UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

ENDO PAR INNOVATION COMPANY, LLC; PAR PHARMACEUTICAL, INC.; and PAR STERILE PRODUCTS, LLC, *Plaintiffs*, v. BPI LABS, LLC and BELCHER PHARMACEUTICALS, LLC, *Defendants*.	Case No. PERMANENT INJUNCTIVE AND DECLARATORY RELIEF REQUESTED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Endo Par Innovation Company, LLC ("EPIC"), Par Pharmaceutical, Inc. ("Par Pharmaceutical"), and Par Sterile Products, LLC ("Par Sterile") (collectively, "Plaintiffs"), for their Complaint against Defendants BPI Labs, LLC ("BPI Labs") and Belcher Pharmaceuticals, LLC ("Belcher") (collectively, "Defendants"), allege as follows:

NATURE AND SUMMARY OF THIS ACTION

1. This is an action for patent infringement of Plaintiffs' U.S. Patent Nos. 9,119,876 ("the '876 patent") and 9,295,657 ("the '657 patent") (collectively, "the Patents-in-Suit) pursuant to the Patent Laws of the United States, 35 U.S.C. § 1, *et seq*.

THE PARTIES

2. Par Pharmaceutical is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 300 Tice Blvd, Suite 230, Woodcliff Lake, New Jersey 07677.

3. Par Sterile is a limited liability company organized and existing under the laws of Delaware, having a place of business at 300 Tice Boulevard, Suite 230, Woodcliff Lake, New Jersey 07677.

4. EPIC is a limited liability company organized and existing under the laws of Delaware, having a place of business at 300 Tice Boulevard, Suite 230, Woodcliff Lake, New Jersey 07677.

5. On information and belief, BPI Labs is a corporation organized and existing under the laws of Florida, having a principal place of business at 12393 South Belcher Road, Suite 450, Largo, FL 33773. On information and belief, BPI Labs is in the business of developing, manufacturing, marketing and/or distributing generic injectable medications throughout the United States, including in this Judicial District.

6. On information and belief, Belcher is a corporation organized and existing under the laws of Florida, having a principal place of business at 6911 Bryan Dairy Road, Suite 210, Largo, FL 33777. On information and belief, Belcher is in the business of developing, manufacturing, marketing and/or distributing generic pharmaceuticals throughout the United States, including in this Judicial District.

7. On information and belief, BPI Labs is a wholly-owned subsidiary of Belcher Pharmaceuticals.

8. On information and belief, Belcher is an alter ego of BPI. On information and belief, Belcher and BPI share managers and officers. On information and belief, Belcher and BPI Labs share headquarters at 6911 Bryan Dairy Road, Suite 210, Largo, Florida 33777. On information and belief, Belcher is the managing member of BPI.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Defendants at least because BPI Labs and Belcher have a place of business at 12393 Belcher Rd S., Largo, FL 33773 and 6911 Bryan Dairy Road, Suite 210, Largo, FL 33777, respectively.

11. This Court has personal jurisdiction over Defendants at least because Defendants have continuous and systematic contacts within this Judicial District. On information and belief, Defendants develop, manufacture, seek approval for, and sell certain FDA-approved pharmaceutical products that are regularly marketed and sold in this Judicial District.

12. This Court has personal jurisdiction over Defendants at least because one or more Defendants consented to jurisdiction in this Judicial District by letter dated August 9, 2023, from Supriya Taneja, Esq., General Counsel, BPI Labs and

Vice President, Belcher to Gina Gencarelli, Esq., Executive Director, Intellectual Property for Plaintiffs.

13. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b). On information and belief, Defendants each have a regular and established place of business in this Judicial District. Venue is also proper in this Judicial District because one or more Defendants consented to venue in this Judicial District by letter dated August 9, 2023, from Supriya Taneja, Esq., General Counsel, BPI Labs and Vice President, Belcher to Gina Gencarelli, Esq., Executive Director, Intellectual Property for Plaintiffs.

THE PATENTS-IN-SUIT

14. The '876 patent, titled "Epinephrine Formulations," was duly and legally issued by the United States Patent and Trademark Office on September 1, 2015, to Par Pharmaceutical as assignee. A true and correct copy of the '876 patent is attached as Exhibit A.

