LAW OFFICES
**DECHERT LLP**
A PENNSYLVANIA LIMITED LIABILITY PARTNERSHIP
502 CARNEGIE CENTER, SUITE 104
PRINCETON, NJ 08540
(609) 955-3200
ATTORNEYS FOR PLAINTIFFS PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, AND ENDO PAR INNOVATION COMPANY, LLC

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

| | |
|---|---|
| PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC<br><br>Plaintiffs,<br><br>v.<br><br>EAGLE PHARMACEUTICALS INC.<br><br>Defendant. | Civil Action No.3:20-cv-18319 |

## FIRST AMENDED COMPLAINT

Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively "Par"), for their first amended complaint against Eagle Pharmaceuticals Inc. ("Eagle") 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 No. 10,844,435 (the '435 Patent") and United States Patent No. 10,920,278 (the "'278 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*.

6. Par also seeks declaratory judgment under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.* that Eagle's marketing and sale of its Proposed ANDA Product (as detailed below), if approved, would induce infringement of the Patents in Suit.

## JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202 (patent infringement).

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) because, *inter alia*, Eagle has its principal place of business in New Jersey, maintains laboratories and facilities in New Jersey, and has committed acts of infringement in New Jersey, including that Eagle prepared Abbreviated New Drug Application No. 211538 in New Jersey and submitted it to the FDA from New Jersey.

9. This Court has personal jurisdiction over Eagle because, *inter alia*, Eagle has its principal place of business in New Jersey and maintains laboratories and facilities in New Jersey, and because Eagle has committed acts of infringement in New Jersey.

## FACTUAL BACKGROUND

### The Drug Approval Process

10. 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).

11. 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 "reference listed drug" or "branded drug").

12. In general, and with a few exceptions, the labeling for a proposed ANDA product must track the labeling for the FDA-approved branded drug. Accordingly, pursuant to 21 C.F.R. § 314.94(a)(8)(iv), an ANDA filer must include as part of the ANDA a side-by-side comparison of the applicant's proposed labeling for its ANDA product with the approved labeling for the branded drug, with all differences annotated and explained.

13. If the labeling for the branded drug is updated or amended while the applicant's ANDA is being reviewed by FDA, the applicant must submit an appropriate amendment to its ANDA to update the proposed labeling for its ANDA product as needed before obtaining final approval of the ANDA by FDA. Thus, FDA Guidance to ANDA applicants states that:

> "It is incumbent on the ANDA applicant (1) to monitor for updates related to the applicant's drug product (e.g., changes in bioequivalence recommendations or requirements; RLD labeling changes or updates; or USP changes or updates) and (2) to ensure that amendments addressing these updates are timely submitted to and are clearly identified for FDA either before a request for final approval (i.e., in a post-TA amendment) or in the request for final approval amendment itself, permitting FDA sufficient assessment time to meet the ANDA's earliest lawful approval date (see sections III and IV of this draft guidance).

*See* Exhibit C hereto at 11 (Guidance for Industry, "ANDA Submissions – Amendments and Requests for Final Approval to Tentatively Approved ANDAs", U.S. Dep't of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (September 2020).

14. Furthermore, 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). *See also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4). This is known as a "Paragraph IV Certification."

15. The filer of an ANDA with a Paragraph IV Certification must also provide notice to both the owner 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. *See* 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95.

16. If a new patent issues and is listed on the Orange Book with respect to the reference listed drug while an ANDA is being reviewed by FDA, the ANDA filer must submit an appropriate amendment to its patent certification, which could include, among other things, a Paragraph IV Certification indicating that the applicant seeks FDA approval to market its proposed ANDA product prior to the expiration of the new patent. *See* 21 C.F.R. § 314.94(a)(12)(viii)(C)(1)(ii).

**VASOSTRICT®**

17. 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.

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

19. 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.

