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,	)	C.A. No. _____
v.	)	
LONG GROVE PHARMACEUTICALS, LLC,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC and Endo Par Innovation Company, LLC (collectively "Plaintiffs"), by and through their undersigned counsel, hereby allege against Defendant Long Grove Pharmaceuticals, LLC ("Long Grove") as follows:

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 9,993,520 ("the '520 patent") and 11,207,372 ("the '372 patent") (collectively "the Patents-in-Suit"), arising under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 21 U.S.C. § 2201, *et seq.*

THE PARTIES

2. Plaintiff Par Pharmaceutical, Inc. ("Par Pharmaceutical") is a corporation organized and existing under the laws of the state of New York, having its principal place of business at 300 Tice Boulevard, Suite 230, Woodcliff Lake, NJ 07677. Par Pharmaceutical develops, manufactures, and markets pharmaceutical products in the United States.

3. Plaintiff Par Sterile Products, LLC ("Par Sterile Products") is a limited liability company organized and existing under the laws of the state of Delaware, having its principal place of business at 300 Tice Boulevard, Suite 230, Woodcliff Lake, NJ 07677. Par Sterile Products develops, manufactures, and markets injectable pharmaceutical products, and provides manufacturing services to the biopharmaceutical and pharmaceutical industry.

4. Plaintiff Endo Par Innovation Company, LLC ("EPIC") is a limited liability company organized and existing under the laws of the state of Delaware, having its principal place of business at 300 Tice Boulevard, Suite 230, Woodcliff Lake, NJ 07677.

5. Upon information and belief, Defendant Long Grove Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the state of Delaware, having a registered agent located at Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware, 19801, and a principal place of business at 9450 W. Bryn Mawr Ave., Rosemont, IL 60018.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, at least because this action arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*.

7. This Court has personal jurisdiction over Long Grove because Long Grove is incorporated in the state of Delaware.

8. This Court has personal jurisdiction over Long Grove because, *inter alia*, Long Grove has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs. For example, on information and belief, following approval of Long Grove's New Drug Application ("NDA") No. 217766 ("the Long

Grove NDA") by the U.S. Food and Drug Administration ("FDA"), Long Grove will commercially manufacture, use, offer for sale, sell, and/or import Vasopressin Injection, 0.2 Unit/mL, 0.4 Unit/mL, 1.0 Unit/mL ("Long Grove's NDA Products") before the expiration of the Patents-in-Suit.

9. This Court also has jurisdiction over Long Grove because, *inter alia*, this action arises from actions of Long Grove directed toward Delaware, and because Long Grove has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Long Grove regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware either directly or indirectly through affiliated companies. Upon information and belief, Long Grove derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

10. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

11. Venue is proper in this Court as to Long Grove under 28 U.S.C. §§ 1391(c)-(d) and 1400(b), because, *inter alia*, Long Grove is a Delaware limited liability company, maintains a registered agent in Delaware, and has committed and will commit further acts of infringement in the State of Delaware.

FACTUAL BACKGROUND

The Patents-in-Suit

12. The '520 patent, entitled "Vasopressin Formulations for Use in Treatment of Hypotension," was issued by the United States Patent and Trademark Office ("the USPTO") on June 12, 2018. A copy of the '520 patent is attached as Exhibit A.

13. The ’520 patent names Matthew Kenney, Vinayagam Kannan, Sunil Vandse, and Suketu Sanghvi as inventors.

14. Par Pharmaceutical is the assignee of the ’520 patent. EPIC is the exclusive licensee of the ’520 patent.

15. The ’372 patent, entitled “Vasopressin Formulations for Use in Treatment of Hypotension,” was issued by the USPTO on December 28, 2021. A copy of the ’372 patent is attached as Exhibit B.

16. The ’372 patent names Matthew Kenney, Vinayagam Kannan, Sunil Vandse, and Suketu Sanghvi as inventors.

17. Par Pharmaceutical is the assignee of the ’372 patent. EPIC is the exclusive licensee of the ’372 patent.

VASOSTRICT®

18. 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.

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

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

21. Par Sterile Products is the holder of NDA No. 204485, including all supplements thereto, for VASOSTRICT®.

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

23. According to the FDA-approved prescribing information, VASOSTRICT® is indicated "to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines." Par markets and sells its VASOSTRICT® products to hospitals, both directly and via group purchasing organizations and wholesalers.

Acts Giving Rise To This Suit

24. Upon information and belief, Long Grove submitted NDA No. 217766 to the FDA pursuant to 21 U.S.C. § 355(b)(2), seeking approval to engage in the commercial manufacture, use, offer to sell, sale, and/or importation of Long Grove's NDA Products.