15. The '657 patent, titled "Epinephrine Formulations," was duly and legally issued by the United States Patent and Trademark Office on March 29, 2016, to Par Pharmaceutical as assignee. A true and correct copy of the '657 patent is attached as Exhibit B.

16. EPIC is the exclusive licensee of the Patents-in-Suit.

PLAINTIFFS' ADRENALIN® PRODUCT

17. Par Sterile is the holder of New Drug Application ("NDA") No. 204200 for epinephrine injection, Eq 1mg base/mL injectable solution ("Plaintiffs' 1 mL

Adrenalin® Product"), which the U.S. Food and Drug Administration ("FDA") approved on December 7, 2012.

18. Par Sterile is also the holder of New Drug Application ("NDA") No. 204640 for epinephrine injection, Eq 30 mg base/30 mL injectable solution (Eq 1 mg base/mL) ("Plaintiffs' 30 mL Adrenalin® Product," and, together with Plaintiffs' 1 mL Adrenalin® Product, "Adrenalin®"), which the U.S. Food and Drug Administration ("FDA") approved on December 18, 2013.

19. Adrenalin® was the first FDA-approved epinephrine injection product for use in a clinical setting available in the United States. Adrenalin® is a clear, colorless, sterile parenteral solution containing the active ingredient L-epinephrine and is intended for intramuscular or subcutaneous administration. Adrenalin® is indicated for emergency treatment of allergic reactions (Type 1), including anaphylaxis, and to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock.

20. The chemical compound epinephrine is a well-known drug that has been in clinical use for over 100 years to treat allergic reactions and anaphylaxis. Anaphylaxis is a serious and life-threatening condition that can lead to death in minutes if not recognized and adequately treated. Epinephrine solution in vials for injection had been marketed as a drug product without FDA approval.

21. In March 2012, Par Sterile's predecessor, JHP Pharmaceuticals ("JHP"), sought FDA approval for the epinephrine formulation it had marketed for over 100 years. Throughout its review of JHP's NDA No. 204200, FDA expressed

concerns regarding the potency of the active ingredient in the product, L-epinephrine, in connection with the levels of certain impurities found therein. Epinephrine can potentially degrade through a variety of routes, and can react with other ingredients to form epinephrine sulfonic acid (ESA), or can racemize in aqueous solution to form D-epinephrine, both of which cause a decrease in the effective concentration of the active ingredient L-epinephrine and therefore decrease potency of the product.

22. Because of these concerns, FDA required JHP to meet strict purity requirements for Adrenalin®. In communications with JHP, FDA expressed that impurities reduced the potency of the product, which could be pharmaceutically unacceptable to patients suffering from emergency anaphylaxis who need potent medication in a short time. FDA ultimately required JHP to evaluate formulation and process improvements to reduce the levels of impurities and ensure adequate potency and stability of Adrenalin®.

23. Par Sterile undertook substantial efforts in response to FDA's requirement. Par Sterile committed both to investigate the cause of impurity formation and to take necessary measures to lower the limits for certain impurities. Par Sterile undertook a significant initiative to develop a new epinephrine formulation that could meet FDA's requirement to minimize the levels of impurities to address the issue of loss of potency.

24. Par Sterile developed new formulations with significantly lower levels of impurities. For example, Par Sterile developed compositions comprising

epinephrine, tonicity regulating agent, pH raising agent, antioxidant comprising sodium bisulfite and/or sodium metabisulfite, pH lowering agent, and transition metal complexing agent, in certain ranges. Par Sterile balanced the compositions' properties, including isotonicity, pH, and stability, in light of using sodium bisulfite and/or sodium metabisulfite as an antioxidant. This reduced the formation of D-epinephrine and ESA without compromising pharmaceutical benefits. Thus, Par Sterile maintained the racemic balance of the active ingredient, resulting in lower impurity levels and thus improved potency. The lower impurity levels and improved potency also allowed Par Sterile to extend the shelf life of its compositions.

25. After its successful reformulation effort, Par Sterile submitted supplemental NDAs to FDA for approval of a new formulation to provide a more stable Adrenalin® product in March 2015 (for Plaintiffs' 30 mL Adrenalin® Product) and January 2016 (for Plaintiffs' 1 mL Adrenalin® Product). FDA approved the supplemental NDAs for the new formulation in January 2016 (for Plaintiffs' 30 mL Adrenalin® Product) and September 2016 (for Plaintiffs' 1 mL Adrenalin® Product).