20. VASOSTRICT® is approved as indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite the provision of fluids and catecholamines. Par markets and sells its VASOSTRICT® products to hospitals, both directly and via group purchasing organizations and wholesalers.

**The Patents in Suit**

21. Since obtaining FDA approval for VASOSTRICT® in April 2014, Par has continued to innovate and make significant investments in the research and development of safer and more effective formulations and uses of vasopressin.

22. For example, Par developed a reformulated version of VASOSTRICT® with a higher pH and new buffer system that has an improved stability and impurity profile, and also developed a safe and effective multi-dose version of VASOSTRICT®. Par submitted supplemental NDAs seeking FDA approval for these developments—supplemental NDA Nos. 204485/S-003 (reformulated version of VASOSTRICT®) and 204485/S-004 (multi-dose vials).

On March 18, 2016, the FDA approved NDA No. 204485/S-003, and on December 17, 2016, it approved NDA No. 204485/S-004.

23. In addition, in an effort to improve patient care and make clinicians' use of vasopressin to treat vasodilatory shock safer and more effective, Par has continued to study the clinical effects of the use of vasopressin on different sub-populations of patients.

24. Septic shock is a life-threatening condition that occurs when a person's blood pressure drops to a dangerously low level after a bacterial, fungal, or viral infection. It can lead to respiratory or heart failure, stroke, failure of other organs, and ultimately death. Indeed, septic shock is the most common cause of death in intensive care units (ICUs) and is reported to have a mortality rate of 40% - 60%.[1]

25. Post-cardiotomy shock can occur as a complication of cardiac surgery and may be characterized by, for example, inability to wean from cardiopulmonary bypass, poor hemodynamics in the operating room, development of poor hemodynamics post-surgery, and hypotension.

26. VASOSTRICT® is one of the medications commonly used to treat septic shock and post-cardiotomy shock (among other forms of vasodilatory shock) in hospital emergency rooms and ICUs across the country, and it can literally save a patient's life.

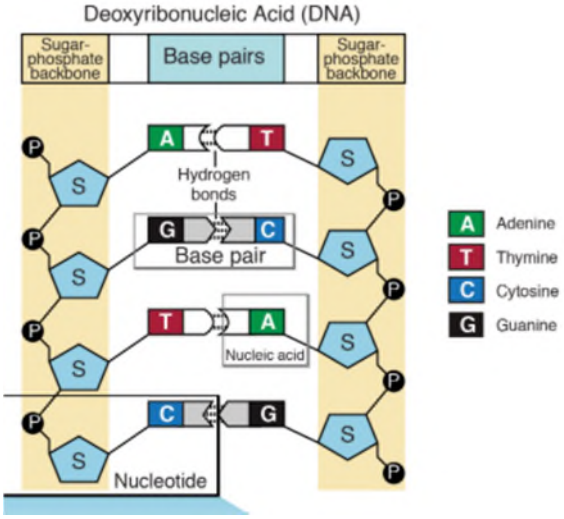
27. But, it is known that overdosage of VASOSTRICT® can cause an over-narrowing of the patient's blood vessels, leading to adverse results such as ventricular tachyarrhythmias, rhabdomyolysis, hyponatremia, and a variety of gastrointestinal symptoms. Accordingly, as with many drugs, there is a delicate balance between ensuring that patients being treated for septic

[1] *See, e.g.*, Russell et al, "*Vasopressin versus Norepinephrine infusion in patients with septic shock*," N. Engl. J. Med. 358 (9): 877-887 (2008).

shock receive an amount of vasopressin sufficient to quickly and effectively raise their blood pressure, without administering too much vasopressin.

28. Vasopressin is fast-acting, but also clears from the body quickly. It was known that the enzyme leucyl/cystinyl aminopeptidase ("LNPEP") degrades vasopressin and is primarily responsible for the short half-life of the drug. For this reason, researcher Taka-Aki Nakada and his coworkers hypothesized that genetic variations in the vasopressin pathway genes, including the gene that encodes for LNPEP, may cause a downstream clinical effect in patients experiencing septic shock.