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

26. Upon information and belief, Long Grove's NDA Products will be marketed as competing products to VASOSTRICT®.

27. Upon information and belief, in connection with the filing of its NDA as described above, Long Grove provided a written certification to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(b)(2)(A)(iv) ("Long Grove's Paragraph IV Certification"), alleging that the claims of United States Patent Nos. 9,919,026 ("the '026 patent"), 9,925,233 ("the '233 patent"), 9,925,234 ("the '234 patent"), 9,962,422 ("the '422 patent"), 9,968,649 ("the '649

patent"), 9,974,827 ("the '827 patent"), 9,981,006 ("the '006 patent"), and 10,010,575 ("the '575 patent") are invalid, unenforceable, and/or will not be infringed by the activities described in Long Grove's NDA.

28. No earlier than September 22, 2023, Long Grove sent written notice of its Paragraph IV Certification to Plaintiffs ("Long Grove's Notice Letter"). Long Grove's Notice Letter alleged that the claims of the '026, '233, '234, '422, '649, '827, '006, and '575 patents are invalid, unenforceable, and/or will not be infringed by Long Grove's NDA Products. Long Grove's Notice Letter also informed Plaintiffs that Long Grove seeks approval to market Long Grove's NDA Products before these patents are scheduled to expire on January 30, 2035.

29. The Patents-in-Suit are in the same patent family as '026, '233, '234, '422, '649, '827, '006, and '575 patents that were the subject of Long Grove's Paragraph IV Certification and are also scheduled to expire on January 30, 2035.

30. During settlement discussions between Plaintiffs and Long Grove, Plaintiffs informed Long Grove of the Patents-in-Suit. Long Grove also has knowledge of the Patents-in-Suit based upon the filing of this Complaint.

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

COUNT I
(Infringement of the '520 Patent)

32. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

33. Long Grove, by submission of its Paragraph IV Certification as part of its NDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale,

offer for sale, or importation in the United States of Long Grove's NDA Products, prior to the expiration of the '520 patent on January 30, 2035.

34. Long Grove's NDA has been pending before the FDA since at least September 22, 2023, the date that Long Grove sent the Long Grove Notice Letter to Plaintiffs.

35. The submission of the Long Grove NDA to the FDA, which seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Long Grove's NDA Products before the expiration of the '520 patent, constitutes infringement by Long Grove of one or more claims of the '520 patent under 35 U.S.C. § 271(e)(2)(A).

36. Unless enjoined by this Court, upon FDA approval of Long Grove's NDA, Long Grove will infringe one or more claims of the '520 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Long Grove's NDA Products in the United States. On information and belief, upon FDA approval of Long Grove's NDA, Long Grove will intentionally encourage acts of direct infringement with knowledge of the '520 patent and knowledge that its acts are encouraging infringement.

37. Unless enjoined by this Court, upon FDA approval of Long Grove's NDA, Long Grove will contributorily infringe one or more claims of the '520 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Long Grove's NDA Products in the United States. On information and belief, Long Grove has had and continues to have knowledge that Long Grove's NDA Products are especially adapted for a use that infringes one or more claims of the '520 patent and that there is no substantial non-infringing use for Long Grove's NDA Products.

38. Claim 1 of the '520 patent reads as follows:

> 1. A method of increasing blood pressure in a human in need thereof, the method comprising:
> a) providing a unit dosage form for intravenous administration, wherein the unit dosage form comprises:
> i) from about 0.1 units/mL to about 1 unit/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
> ii) from about 1 mM to about 10 mM acetate buffer;
> iii) 0-2% vasopressin degradation products;
> iv) sodium chloride; and
> v) water; and
> b) storing the unit dosage form for at least about 24 hours at from about 0.1 units/ml to about 1 unit/ml of vasopressin or a pharmaceutically-acceptable salt thereof; and
> c) after the storing, administering the unit dosage form to the human by intravenous administration, wherein the unit dosage form that is administered to the human comprises from about 0.1 units/mL to about 1 unit/mL of vasopressin or the pharmaceutically-acceptable salt thereof; wherein:
> the unit dosage form has a pH of 3.4 to 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.

39. Long Grove's NDA Products satisfy each and every element of at least claim 1 of the '520 patent, either literally or under the doctrine of equivalents, such that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States by Long Grove of Long Grove's NDA Products would infringe at least claim 1 of the '520 patent.