26. Based on the significant research and development it had conducted in the course of reformulating and improving its Adrenalin® product, Par Pharmaceutical obtained several patents, including the Patents-in-Suit.

27. The '876 patent covers the technological advance Par Sterile achieved in its reformulation work. For example, the claims of the '876 patent are directed to compositions comprising epinephrine, tonicity regulating agent, pH raising agent,

antioxidant comprising sodium bisulfite and/or sodium metabisulfite, pH lowering agent, and transition metal complexing agent, in certain ranges. The new Adrenalin® formulation is a composition that falls within the claims of the '876 patent.

28. The '657 patent covers methods of using the inventive formulations to treat Type 1 allergic reactions, including anaphylaxis. For example, the claims of the '657 patent are directed to methods of treating certain conditions, including Type 1 allergic reactions and anaphylaxis, by administering to a patient in need a composition comprising epinephrine, tonicity regulating agent, pH raising agent, antioxidant comprising sodium bisulfite and/or sodium metabisulfite, pH lowering agent, and transition metal complexing agent, in certain ranges. The new Adrenalin® formulation, which is a composition that falls within the claims of the '657 patent, is used to treat Type 1 allergic reactions and anaphylaxis, as claimed in the '657 patent.

29. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the Patents-in-Suit are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") with respect to Adrenalin® brand epinephrine injection.

DEFENDANTS' NDA

30. According to FDA's electronic database, BPI Labs is the holder of New Drug Application ("NDA") No. 205029 for epinephrine injection, 1 mg/mL, which was approved on July 29, 2014.

31. On information and belief, BPI Labs submitted to FDA a supplement to NDA No. 205029, under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a 30 mg/30 mL vial presentation of Epinephrine Injection, USP, 1 mg/mL ("Defendants' Proposed Product"), prior to the expiration of the '876 and '657 Patents.

32. By letter dated July 17, 2023 (the "First Notice Letter"), BPI Labs sent to Plaintiffs a correspondence stating that it had submitted a supplement to NDA No. 205029 for Defendants' Proposed Product.

33. The First Notice Letter failed to meet several notice-of-certification requirements of 21 U.S.C. § 355(b)(3)(D) and 21 C.F.R. § 314.52. For example, the First Notice Letter misquoted certain patent claim limitations and failed to provide, for each claim of the '876 and '657 patents, a full and detailed explanation of why the claim is not infringed or is invalid or unenforceable. The First Notice Letter also did not include an offer of confidential access to NDA No. 205029 pursuant to 21 U.S.C. § 355(c)(3)(D)(III) and 21 C.F.R. § 314.52. Plaintiffs notified Defendants of these deficiencies by email dated August 1, 2023, from Gina Gencarelli, Esq., Executive Director, Intellectual Property for Plaintiffs, to Supriya Taneja, Esq., General Counsel, BPI Labs and Vice President, Belcher.

34. By letter dated August 9, 2023 (the "Second Notice Letter"), BPI Labs sent to Plaintiffs a second correspondence purporting to cure the deficiencies of the First Notice Letter.

35. The Second Notice Letter also failed to provide, for each claim of the '876 and '657 patents, a full and detailed explanation of why the claim is not infringed or is invalid or unenforceable.

36. The Second Notice Letter purported to offer confidential access to NDA No. 205029.

37. On August 18, 2023, BPI Labs produced certain parts of NDA No. 205029 to the Plaintiffs' outside counsel. This production did not provide the entirety of NDA No. 205029 or the supplement thereto. The production also redacted relevant parts of NDA No. 205029.

38. On information and belief, one or more Defendants were aware of the Patents-in-Suit when the Paragraph IV Certification was submitted to FDA.

39. Plaintiffs commenced this action within 45 days of receiving the First Notice Letter.

COUNT I
INFRINGEMENT OF THE '876 PATENT

40. Plaintiffs re-allege and incorporate Paragraphs 1-39 as if fully set forth herein.

41. The submission of the BPI Labs' supplement to NDA No. 205029 to FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, importation, use, marketing, and sale of Defendants' Proposed Product prior to the expiration of the '876 Patent,

constitutes infringement by Defendants of the '876 Patent under 35 U.S.C. § 271(e)(2)(A).

