271(a)-(c).

65. In particular, and among other things, upon information and belief, and subject to Par's ongoing investigation and discovery efforts, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product would lead to such infringement of at least claim 1 of the '526 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising:
> a) providing a pharmaceutical composition for intravenous administration comprising:
> i) from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
> ii) acetic acid; and
> iii) water; wherein:
> the pharmaceutical composition has a pH of 3.8;
> b) storing the pharmaceutical composition at 2-8° C. for at least 4 weeks; and
> c) intravenously administering the pharmaceutical composition to the human; wherein:
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; wherein:
> the human is hypotensive; wherein:
> the pharmaceutical composition exhibits less than about 5% degradation after storage at 2-8° C. for about four weeks.

66. Upon information and belief, and subject to Par's ongoing investigation and discovery efforts, if the Proposed ANDA Product is administered as intended, doctors, nurses and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Eagle would actively and intentionally induce such infringement.

67. Any launch by Eagle of its Proposed ANDA Product before expiration of the '526 Patent would cause Par to suffer immediate and irreparable harm.

68. Upon information and belief, Eagle was aware of the existence of the '526 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product will lead to infringement of the '526 Patent.

69. Eagle's infringement of the '526 Patent is willful.

COUNT V:
INFRINGEMENT OF THE '785 PATENT

70. Par incorporates each of the preceding paragraphs as if fully set forth herein.

71. Upon information and belief, and subject to Par's ongoing investigation and discovery efforts, Eagle's submission of its ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed ANDA Product prior to the expiration of the '785 Patent, constitutes infringement of the '785 Patent under 35 U.S.C. § 271(e)(2)(A).

72. Upon information and belief, and subject to Par's ongoing investigation and discovery efforts, any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product before expiration of the '785 patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '785 Patent under 35 U.S.C. §§ 271(a)-(c).

73. In particular, and among other things, upon information and belief, and subject to Par's ongoing investigation and discovery efforts, the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product would lead to such infringement of at least claim 1 of the '785 Patent, which recites as follows:

> Claim 1: A pharmaceutical composition comprising, in a unit dosage form, from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically-acceptable salt thereof, wherein the unit dosage form further comprises impurities that are present in an amount of 0.9% to 1.7%; wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1, and wherein the unit dosage form has a pH of 3.7-3.9.

74. Upon information and belief, and subject to Par's ongoing investigation and discovery efforts, the Proposed ANDA Product satisfies each of the recited elements of the pharmaceutical composition recited in claim 1, such that the commercial manufacture, use, offer

for sale, sale, and/or importation into the United States of the Proposed ANDA Product by Eagle would constitute infringement of claim 1 of the '785 Patent.

75. Any launch by Eagle of its Proposed ANDA Product before expiration of the '785 Patent would cause Par to suffer immediate and irreparable harm.

76. Upon information and belief, Eagle was aware of the existence of the '785 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product infringes the '785 Patent.

77. Eagle's infringement of the '785 Patent is willful.

COUNT VI:
INFRINGEMENT OF THE '209 PATENT

78. Par incorporates each of the preceding paragraphs as if fully set forth herein.

79. Upon information and belief, and subject to Par's ongoing investigation and discovery efforts, Eagle's submission of its ANDA to the FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed ANDA Product prior to the expiration of the '209 Patent, constitutes infringement of the '209 Patent under 35 U.S.C. § 271(e)(2)(A).

80. Upon information and belief, and subject to Par's ongoing investigation and discovery efforts, any commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product before expiration of the '209 patent would lead to direct infringement, contributory infringement, and/or active inducement of infringement of the '209 Patent under 35 U.S.C. §§ 271(a)-(c).

81. In particular, and among other things, upon information and belief, and subject to Par's ongoing investigation and discovery efforts, the commercial manufacture, use, offer for

sale, sale, and/or importation into the United States of the Proposed ANDA Product would lead to such infringement of at least claim 1 of the '209 Patent, which recites as follows:

> Claim 1: A method of increasing blood pressure in a human in need thereof, the method comprising administering to the human a unit dosage form, wherein the unit dosage form comprises from about 0.01 mg/mL to about 0.07 mg/mL of vasopressin or a pharmaceutically acceptable salt thereof; wherein:
>
> the unit dosage form has a pH of 3.7-3.9;
>
> the unit dosage form further comprises impurities that are present in an amount of 0.9% - 1.7%, wherein the impurities have from about 85% to about 100% sequence homology to SEQ ID NO.: 1;
>
> the administration provides to the human from about 0.01 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute to about 0.1 units of vasopressin or the pharmaceutically-acceptable salt thereof per minute; and
>
> the human is hypotensive.

