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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 Plaintiffs, v. DR. REDDY'S LABORATORIES, INC., and DR. REDDY'S LABORATORIES, LTD. Defendants.	Civil Action No. _____

COMPLAINT

Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively "Par"), for their complaint against Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "DRL"), 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 Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the law of New Jersey, having its principal place of business 107 College Road East, Princeton, New Jersey 08540. Dr. Reddy's Laboratories, Inc. is a pharmaceutical company engaged in the research, development, production, distribution, and sale of generic pharmaceuticals throughout the United States, including sales within this judicial district

5. Upon information and belief, Defendant Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the law of India, having its corporate offices and principal place of business at 8-2-377, Road No. 3, Banjara Hills, Hyderabad, Andhra Pradesh 50034, India. Dr. Reddy's Laboratories, Ltd. is a pharmaceutical company engaged in the research, development, production, distribution, and sale of generic pharmaceuticals throughout the United States, including sales within this judicial district.

NATURE OF ACTION

6. This is an action for infringement of United States Patent No. 10,844,435 (the '435 Patent" or "the Patent in Suit"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*

7. Par 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 DRL's marketing and sale of its Proposed ANDA Product (as detailed below), if approved, would induce infringement of the '435 Patent.

JURISDICTION AND VENUE

8. 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).

9. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) because, *inter alia*, Dr. Reddy's Laboratories, Inc. resides in New Jersey, and Dr. Reddy's Laboratories, Ltd. is not resident in the United States, such that pursuant to 28 U.S.C. § 1391(c)(3), venue as to it is proper in any judicial district, including this judicial district.

10. This Court has personal jurisdiction over Defendants because, *inter alia*, they have committed and will commit acts of infringement in this judicial district, have purposely availed themselves of the benefits and protections of the laws in New Jersey, and have continuous and systematic contacts with this judicial district, including by acting in partnership and agency with each other, including conducting business in New Jersey and marketing, selling and distributing pharmaceutical products throughout the United States and in this judicial district. In addition, Dr. Reddy's Laboratories, Inc. resides in and has its principal place of business in this judicial district.

FACTUAL BACKGROUND

The Drug Approval Process

11. 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).

12. 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").

13. 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.

14. 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)).

15. 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."

16. 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.

17. 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®

18. 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.

19. 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®.

20. 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.

21. 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 Patent-in-Suit

22. 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.

23. 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.

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

25. 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] VASOSTRICT® is one of the medications commonly used to

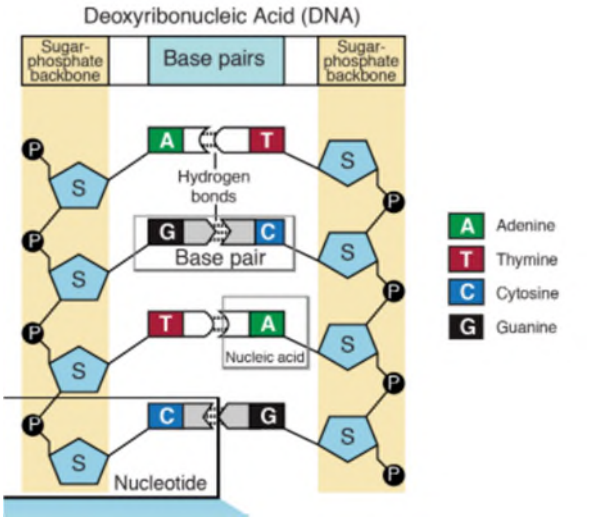
[1] *See, e.g.*, Russell et al, "*Vasopressin versus Norepinephrine infusion in patients with septic shock*," N. Engl. J. Med. 358 (9):877-887 (2008).

treat septic 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.

26. 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 shock receive an amount of vasopressin sufficient to quickly and effectively raise their blood pressure, and administering too much vasopressin.

27. 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.

28. 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.



29. 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".

30. 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.

31. 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. 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 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®.

32. 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:

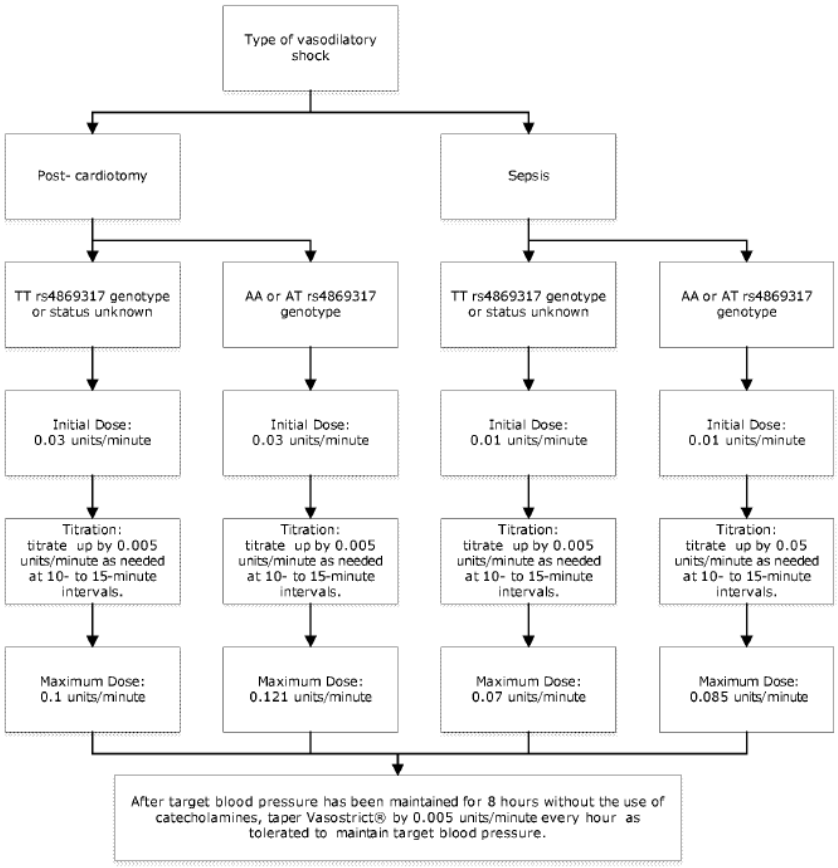


Figure 1

33. 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.