29. Genes consist of DNA, which is a molecule composed of strands of four types of nucleotides: A, T, C and G. Each of the nucleotides on one side of the strand pairs with a specific nucleotide on the other side of the strand, and this makes up the double helix. Accordingly, the genetic code for each gene is written in the form of a string of As, Ts, Cs, Gs.




30. A variation in a gene is known as an allele, and an individual's collection of genes is known as the genotype. A single genetic variation, for instance, when some people have an "A" in a particular location and some have a "T", is known as a single nucleotide polymorphism ("SNP"). Human beings typically carry two copies of each gene. When an SNP is present, the

genes may have different nucleotides at the SNP location. Thus, if A is dominant at a particular location, but T is also present in some members of a population, there would be three possible combinations of genotypes: "AA", "AT", "TT".

31. Nakada and his coworkers analyzed available data from a multicenter, randomized, double blind, controlled trial evaluating the efficacy of vasopressin versus norepinephrine in treating patients with septic shock, and found that the major [T] allele of LNPEP rs4869317 [A/T] SNP correlated with an increase in 28-day mortality. From this, they established a major allele model (TT vs. AA/AT genotype) and found that patients with the TT genotype appeared to have a higher hazard ratio and an increase in vasopressin clearance as compared with the AA or AT genotyped patients.

32. In view of the findings by Nakada and other researchers and the unpredictable nature of pharmaceutical dosing needed to achieve safety and efficacy, there was a need to better understand the dosing, efficacy, and safety of administering vasopressin to patients having the TT, AA, and AT genotypes. Accordingly, Par designed and implemented a clinical study to determine the effects of the TT, AA, and AT genotypes on the safe and effective use of vasopressin to treat septic shock and post-cardiotomy shock.

33. Par surprisingly found that patients with the AA or AT genotype unexpectedly exhibit lower concentrations of vasopressin in the bloodstream and increased vasopressin clearance, while those with TT genotype exhibit increased vasopressin blood levels and lower vasopressin clearance as compared to the AA or AT genotyped patients. Par further determined that treating patients suffering from septic shock and post-cardiotomy shock with AA or AT genotypes differently than other patients would result in improved survival rates and reduced adverse events. In particular, Par discovered that patents with AA or AT genotypes could and, if

medically warranted under the circumstances, should be treated with a dose of vasopressin that is higher than the currently-labelled maximum dose of VASOSTRICT®.

34. Par has reported results from its clinical study in, *inter alia*, a patent application it filed with the United States Patent and Trademark Office ("PTO") on July 17, 2020—U.S. Patent Application No. 16/932,351. This difference in treatment of patients depending on their genotype is reflected in the following flow-chart included as Figure 1 of that application:

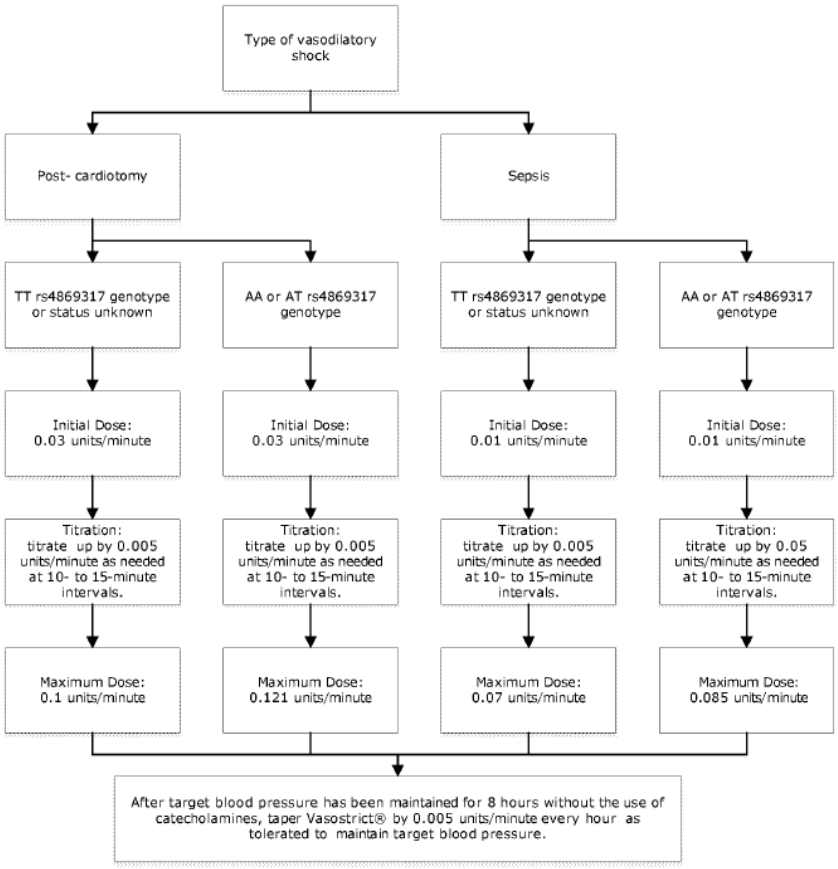



**Figure 1**

35. On November 24, 2020, the PTO granted Par a patent on its new treatment regimen, and duly and legally issued the '435 Patent, entitled "Method to Treat Hypotension Using Vasopressin in Certain Genotypes." A true and correct copy of the '435 Patent is attached

as Exhibit A. Par Pharmaceutical owns the '435 Patent. EPIC is the exclusive licensee of the '435 Patent.

36. On February 16, 2021, the PTO also granted Par a patent on a new treatment regimen for post-cardiotomy shock, and duly and legally issued the '278 Patent, titled "Method to Treat Hypotension Using Vasopressin in Certain Genotypes." A true and correct copy of the '278 Patent is attached as Exhibit B. Par Pharmaceutical owns the '278 Patent. EPIC is the exclusive licensee of the '278 Patent.

37. These innovative treatment regimens represent important medical advances in the way patients suffering from septic shock and post-cardiotomy shock can and should be treated with vasopressin. Upon information and belief, armed with the knowledge obtained from Par's clinical study, medical practitioners have begun to and/or will increasingly alter their use of vasopressin to treat septic shock and post-cardiotomy shock patients based on patient genotypes, and will continue to do so in the future. Indeed, failure to treat patients with AA or AT genotypes in accordance with Par's new treatment regimens could mean that they are treated less effectively with an insufficient amount of vasopressin, thereby creating a risk of an adverse treatment outcome including, in a worst-case scenario, death.

38. Par has filed a request to FDA seeking approval pursuant to 21 CFR § 314.70 for a proposed amendment to the current label for VASOSTRICT®, in order to include new instructions concerning the dosage and administration of VASOSTRICT® in view of the important, newly discovered information concerning the improved methods of administering VASOSTRICT® to patients with AA or AT genotypes. In particular, if approved, VASOSTRICT®'s label would instruct, in relevant part, as follows:

**Patients with AA/AT rs4869317 genotype**

- For post-cardiotomy shock, start with a dose of 0.03 units/minute. For septic shock, start with a dose of 0.01 units/minute. If the target blood pressure response is not achieved, titrate up by 0.005 units/minute at 10- to 15-minute intervals. The maximum dose for post-cardiotomy shock is 0.121 units/minute and for septic shock is 0.085 units/minute. After target blood pressure has been maintained for 8 hours without the use of catecholamines, taper Vasostrict® by 0.005 units/minute every hour as tolerated to maintain target blood pressure.

