IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC, Plaintiffs, v. HOSPIRA, INC., Defendant.	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Par Pharmaceutical, Inc. ("Par"), Par Sterile Products, LLC ("Par Sterile"), and Endo Par Innovation Company, LLC ("EPIC"), for their Complaint against Defendant Hospira, Inc. ("Hospira"), herein allege as follows:

NATURE OF ACTION

1. This is a civil action for infringement of U.S. Patent No. 9,119,876 ("the '876 patent") and U.S. Patent No. 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.*

PARTIES

2. Par is a corporation organized and existing under the laws of the State of New York, having a principal place of business at One Ram Ridge Road, Chestnut Ridge, New York 10977.

3. Par Sterile is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at One Ram Ridge Road, Chestnut Ridge, New York 10977.

4. EPIC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at One Ram Ridge Road, Chestnut Ridge, New York 10977.

5. On information and belief, Hospira is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. This Court has personal jurisdiction over Hospira. On information and belief, Hospira is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Hospira maintains a corporate agent for service of process at The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware, 19801.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b). On information and belief, Hospira resides in this judicial district by virtue of its incorporation in Delaware.

THE PATENTS-IN-SUIT

9. The ’876 patent, titled “Epinephrine Formulations,” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on September 1, 2015, to Par

Pharmaceutical, Inc., the assignee of the named inventors. Plaintiffs own and have exclusive rights to the '876 patent, including all rights to sue for infringement thereof.

10. A true and correct copy of the '876 patent is attached hereto as Exhibit A.

11. The '657 patent, titled "Epinephrine Formulations," was duly and legally issued by the USPTO on March 29, 2016, to Par Pharmaceutical, Inc., the assignee of the named inventors. Plaintiffs own and have exclusive rights to the '876 patent, including all rights to sue for infringement thereof.

12. A true and correct copy of the '657 patent is attached hereto as Exhibit B.

PAR'S ADRENALIN® PRODUCT

13. Par Sterile is the holder of approved New Drug Application ("NDA") No. 204200 for Adrenalin® brand epinephrine injection 1 mg/mL. 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.

14. The chemical compound epinephrine is an old drug that has been in clinical use for over 100 years for the treatment of 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.

15. In March 2012, Par Sterile's predecessor, JHP Pharmaceuticals ("JHP"), sought FDA approval of 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.

16. 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 are in need of potent medication in a short amount of 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®.

17. 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.

18. 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 the use of sodium bisulfite and/or sodium metabisulfite as an antioxidant. This reduced formation of D-epinephrine and ESA, without compromising pharmaceutical benefits. Thus, Par

Sterile was able to maintain 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.

19. After its successful reformulation effort, Par Sterile submitted a supplemental NDA to FDA for approval of a new formulation to provide a more stable Adrenalin® product, in January 2016. FDA approved the supplemental NDA for the new formulation in September 2016.

20. Based on the significant research and development it had conducted in the course of reformulating and improving its Adrenalin® product, Par obtained the '876 and '657 patents.

21. The '876 patent covers the technological advance Par 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 (1 mg/mL) is a composition that falls within the claims of the '876 patent.

22. 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.

23. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the ’876 and ’657 patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) with respect to Adrenalin® brand epinephrine injection.

HOSPIRA’S ANDA

24. Upon information and belief, Hospira submitted Abbreviated New Drug Application (“ANDA”) No. 208908 to FDA, under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a generic version of Adrenalin® epinephrine injection, 1 mg/mL (“the Hospira ANDA Product”), prior to the expiration of the Patents-in-Suit.

25. By letter dated June 1, 2017 (the “Notice Letter”), Hospira stated that it had submitted ANDA No. 208908 to FDA seeking approval to engage in the manufacture, use, importation, offer for sale, or sale of a generic version of Adrenalin® prior to the expiration of the Patents-in-Suit.

26. The Notice Letter also stated that ANDA No. 208908 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the Hospira ANDA Product.

27. On information and belief, Hospira was aware of the Patents-in-Suit at the time the Paragraph IV Certification was submitted to FDA.

28. An ANDA is required to have the same active ingredient as that of the reference drug. *See* 21 U.S.C. § 355(j)(2)(A)(ii). Therefore, a generic version of Adrenalin®, such as the

Hospira ANDA product, is required to have the same active ingredient, epinephrine, as Adrenalin®.

29. The Notice Letter contains no argument that any claim of the Patents-in-Suit is invalid.

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

COUNT ONE
Hospira's Infringement of the '876 Patent

31. Plaintiffs reallege and incorporate each of the preceding paragraphs as if fully set forth herein.

32. Hospira's submission of ANDA No. 208908 to FDA to engage in the commercial manufacture, use, sale, offer for sale, or importation of the Hospira ANDA Product, prior to the expiration of the '876 patent, constitutes infringement of at least one claim, including at least claim 1 of the '876 patent, under 35 U.S.C. § 271(e)(2), literally and/or by the doctrine of equivalents.