34. This innovative treatment regimen represents an important medical advance in the way patients suffering from septic 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 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 regimen 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.

35. Par has submitted 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 method 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 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 B hereto (true and correct copy of proposed new labeling).

36. In addition to submitting that request, Par has also timely submitted information regarding the '435 Patent 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 information and belief, the FDA has listed, or shortly will list, the '435 Patent in the Orange Book, pursuant to 21 C.F.R. § 314.53(e).

DRL's Infringing Conduct

37. On or before March 4, 2020, DRL submitted ANDA No. 213988 (the "DRL 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").

38. DRL's ANDA is still being reviewed by FDA, and DRL is seeking FDA approval to market its Proposed ANDA Product prior to expiration of the '435 Patent.

39. 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 DRL's ANDA, DRL 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.

40. In that event, the proposed labeling for DRL'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 35 above—*i.e.*, that when treating such patients: ". . . 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 septic shock [is] 0.085 units/minute."

41. Upon information and belief, if DRL 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 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®.

42. For the reasons detailed above, upon approval, the proposed labeling for DRL'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 '435 Patent, thereby inducing direct infringement of the '435 Patent.

43. Even if the FDA were to approve DRL's ANDA without those instructions included in the labeling for the Proposed ANDA Product, DRL will nevertheless still induce infringement of the '435 Patent. Upon FDA approval, DRL 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 patients with AA or AT genotypes, those patients can and should be treated in accordance with the new treatment regimen claimed in the '435 Patent.

44. Indeed, it would irresponsible for DRL to do otherwise. As described above, septic shock is a life-threatening condition that needs to be treated on an emergent basis. The proper treatment of septic shock patients can, quite literally, be a matter of life or death. Failure to treat septic shock patients with AA or AT genotypes in accordance with Par's new treatment regimen 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.

45. Par expects that DRL will act in accordance with the best interests of patients, and that in doing so, DRL 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 patients with AA or AT genotypes in accordance with Par's new treatment regimen.

46. In these ways, DRL 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.

47. And, DRL would be doing so with full knowledge of the '435 Patent and the claimed inventions thereof. Upon information and belief, DRL has been monitoring the PTO's website for the issuance of any patents obtained by Par relating to vasopressin. Thus, upon

information and belief, DRL has been aware of the '435 Patent since the day it issued. In any event, at the very latest, DRL became aware of the '435 Patent upon the filing of this lawsuit.

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

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

49. 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®).

50. Accordingly, DRL'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).

51. Moreover, for the reasons discussed above, if the FDA were to approve DRL's ANDA, DRL'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 DRL's Proposed ANDA Product in a manner that directly infringes at least Claim 1 of the '435 Patent.

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

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

54. DRL'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)

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

56. 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 DRL's ANDA, DRL would actively induce infringement of the '435 Patent by others.

57. In particular, if the FDA were to approve DRL's ANDA, DRL'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 DRL's proposed ANDA product in a manner that directly infringes at least Claim 1 of the '435 Patent.

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

59. DRL 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.

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

61. DRL's inducement of infringement of the '435 Patent would be willful.

62. Notwithstanding the fact that DRL's infringement of the '435 Patent under § 271(b) would be clear, upon information and belief, Par understands that DRL would dispute that it is liable for such infringement.

63. Accordingly, there is a definite and concrete controversy between Par and DRL as to whether DRL'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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that DRL has infringed the '435 patent pursuant to 35 U.S.C. § 271(e) and that DRL'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. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of DRL's ANDA No. 213988 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 '435 Patent, including any extensions;

C. A permanent injunction, pursuant to 35 U.S.C. §271(e)(4)(B) and 35 U.S.C. § 283, restraining and enjoining DRL, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringement of '435 Patent for the full term thereof, including any extensions;

D. An order that damages or other monetary relief be awarded to Plaintiffs if DRL engages in the commercial manufacture, use, offer to sale, sale, distribution, or importation of DRL's Proposed ANDA Product, or induces such conduct by others, prior to the expiration of the '435 Patent, and any additional period 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;

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

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

Dated: December 7, 2020

/s/ *Robert D. Rhoad*

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

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned attorney for Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC certifies that to the best of his knowledge, the matter in controversy is not the subject of another action pending in any court or of any pending arbitration or administrative proceeding. Plaintiffs do note, however, that this matter is related to actions that Par is filing in this District contemporaneously herewith against other ANDA filers alleging infringement of the '435 Patent. Those actions have not been assigned a civil action number yet, but are encaptioned: *Par Pharmaceutical, Inc. et al v. Amneal EU, Ltd. et al*; *Par Pharmaceutical, Inc. et al v. Aurobindo Pharma U.S.A., Inc.*; *Par Pharmaceutical, Inc. et al v. Eagle Pharmaceuticals, Inc.* Par further notes that there is another action in this District involving related drug products, but a different patent (encaptioned *Par Pharmaceutical, Inc. et al v. QuVa Pharma, Inc. et al*, CA No. 3:17-06115-BRM-DEA (D.N.J.)).

Dated: December 7, 2020

Respectfully submitted,

/ / *Robert D. Rhoad*
Robert D. Rhoad