**Table 3 Dosing recommendation for patients with AA/AT rs4869317 genotype**

| | Post-cardiotomy shock | | | Septic shock | | |
|---|---|---|---|---|---|---|
| AA/AT rs4869317 Genotype | Starting Dose | Titrating Dose | Maximum Dose | Starting Dose | Titrating Dose | Maximum Dose |
| | 0.03 U/min | 0.005 U/min every 10 to 15 min | 0.121 U/min | 0.01 Units/min | 0.005 U/min every 10 to 15 min | 0.085 Units/min |

*See* Exhibit D hereto (true and correct copy of proposed new labeling).

39. In addition to submitting that request, Par has also timely submitted information regarding the Patents in Suit to the FDA for listing in the Orange Book with respect to VASOSTRICT®, pursuant to 21 U.S.C. § 355(b)(1) and (c)(2) upon approval of the label change. Upon information and belief, the FDA will list the Patents in Suit in the Orange Book, pursuant to 21 C.F.R. § 314.53(e).

**Eagle's Infringing Conduct**

40. On or before March 23, 2018, Eagle submitted ANDA No. 211538 (the "Eagle ANDA") pursuant to 35 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, and sale of a proposed generic Vasopressin Injection USP, 20 units/1 mL (20 units/mL) product, referencing Par's VASOSTRICT® products as the reference listed drug (the "Proposed ANDA Product").

41. Eagle's ANDA is still being reviewed by FDA, and Eagle is seeking FDA approval to market its Proposed ANDA Product prior to expiration of the Patents in Suit.

42. In accordance with FDA regulations (discussed in more detail above), if Par's request to update and amend the labeling for VASOSTRICT® is approved by FDA prior to approving Eagle's ANDA, Eagle will be required as a matter of law to amend the proposed labeling for its Proposed ANDA Product to conform to the amendments to the labeling for VASOSTRICT®. This is further reflected, for example, in FDA Guidance to generic manufacturers, which includes the following on the list of common developments that may impact the grant of final approval and require an amendment to the ANDA:

> Labeling Updates
>
> - Changes to labeling to reflect approved changes to the labeling for the RLD
>
> * * * *

*See* Ex. C at 9-11. Eagle will not be permitted to carve the new instructions out of the label by filing a so-called "Section viii statement" pursuant to 21 U.S.C. § 355(j)(2)(A)(viii), because the instructions relate to the safe and effective dosing and administration of the product, not a new indication for or use of the product. 21 CFR § 314.127(a)(7) (FDA will refuse to approve an ANDA with labeling different from the RLD if the differences do not render the proposed drug product less safe or effective than the RLD for the indicated treatments).

43. In that event, the proposed labeling for Eagle's Proposed ANDA Product would include, as part of the instructions regarding the dosage and administration of the product, the same instructions for treating patients with the AA or AT genotypes as is quoted in paragraph 38 above—*i.e.*, that when treating such patients: "For post-cardiotomy shock, start with a dose of 0.03 units/minute. For septic shock, start with a dose of 0.01 units/minute. If the target blood pressure response is not achieved, titrate up by 0.005 units/minute at 10- to 15-minute intervals.

The maximum dose for post-cardiotomy shock is 0.121 units/minute and for septic shock 0.085 units/minute."

44. Upon information and belief, if Eagle were to obtain FDA approval to market and sell its Proposed ANDA Product, it would market and sell it to hospitals and/or group purchasing organizations ("GPOs") and other distributors throughout the United States, including in this District, as a generic substitute for VASOSTRICT® to be used and administered in the same manner as VASOSTRICT®.

45. And, because Eagle's Proposed ANDA Product would not be "AB"-rated to VASOSTRICT®, Eagle cannot rely on its generic product being automatically substituted for VASOSTRICT® by pharmacists. Accordingly, Eagle will instead have to use its sales force to affirmatively market its ANDA Product to hospitals and GPOs and try to convince them to switch from VASOSTRICT® to Eagle's ANDA Product. In doing so, Eagle's sales force will make affirmative representations to its customers that Eagle's ANDA Product is equivalent to VASOSTRICT® and can and should be administered in the same manner as VASOSTRICT®.