42. Upon FDA's approval of the supplement to NDA No. 205029, Defendants' commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Defendants' Proposed Product will infringe at least claim 1 of the '876 patent, both directly under 35 U.S.C. §§ 271(a) and (g) and indirectly under 35 U.S.C. §§ 271(b) and 271(c), literally and/or under the doctrine of equivalents.

43. Claim 1 of the '876 patent reads as follows:

> A composition comprising:
>
> in the range of about 0.5 to 1.5 mg/mL of epinephrine and/or salts thereof,
>
> in the range of about 6 to 8 mg/mL of a tonicity regulating agent,
>
> in the range of about 2.8 to 3.8 mg/mL of a pH raising agent,
>
> in the range of about 0.1 to 1.1 mg/mL of an antioxidant,
>
> in the range of about 0.001 to 0.010 mL/mL of a pH lowering agent, and
>
> in the range of about 0.01 to 0.4 mg/mL of a transition metal complexing agent, wherein the antioxidant comprises sodium bisulfite and/or sodium metabisulfite.

44. Adrenalin® is an embodiment of one or more claims of the '876 patent.

45. On information and belief, Defendants' Proposed Product contains the same active ingredient and in the same concentration as Adrenalin®.

46. On information and belief, Defendants' Proposed Product infringes at least one claim, including at least claim 1 of the '876 patent, literally and/or by the doctrine of equivalents.

47. On information and belief, Defendants' Proposed Product comprises epinephrine, a tonicity regulating agent, a pH raising agent, an antioxidant comprising sodium bisulfite and/or sodium metabisulfite, a pH lowering agent, and a transition metal complexing agent, in the ranges claimed in at least one claim, including at least claim 1 of the '876 patent, literally and/or by the doctrine of equivalents.

48. Unless enjoined by the Court, upon FDA's approval of the supplement to NDA No. 205029, Defendants will infringe at least one claim, including at least claim 1 of the '876 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Product into the United States.

49. Unless enjoined by the Court, upon FDA's approval of the supplement to NDA No. 205029, Defendants will infringe at least one claim, including at least claim 1 of the '876 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing the Defendants' Proposed Product into the United States. On information and belief,

Defendants will knowingly encourage direct infringement of the '876 patent and possess specific intent to encourage another's direct infringement of the '876 patent.

50. Unless enjoined by the Court, upon FDA's approval of the supplement to NDA 205029, Defendants will infringe at least one claim, including at least claim 1 of the '876 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing the Defendants' Proposed Product into the United States. On information and belief, the act of direct infringement of the '876 patent is attributed to a single entity. On information and belief, the Defendants' Proposed Product is a material part of the claimed invention and is not suitable for substantial non-infringing uses.

51. Plaintiffs are entitled to a declaratory judgment that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Defendants' Proposed Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Defendants' Proposed Product before expiration of the '876 patent by Defendants, will constitute infringement, inducement of infringement, and/or contributory infringement of the '876 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

52. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, inducing, or contributing to infringement of the '876 patent. Plaintiffs do not have an adequate remedy at law to fully compensate Plaintiffs for their damages.

53. This case is exceptional, and Plaintiffs are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT II

INFRINGEMENT OF THE '657 PATENT

54. Plaintiffs re-allege and incorporate Paragraphs 1-39 as if fully set forth herein.

55. The submission of the BPI Labs' supplement to NDA No. 205029 to FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, importation, use, marketing, and sale of Defendants' Proposed Product prior to the expiration of the '657 Patent, constitutes infringement by Defendants of the '657 Patent under 35 U.S.C. § 271(e)(2)(A).

56. Upon FDA's approval of the supplement to NDA No. 205029, Defendants' commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Defendants' Proposed Product will infringe at least claim 1 of the '657 patent, both directly under 35 U.S.C. §§ 271(a) and (g) and indirectly under 35 U.S.C. §§ 271(b) and 271(c), literally and/or under the doctrine of equivalents.