82. Upon information and belief, and subject to Par's ongoing investigation and discovery efforts, if the Proposed ANDA Product is administered as intended, doctors, nurses and/or other medical personnel would perform each and every step of the method of treatment recited in claim 1. By virtue of its proposed product label and other conduct, Eagle would actively and intentionally induce such infringement.

83. Any launch by Eagle of its Proposed ANDA Product before expiration of the '209 Patent would cause Par to suffer immediate and irreparable harm.

84. Upon information and belief, Eagle was aware of the existence of the '209 Patent, and is aware that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product will lead to infringement of the '209 Patent.

85. Eagle's infringement of the '209 Patent is willful.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests the following relief:

A. A judgment that Eagle has infringed the '239 Patent, and a declaration that Eagle's commercial manufacture, distribution, use, and sale of its Proposed ANDA Product would induce infringement of the '239 Patent;

B. A judgment that Eagle has infringed the '223 Patent, and a declaration that Eagle's commercial manufacture, distribution, use, and sale of its Proposed ANDA Product would induce infringement of the '223 Patent.

C. A judgment that Eagle has infringed the '478 Patent, and a declaration that Eagle's commercial manufacture, distribution, use, and sale of its Proposed ANDA Product would induce infringement of the '478 Patent;

D. A judgment that Eagle has infringed the '526 Patent, and a declaration that Eagle's commercial manufacture, distribution, use, and sale of its Proposed ANDA Product would induce infringement of the '526 Patent;

E. A judgment that Eagle has infringed the '785 Patent, and a declaration that Eagle's commercial manufacture, distribution, use, and sale of its Proposed ANDA Product would infringe the '785 Patent;

F. A judgment that Eagle has infringed the '209 Patent, and a declaration that Eagle's commercial manufacture, distribution, use, and sale of its Proposed ANDA Product would induce infringement of the '209 Patent;

G. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Eagle's ANDA No. 211538 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the last expiration date of the Patents-in-Suit, including any extensions;

H. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283, restraining and enjoining Eagle, its officers, agents, servants and employees, and those person in active concert or participation with any of them, from infringement of the Patents-in-Suit for the full terms thereof, including any extensions;

I. An order that damages or other monetary relief be awarded to Plaintiffs if Eagle engages in the commercial manufacture, use, offer to sell, sale, distribution or importation of Eagle's Proposed ANDA Products, or induces such conduct by others, prior to the expiration of the Patents-in-Suit, and any additional period of exclusivity to which Plaintiffs are or become entitled, and that any such damages or monetary relief be trebled and awarded to Plaintiffs with prejudgment interest;

J. Reasonable attorneys' fees, filing fees, and reasonable costs of suit incurred by Plaintiffs in this action; and

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

Dated: May 31, 2018

FARNAN LLP

/s/ *Brian E. Farnan*
Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
919 North Market St.
12th Floor
Wilmington, DE 19801
Tel: 302-777-0300
Fax: 302-777-0301
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Attorneys for Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC

OF COUNSEL:

Martin J. Black
Sharon K. Gagliardi
Brian M. Goldberg
DECHERT LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104
Tel: (215) 994-4000
martin.black@dechert.com
sharon.gagliardi@dechert.com
brian.goldberg@dechert.com

Robert D. Rhoad
DECHERT LLP
100 Overlook Center
2nd Floor
Princeton, NJ 08540-7814
Tel: (609) 955-3200
robert.rhoad@dehcert.com

Johnathan D.J. Loeb, Ph.D
DECHERT LLP
2400 W. El Camino Real, Suite 700
Mountain View, CA 94040-1499
Tel: (650) 813-4995
jonathan.loeb@dechert.com

Blake B. Greene
DECHERT LLP
300 W. 6th Street, Suite 2010
Austin, TX 78701
Tel: (512) 394-3000
blake.greene@dechert.com