46. For the reasons detailed above, upon approval, the proposed labeling for Eagle's Proposed ANDA Product is likely to include specific instructions directing physicians and other medical professionals to use the product to treat patients with AA or AT genotypes in accordance with the methods claimed in the Patents in Suit, thereby inducing direct infringement of the Patents in Suit.

47. Moreover, Eagle will nevertheless induce infringement of the Patents in Suit in ways beyond just the instructions included on the label. Upon FDA approval, Eagle will market and sell its Proposed ANDA Product as a generic substitute for VASOSTRICT® to be used and administered in the same manner as VASOSTRICT®, with the knowledge and expectation that

physicians will treat patients based on the most up-to-date clinical information available—including Par's discovery that in order to improve the treatment of septic shock and post-cardiotomy shock patients with AA or AT genotypes, those patients can and should be treated in accordance with the new treatment regimens claimed in the Patents in Suit.

48. Indeed, it would be irresponsible for Eagle to do otherwise. As described above, vasodilatory shock, including septic shock and post-cardiotomy shock, is a life-threatening condition that need to be treated on an emergent basis. The proper treatment of patients suffering from vasodilatory shock can, quite literally, be a matter of life or death. Failure to treat septic shock or post-cardiotomy shock patients with AA or AT genotypes in accordance with Par's new treatment regimens could result in a sub-optimal treatment of those patients, thereby creating a risk of an adverse treatment outcome including, in a worst-case scenario, death.

49. Par expects that Eagle will act in accordance with the best interests of patients, and that, in doing so, Eagle will market and sell its Proposed ANDA Product (if approved) with explicit or implicit instructions, and the specific intent, that its product be used to treat septic shock and post-cardiotomy shock patients with AA or AT genotypes in accordance with Par's patented treatment regimens.

50. In these ways, Eagle would be inducing infringement of at least claim 1 of the '435 Patent, which recites the following:

> 1. A method of increasing blood pressure to a target blood pressure in a human patient with septic shock wherein the patient has an LNPEP AA or AT rs4869317 genotype, the method comprising: intravenously administering to the patient a pharmaceutical formulation comprising vasopressin at a starting dose of 0.01 units/minute and titrating the dose up by 0.005 units/minute at 10 to 15 minute intervals to maintain the target blood pressure, wherein the maximum dose is 0.085 units/minute.

*See* Ex. A.

51. Eagle would also be inducing infringement of at least claim 1 of the ’278 Patent, which recites the following:

> 1. A method of increasing blood pressure to a target blood pressure in a human patient with post-cardiotomy shock wherein the patient has an LNPEP AA or AT rs4869317 genotype, the method comprising: intravenously administering to the patient a pharmaceutical formulation comprising vasopressin at a starting dose of 0.03 units/minute and titrating the dose up by 0.005 units/minute at 10 to 15 minute intervals to maintain the target blood pressure, wherein the maximum dose is 0.121 units/minute.

*See* Ex. B.

52. And, Eagle would be doing so with full knowledge of the Patents in Suit and the claimed inventions thereof. Eagle was aware that Par had a pending patent application relating to the use and administration of vasopressin, and upon information and belief, has been monitoring the PTO’s website for the issuance of a patent based on that application. Thus, upon information and belief, Eagle has been aware of the Patents in Suit since the day they issued. In any event, at the very latest, Eagle became aware of the ’435 Patent upon the filing of this lawsuit and the ’278 Patent upon the filing of this Amended Complaint.

**COUNT I**
**INFRINGEMENT OF THE ’435 PATENT UNDER 271(e)(2)**

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

54. Section 271(e)(2) of the Patent Act provides in relevant part that: “It shall be an act of infringement to submit – (A) an [ANDA or 505(b)(2) NDA] for a drug claimed in a patent or the use of which is claimed in a patent … .” 35 U.S.C. § 271(e)(2). The ’435 Patent is just such a patent—it claims the use of an FDA-approved drug product (VASOSTRICT®).