57. Claim 1 of the '657 patent reads as follows:

> A method of treating a condition comprising administering to a patient in need thereof a composition comprising:

in the range of about 0.5 to 1.5 mg/mL of epinephrine and/or salts thereof,

in the range of about 6 to 8 mg/mL of a tonicity regulating agent,

in the range of about 2.8 to 3.8 mg/mL of a pH raising agent,

in the range of about 0.1 to 1.1 mg/mL of an antioxidant,

in the range of about 0.001 to 0.010 mL/mL of a pH lowering agent, and

in the range of about 0.01 to 0.4 mg/mL of a transition metal complexing agent;

wherein the antioxidant comprises sodium bisulfite and/or sodium metabisulfite, and wherein the condition is selected from the group consisting of anaphylaxis, bronchospasm, sensitivity reactions, cardiac arrhythmias, GI and renal hemorrhage, superficial bleeding, premature labor, hypoglycemia,

58. Upon FDA approval of the supplement to NDA No. 205029, Defendants will induce infringement of at least one claim, including at least claims 1 and 20 of the '657 patent, by promoting, encouraging, and/or recommending that medical personnel perform methods of treating certain conditions, including Type 1 allergic reactions and anaphylaxis, by administering to a patient in need a composition comprising epinephrine, tonicity regulating agent, pH raising agent, antioxidant comprising sodium bisulfite and/or sodium metabisulfite, pH lowering agent, and transition metal complexing agent, in certain ranges and/or by

contributing to the performance of said method, in violation of 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or by the doctrine of equivalents.

59. Adrenalin® is an embodiment of one or more claims of the '657 patent. The use of Adrenalin® to treat Type 1 allergic reactions, including anaphylaxis, falls within one or more claims of the '657 patent.

60. As part of its supplement to NDA No. 205029, Defendants must show that "the labeling proposed for the new drug is the same as the labeling approved for the listed drug," except for changes indicating that the drug is produced or distributed by different manufacturers. 21 U.S.C. § 355(j)(2)(A)(v).

61. The label for Adrenalin® states that Adrenalin® is indicated for emergency treatment of allergic reactions (Type 1), including anaphylaxis. *See* Exhibit C.

62. On information and belief, the label for BPI Labs' supplement to NDA No. 205029 is substantially identical to the approved label for Adrenalin®, and Defendants' Proposed Product, if approved, will be marketed, sold, and/or distributed with labeling that is substantially identical to the labeling for Adrenalin®.

63. On information and belief, the label for Defendants' Proposed Product also states that Defendants' Proposed Product is indicated for emergency treatment of allergic reactions (Type 1), including anaphylaxis. Therefore, the label promotes or encourages medical personnel to administer Defendants' Proposed Product to treat Type 1 allergic reactions and anaphylaxis.

64. On information and belief, Defendants' Proposed Product contains the same active ingredient and in the same concentration as Adrenalin®, epinephrine 30 mg/30 mL (1 mg/mL) dose vial.

65. On information and belief, Defendants' Proposed Product infringes at least one claim, including at least claim 1 of the '657 patent, literally and/or by the doctrine of equivalents.

66. On information and belief, Defendants' Proposed Product comprises epinephrine, tonicity regulating agent, pH raising agent, antioxidant comprising sodium bisulfite and/or sodium metabisulfite, pH lowering agent, and transition metal complexing agent, in the ranges claimed in at least one claim, including at least claim 1 of the '657 patent, literally and/or by the doctrine of equivalents.

67. On information and belief, Defendants knowingly provide instruction in the label for medical personnel to administer Defendants' Proposed Product to treat allergic reactions (Type 1), including anaphylaxis, and the label reflects a specific intent to encourage medical personnel to directly infringe at least one claim, including at least claim 1 of the '657 patent, literally and/or by the doctrine of equivalents.

68. Unless enjoined by the Court, upon FDA's approval of the supplement to NDA No. 205029, Defendants will infringe at least one claim, including at least claim 1 of the '657 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Product into the United States.

69. Unless enjoined by the Court, upon FDA's approval of the supplement to NDA No. 205029, Defendants will infringe at least one claim, including at least claim 1 of the '657 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing the Defendants' Proposed Product into the United States. On information and belief, Defendants will knowingly encourage direct infringement of the '657 patent and possess specific intent to encourage another's direct infringement of the '657 patent.