33. Upon FDA approval of ANDA No. 208908, Hospira will infringe at least one claim, including at least claim 1 of the '876 patent, by manufacturing, using, offering to sell, or selling the Hospira ANDA Product in the United States and/or importing the Hospira ANDA Product into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or by the doctrine of equivalents.

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

35. On information and belief, the Hospira ANDA Product contains the same active ingredient and in the same concentration as Adrenalin®, epinephrine 1 mg/mL.

36. On information and belief, the Hospira ANDA Product infringes at least one claim, including at least claim 1 of the ’876 patent, literally and/or by the doctrine of equivalents.

37. On information and belief, the Hospira ANDA 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 ’876 patent, literally and/or by the doctrine of equivalents.

38. Unless enjoined by the Court, on FDA approval of ANDA No. 208908, Hospira 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 the Hospira ANDA Product into the United States.

39. Unless enjoined by the Court, on FDA approval of ANDA No. 208908, Hospira 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 Hospira ANDA Product into the United States. On information and belief, Hospira will knowingly encourage direct infringement of the ’876 patent, and possesses specific intent to encourage another’s direct infringement of the ’876 patent.

40. Unless enjoined by the Court, on FDA approval of ANDA No. 208908, Hospira 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 Hospira ANDA 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 Hospira ANDA Product is a material part of the claimed invention, and is not suitable for substantial non-infringing uses.

41. 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 Hospira ANDA 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 Hospira ANDA Product before expiration of the '876 patent by Hospira or its agents, 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).

42. Plaintiffs will be irreparably harmed if Hospira is not enjoined from infringing, inducing, or contributing to infringement of the '876 patent. Plaintiffs do not have an adequate remedy at law.

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

COUNT TWO
Hospira's Infringement of the '657 Patent

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

45. Hospira's submission of ANDA No. 208908 to FDA to engage in the commercial manufacture, use, sale, offer for sale, or importation of the Hospira ANDA Product, prior to the expiration of the '657 patent, constitutes infringement of at least one claim, including at least claims 1 and 20 of the '657 patent, under 35 U.S.C. § 271(e)(2), literally and/or by the doctrine of equivalents.

46. Upon FDA approval of ANDA No. 208908, Hospira 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.

47. 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.

48. As part of its ANDA, Hospira 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).

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

50. On information and belief, the label for the Hospira ANDA Product is substantially identical to the approved label for Adrenalin®, and the Hospira ANDA Product, if approved, will be marketed, sold, and/or distributed with labeling that is substantially identical to the labeling for Adrenalin®.

51. On information and belief, the label for the Hospira ANDA Product also states that the Hospira ANDA Product is indicated for emergency treatment of allergic reactions (Type

1), including anaphylaxis. Therefore, the label promotes or encourages medical personnel to administer the Hospira ANDA Product to treat Type 1 allergic reactions and anaphylaxis.

52. On information and belief, the Hospira ANDA Product contains the same active ingredient and in the same concentration as Adrenalin®, epinephrine 1 mg/mL.

53. On information and belief, the Hospira ANDA Product infringes at least one claim, including at least claims 1 and 20 of the '657 patent, literally and/or by the doctrine of equivalents.

54. On information and belief, the Hospira ANDA 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 claims 1 and 20 of the '657 patent, literally and/or by the doctrine of equivalents.

55. On information and belief, Hospira knowingly provides instruction in the label for medical personnel to administer the Hospira ANDA 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 claims 1 and 20 of the '657 patent, literally and/or by the doctrine of equivalents.

56. Unless enjoined by the Court, on FDA approval of ANDA No. 208908, Hospira will infringe at least one claim, including at least claims 1 and 20 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 the Hospira ANDA Product into the United States.

57. Unless enjoined by the Court, on FDA approval of ANDA No. 208908, Hospira will infringe at least one claim, including at least claims 1 and 20 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 Hospira ANDA Product into the United States. On information and belief, Hospira will knowingly encourage direct infringement of the '657 patent, and possesses specific intent to encourage another's direct infringement of the '657 patent.

58. Unless enjoined by the Court, on FDA approval of ANDA No. 208908, Hospira will infringe at least one claim, including at least claims 1 and 20 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 Hospira ANDA 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 Hospira ANDA Product is a material part of the claimed invention, and is not suitable for substantial non-infringing uses.

59. 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 Hospira ANDA 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 Hospira ANDA Product before expiration of the '657 patent by Hospira or its agents, 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).

60. Plaintiffs will be irreparably harmed if Hospira is not enjoined from infringing, inducing, or contributing to infringement of the '657 patent. Plaintiffs do not have an adequate remedy at law.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Hospira 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 ANDA No. 208908 to FDA;

B. A judgment that Hospira 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 ANDA No. 208908 to FDA;

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

E. A permanent injunction restraining and enjoining Hospira, and its officers, agents, attorneys, employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Hospira ANDA 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 Hospira, and its officers, agents, attorneys, employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into

the United States, of the Hospira ANDA 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 Hospira's ANDA No. 208908 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 Hospira's ANDA No. 208908 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. A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and an award of reasonable attorney fees, costs, and expenses in this action; and

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

/s/ Steven J. Fineman
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