40. Plaintiffs will be substantially and irreparably damaged and harmed if Long Grove's infringement of the '520 patent is not enjoined.

41. Plaintiffs do not have an adequate remedy at law.

42. Long Grove's infringement of the '520 patent would be willful, wanton, and deliberate.

43. There is a justiciable controversy between the parties as to the infringement of the '520 patent.

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COUNT II
(Infringement of the '372 Patent)

44. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

45. Long Grove, by submission of its Paragraph IV Certification as part of its NDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation in the United States of Long Grove's NDA Products, prior to the expiration of the '372 patent on January 30, 2035.

46. Long Grove's NDA has been pending before the FDA since at least September 22, 2023, the date that Long Grove sent the Long Grove Notice Letter to Plaintiffs.

47. The submission of the Long Grove NDA to the FDA, which seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Long Grove's NDA Products before the expiration of the '372 patent, constitutes infringement by Long Grove of one or more claims of the '372 patent under 35 U.S.C. § 271(e)(2)(A).

48. Unless enjoined by this Court, upon FDA approval of Long Grove's NDA, Long Grove will infringe one or more claims of the '372 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Long Grove's NDA Products in the United States. On information and belief, upon FDA approval of Long Grove's NDA, Long Grove will intentionally encourage acts of direct infringement with knowledge of the '372 patent and knowledge that its acts are encouraging infringement.

49. Unless enjoined by this Court, upon FDA approval of Long Grove's NDA, Long Grove will contributorily infringe one or more claims of the '372 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Long Grove's NDA Products in the United States. On information and belief, Long Grove has had and continues to have knowledge

that Long Grove's NDA Products are especially adapted for a use that infringes one or more claims of the '372 patent and that there is no substantial non-infringing use for Long Grove's NDA Products.

50. Claim 1 of the '372 patent reads as follows:

> 1. A method of increasing blood pressure in a human in need thereof, the method comprising providing a unit dosage form, wherein the unit dosage form consists essentially of:
>
> a) from about 0.1 units/mL to about 1 unit/mL of vasopressin or a pharmaceutically-acceptable salt thereof;
> b) a pH-adjusting agent;
> c) an acetate buffer;
> d) about 0.9% NaCl; and
> e) water;
>
> wherein the unit dosage form has a pH of from about 3.5 to about 3.7, storing the unit dosage form for at least about 24 hours at from about 0.1 units/mL to about 1 unit/mL vasopressin or the pharmaceutically-acceptable salt thereof;
> after the storing, intravenously administering the unit dosage form to the human;
> wherein the unit dosage form that is administered to the human comprises from about 0.1 units/mL to about 1 unit/mL of vasopressin or the pharmaceutically-acceptable salt thereof.

51. Long Grove's NDA Products satisfy each and every element of at least claim 1 of the '372 patent, either literally or under the doctrine of equivalents, such that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States by Long Grove of Long Grove's NDA Products would infringe at least claim 1 of the '372 patent.

52. Plaintiffs will be substantially and irreparably damaged and harmed if Long Grove's infringement of the '372 patent is not enjoined.

53. Plaintiffs do not have an adequate remedy at law.

54. Long Grove's infringement of the '372 patent would be willful, wanton, and deliberate.

55. There is a justiciable controversy between the parties as to the infringement of the '372 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Long Grove has infringed the '520 patent under 35 U.S.C. § 271(e)(2)(A) by submitting or causing to be submitted to the FDA NDA No. 217766, and a declaration that Long Grove will directly infringe, contributorily infringe, and/or induce infringement of one or more claims of the '520 patent under 35 U.S.C. §§ 271(b) and/or (c) if Long Grove commercially manufactures, uses, offers for sale, sells, and/or imports into the United States its NDA Products before the expiration of the '520 patent;

B. A judgment that Long Grove has infringed the '372 patent under 35 U.S.C. § 271(e)(2)(A) by submitting or causing to be submitted to the FDA NDA No. 217766, and a declaration that Long Grove will directly infringe, contributorily infringe, and/or induce infringement of one or more claims of the '372 patent under 35 U.S.C. §§ 271(b) and/or (c) if Long Grove commercially manufactures, uses, offers for sale, sells, and/or imports into the United States its NDA Products before the expiration of the '372 patent;

C. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval by the FDA of Long Grove's NDA No. 217766 be a date that is not earlier than the last expiration date of the Patents-in-Suit, including any extensions;

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

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

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

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

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

H. Costs and expenses incurred by Plaintiffs in this actions; and

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

Dated: December 8, 2023

Respectfully submitted,

/s/ Kaan Ekiner

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