70. Unless enjoined by the Court, upon FDA's approval of the supplement to NDA 205029, Defendants will infringe at least one claim, including at least claim 1 of the '657 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing the Defendants' Proposed Product into the United States. On information and belief, the act of direct infringement of the '657 patent is attributed to a single entity. On information and belief, the Defendants' Proposed Product is a material part of the claimed invention and is not suitable for substantial non-infringing uses.

71. Plaintiffs are entitled to a declaratory judgment that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of the Defendants' Proposed Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the Defendants' Proposed Product before expiration of the '657 patent by Defendants, will constitute

infringement, inducement of infringement, and/or contributory infringement of the '657 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

72. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, inducing, or contributing to infringement of the '657 patent. Plaintiffs do not have an adequate remedy at law to fully compensate Plaintiffs for their damages.

73. This case is exceptional, and Plaintiffs are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment declaring that Defendants have infringed, contributed to, or induced the infringement of one or more claims of the '876 patent, literally and/or by the doctrine of equivalents, by submitting the supplement to NDA No. 205209 to FDA for Defendants' Proposed Product;

B. A judgment declaring that Defendants have infringed, contributed to, or induced the infringement of one or more claims of the '657 patent, literally and/or by the doctrine of equivalents, by submitting the supplement to NDA No. 205209 to FDA for Defendants' Proposed Product;

C. A judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' Proposed Product within the United States, prior to expiration, infringes the '876 patent;

D. A judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' Proposed Product within the United States, prior to expiration, infringes the '657 patent;

E. A permanent injunction restraining and enjoining Defendants, and its officers, agents, attorneys, servants and employees, and those in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation within the United States, of Defendants' Proposed Product, until the expiration of the '876 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

F. A permanent injunction restraining and enjoining Defendants, and its officers, agents, attorneys, servants and employees, and those in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation within the United States, of Defendants' Proposed Product, until the expiration of the '657 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

G. An order that the effective date of any approval of the supplement to NDA No. 205029 for Defendants' Proposed Product under 21 U.S.C. § 355(j) shall not be earlier than the expiration date of the '876 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

H. An order that the effective date of any approval of the supplement to NDA No. 205029 for Defendants' Proposed Product under 21 U.S.C. § 355(j) shall

not be earlier than the expiration date of the '657 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

I. An award of compensatory damages to Plaintiffs for Defendants' infringement of the '876 patent;

J. An award of compensatory damages to Plaintiffs for Defendants' infringement of the '657 patent;

K. An award of increased damages to Plaintiffs under 35 U.S.C. § 284 for Defendants' willful and deliberate infringement of the '876 patent;

L. An award of increased damages to Plaintiffs under 35 U.S.C. § 284 for Defendants' willful and deliberate infringement of the '657 patent;

M. A judgment declaring this to be an exceptional case under 35 U.S.C. § 285 in Plaintiffs' favor and awarding Plaintiffs their reasonable attorneys' fees;

N. An award of Plaintiffs' costs and expenses for defending this action, together with pre-judgment and post-judgment interest; and

O. An award to Plaintiffs of such other and further relief as the Court may deem just and proper.

Dated: August 29, 2023

s/ *Michael E. Lockamy*
Michael E. Lockamy
Florida Bar No. 69626
mel@bedellfirm.com
John G. Woodlee
Florida Bar No. 0100990
jgw@bedellfirm.com
BEDELL, DITTMAR, DEVAULT,
PILLANS & COXE, P.A.
101 East Adams Street
Jacksonville, FL 32202
Telephone: (904)353-0211
Facsimile: (904) 353-9307

Aziz Burgy*
AXINN, VELTROP & HARKRIDER LLP
1901 L Street NW
Washington, DC 20036
Telephone: (202) 912-4700
Facsimile: (202) 912-4701
aburgy@axinn.com

Matthew J. Becker*
AXINN, VELTROP & HARKRIDER LLP
90 State House Square
Hartford, CT 06103
Telephone: (860) 275-8100
Facsimile: (860) 275-8101
mbecker@axinn.com

Ricardo S. Camposanto*
AXINN, VELTROP & HARKRIDER LLP
55 Second Street
San Francisco, CA 92105
Telephone: (415) 490-1518
Facsimile: (415) 490-2001
rcamposanto@axinn.com

**motions for special admission forthcoming*

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