55. Accordingly, Eagle’s submission of its ANDA to the FDA, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed ANDA Product prior to the expiration of the ’435 Patent, constitutes infringement of the ’435 Patent under § 271(e)(2).

56. Moreover, for the reasons discussed above, if the FDA were to approve Eagle's ANDA, Eagle's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product would induce physicians and other medical professionals to use and administer Eagle's Proposed ANDA Product in a manner that directly infringes at least Claim 1 of the '435 Patent.

57. Eagle would knowingly, intentionally, and actively induce and encourage that infringement, by virtue of the labeling to be included for the product and Eagle's marketing of the product as described above, including marketing it as a generic substitute for VASOSTRICT® to be used and administered in the same manner as VASOSTRICT®.

58. Any launch by Eagle of its Proposed ANDA Product before expiration of the '435 Patent would cause Par to suffer immediate and irreparable harm.

59. Eagle's inducement of infringement of the '435 Patent would be willful.

**COUNT II**
**DECLARATORY JUDGMENT OF INDUCED INFRINGEMENT OF THE '435 PATENT UNDER 271(b)**

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

61. Section 271(b) of the Patent Act provides that: "Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). As detailed at length herein, if the FDA were to approve Eagle's ANDA, Eagle would actively induce infringement of the '435 Patent by others.

62. In particular, if the FDA were to approve Eagle's ANDA, Eagle's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product would induce physicians and other medical professionals to use and administer Eagle's Proposed ANDA Product in a manner that directly infringes at least Claim 1 of the '435 Patent.

63. Eagle would knowingly, intentionally, and actively induce and encourage that infringement, by virtue of the labeling to be included for the product and Eagle's marketing of the product described above, including marketing it as as a generic substitute for VASOSTRICT® to be used and administered in the same manner as VASOSTRICT®.

64. Eagle would induce that infringement with full knowledge of the '435 Patent, knowing that the conduct it was encouraging would constitute infringement of the '435 Patent.

65. Any launch by Eagle of its Proposed ANDA Product before expiration of the '435 Patent would cause Par to suffer immediate and irreparable harm.

66. Eagle's inducement of infringement of the '435 Patent would be willful.

67. Notwithstanding the fact that Eagle's infringement of the '435 Patent under § 271(b) would be clear, upon and information, Par understands that Eagle would dispute that it is liable for such infringement. Eagle has made public statements indicating that it expects that the FDA will approve its Proposed ANDA Product in the near future, and that it will launch its Proposed ANDA Product without waiting for any patent disputes to be resolved.

68. Accordingly, there is a definite and concrete controversy between Par and Eagle as to whether Eagle's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product would infringe the '435 Patent. Par is entitled to a declaratory judgment that it would.

**COUNT III**
**INFRINGEMENT OF THE '278 PATENT UNDER 271(e)(2)**

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

70. Section 271(e)(2) of the Patent Act provides in relevant part that: "It shall be an act of infringement to submit – (A) an [ANDA or 505(b)(2) NDA] for a drug claimed in a patent

or the use of which is claimed in a patent … .” 35 U.S.C. § 271(e)(2). The ’278 Patent is just such a patent—it claims the use of an FDA-approved drug product (VASOSTRICT®).

71. Accordingly, Eagle’s submission of its ANDA to the FDA, which seeks approval to engage in the commercial manufacture, use, and sale of its Proposed ANDA Product prior to the expiration of the ’278 Patent, constitutes infringement of the ’278 Patent under § 271(e)(2).

72. Moreover, for the reasons discussed above, if the FDA were to approve Eagle’s ANDA, Eagle’s commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product would induce physicians and other medical professionals to use and administer Eagle’s Proposed ANDA Product in a manner that directly infringes at least Claim 1 of the ’278 Patent.

73. Eagle would knowingly, intentionally, and actively induce and encourage that infringement, by virtue of the labeling to be included for the product and Eagle’s marketing of the product described above, including marketing it as as a generic substitute for VASOSTRICT® to be used and administered in the same manner as VASOSTRICT®.

74. Any launch by Eagle of its Proposed ANDA Product before expiration of the ’278 Patent would cause Par to suffer immediate and irreparable harm.

75. Eagle’s inducement of infringement of the ’278 Patent would be willful.

**COUNT IV**
**DECLARATORY JUDGMENT OF INDUCED INFRINGEMENT OF THE ’278 PATENT UNDER 271(b)**

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

77. Section 271(b) of the Patent Act provides that: “Whoever actively induces infringement of a patent shall be liable as an infringer.” 35 U.S.C. § 271(b). As detailed at length herein, if the FDA were to approve Eagle’s ANDA, Eagle would actively induce infringement of the ’278 Patent by others.

78. In particular, if the FDA were to approve Eagle's ANDA, Eagle's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product would induce physicians and other medical professionals to use and administer Eagle's Proposed ANDA Product in a manner that directly infringes at least Claim 1 of the '278 Patent.

79. Eagle would knowingly, intentionally, and actively induce and encourage that infringement, by virtue of the labeling to be included for the product and Eagle's marketing of the product described above, including marketing it as as a generic substitute for VASOSTRICT® to be used and administered in the same manner as VASOSTRICT®.

80. Eagle would induce that infringement with full knowledge of the '278 Patent, knowing that the conduct it was encouraging would constitute infringement of the '278 Patent.

81. Any launch by Eagle of its Proposed ANDA Product before expiration of the '278 Patent would cause Par to suffer immediate and irreparable harm.

82. Eagle's inducement of infringement of the '278 Patent would be willful.

83. Notwithstanding the fact that Eagle's infringement of the '278 Patent under § 271(b) would be clear, upon and information, Par understands that Eagle would dispute that it is liable for such infringement. Eagle has made public statements indicating that it expects that the FDA will approve its Proposed ANDA Product in the near future, and that it will launch its Proposed ANDA Product without waiting for any patent disputes to be resolved.

84. Accordingly, there is a definite and concrete controversy between Par and Eagle as to whether Eagle's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the Proposed ANDA Product would infringe the '278 Patent. Par is entitled to a declaratory judgment that it would.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Eagle has infringed the '435 Patent pursuant to 35 U.S.C. § 271(e) and that Eagle's commercial manufacture, distribution, use, and sale of its Proposed ANDA Product would induce infringement of the '435 Patent pursuant to 35 U.S.C. § 271(b);

B. A judgment that Eagle has infringed the '278 Patent pursuant to 35 U.S.C. § 271(e) and that Eagle's commercial manufacture, distribution, use, and sale of its Proposed ANDA Product would induce infringement of the '278 Patent pursuant to 35 U.S.C. § 271(b);

C. 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 expiration date of the Patents in Suit, including any extensions;

D. 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 persons in active concert or participation with any of them, from infringement of the Patents in Suit for the full terms thereof, including any extensions;

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

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

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

Dated: March 22, 2021

/s/ *Robert D. Rhoad*

Robert D. Rhoad
DECHERT LLP
502 Carnegie Center, Suite #104
Princeton, NJ 08540
Tel: (609)-955-3200
robert.rhoad@dechert.com

Martin J. Black
Sharon K. Gagliardi
Brian M. Goldberg
Luke M. Reilly
Daniel R. Roberts
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
luke.reilly@dechert.com
daniel.roberts@dechert.com

Jonathan D.J. Loeb, Ph.D
DECHERT LLP
2440 W. El Camino Real
Suite 700
Mountain View, CA 94040
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

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