IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BELCHER PHARMACEUTICALS, LLC,	)	
Plaintiff,	)	
v.	)	
	)	C.A. No. _____
HOSPIRA, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Belcher Pharmaceuticals, LLC ("Belcher"), for its Complaint against defendant Hospira, Inc. ("Hospira"), hereby alleges as follows:

THE PARTIES

1. Belcher is a limited liability company organized and existing under the laws of the State of Florida and having its corporate headquarters at 6911 Bryan Diary Road, Suite 210, Largo, Florida 33777.

2. Hospira is a corporation organized and existing under the laws of the State of Delaware and having its corporate headquarters at 275 North Field Drive, Lake Forest, Illinois 60045-2510. Hospira is a subsidiary of Pfizer and develops, manufactures, markets, sells and/or distributes pharmaceutical drugs throughout the United States, including in this District.

JURISDICTION AND VENUE

3. This is an action for patent infringement arising under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, respectively, of the United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338.

4. This Court has personal jurisdiction over Hospira since Hospira is incorporated in Delaware. It is registered with the Delaware Department of State: Division of Corporations under file number 3704721 and maintains a registered agent for service of process in Delaware.

5. Hospira regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, demonstrating that Hospira has continuous and systematic contacts with Delaware.

6. Hospira is in the business of manufacturing and selling pharmaceutical products that are distributed throughout the United States, including in the state of Delaware. Hospira directly or through its affiliates and agents develops, formulates, manufactures, markets, sells and/or distributes pharmaceutical products, including drug products, throughout the United States and in this District.

7. Hospira has purposefully availed itself of the privilege of conducting activities in Delaware and its conduct and connection with Delaware are such that it should reasonably anticipate being haled into court in the state.

8. Upon approval of Hospira's New Drug Application ("NDA") No. 209359, Hospira and/or its affiliates or agents will market and sell Hospira's Epinephrine Injection USP, Abboject™ Syringe 1 mg/10 mL ("NDA Product") in Delaware and throughout the United States and will derive substantial revenue therefrom. Upon approval of Hospira's NDA, Hospira will sell the NDA Product in the state of Delaware and throughout the United States, and will be involved in the development, manufacture, distribution, and/or marketing of the NDA Product.

9. Upon approval of Hospira's NDA, Hospira and/or its affiliates or agents will place the NDA Product into the stream of commerce with the reasonable expectation or

knowledge and the intent that such products will ultimately be administered and used by consumers in this judicial district.

10. This Court further has personal jurisdiction over Hospira because Hospira regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things administered or used in Delaware and committed the tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Belcher.

11. Venue is proper in this judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

12. Belcher holds approved New Drug Application No. 205029 for Epinephrine Injection USP, 1 mg/mL which is prescribed and sold in the United States.

13. Belcher's Epinephrine Injection USP, 1 mg/mL is indicated to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock, for emergency treatment of allergic reactions (Type 1), including anaphylaxis, and for induction and maintenance of mydriasis during intraocular surgery.

A. The '700 Patent

14. Belcher is the assignee of United States Patent No. 10,004,700 (the "'700 Patent," copy attached as **Exhibit A**) titled "More Potent And Less Toxic Formulations Of Epinephrine And Methods Of Medical Use" and was duly and legally issued by the United Patent and Trademark Office on June 26, 2018. The '700 Patent claims, inter alia, liquid pharmaceutical formulations of l-epinephrine. In accordance with 21 U.S.C. § 355(b)(2), the '700 Patent is listed

in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (a/k/a "the Orange Book") for Epinephrine formulations (NDA No. 205029).

15. Upon realization of a defect in the '700 Patent, a reissue application was filed on December 28, 2018 having application number 16/235,712. Upon grant of the reissue, the '700 Patent will be surrendered and the reissued patent will be enforceable as to the invention in the '700 Patent.

16. On information and belief, the original claims of the '700 Patent and any amendments made to those claims during the reissue proceedings are or will be valid and enforceable against Hospira's infringing NDA Product.

B. The '728 Patent

17. Belcher is the assignee of United States Patent No. 10,039,728 (the "'728 Patent," copy attached as **Exhibit B**) titled "More Potent And Less Toxic Formulations Of Epinephrine And Methods Of Medical Use" and was duly and legally issued by the United Patent and Trademark Office on August 7, 2018. The '728 Patent claims, inter alia, liquid pharmaceutical formulations of l-epinephrine. In accordance with 21 U.S.C. § 355(b)(2), the '728 Patent is listed in the FDA's Orange Book for Epinephrine formulations (NDA No. 205029).

18. Upon realization of a defect in the '728 Patent, a reissue application was filed on December 28, 2018 having application number 16/235,920. Upon grant of the reissue, the '728 Patent will be surrendered and the reissued patent will be enforceable as to the invention in the '728 Patent.

19. On information and belief, the original claims of the '728 Patent and any amendments made to those claims during the reissue proceedings are or will be valid and enforceable against Hospira's infringing NDA Product.

CLAIMS FOR RELIEF - PATENT INFRINGEMENT

20. Hospira submitted NDA No. 209359 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the NDA Product.

21. By letter dated August 19, 2019 (the "Notice Letter"), and pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95, Hospira notified Belcher that Hospira had amended its pending NDA No. 209359 seeking approval to engage in the commercial manufacture, use, or sale of the NDA Product before the expiration of both the '700 Patent and the '728 Patent.

22. In the Notice Letter, Hospira notified Belcher that, as a part of Hospira's NDA, Hospira had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a/k/a "Paragraph IV Certification") with respect to both the '700 Patent and the '728 Patent.

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

24. The manufacture and use or Hospira's NDA Product is covered by one or more claims of both the '700 Patent and the '728 Patent, including but not limited to, independent claim 1 of the '700 Patent and independent claims 1-3 of the '728 Patent.

25. The Notice Letter contains no argument that Claims 3 or 5-16 of the '700 Patent are invalid.

26. The Notice Letter contains no argument that the NDA Product would not infringe Claims 1 or 2 of the '728 Patent.

27. The Notice Letter contains no argument that Claim 3 of the '728 Patent is invalid.

28. This action is being commenced before the expiration of 45 days from the date Belcher received the Notice Letter, which Belcher received on or about August 19, 2019.

COUNT I
(Infringement of U.S. Patent No. 10,004,700 Under 35 U.S.C. § 271)

29. Belcher repeats and realleges paragraphs 1-28 as if fully set forth herein.

30. By amending NDA No. 209359 to the FDA to obtain approval under the Federal Food, Drug and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, and/or importation of the NDA Product throughout the United States prior to the expiration of the ’700 Patent, Hospira committed an act of infringement of the ’700 Patent under 35 U.S.C. § 271(e)(2).

31. Hospira is liable for indirectly infringing the above-identified claims of the ’700 Patent in this judicial district and elsewhere in the United States by inducing direct infringement in violation of 35 U.S.C. § 271(b) and by contributing to direct infringement in violation of 35 U.S.C. § 271(c).

32. By submitting its Paragraph IV Certification, Hospira is and has been aware of the ’700 Patent and deliberately and intentionally submitted the NDA with knowledge that one or more claims of the ’700 Patent were covered by the use of the NDA Product.

33. The direct infringement induced or contributed to by Hospira will include at least the use of the NDA Product by medical personnel at medical treatment facilities, including but not limited to, physicians and nurses administering the NDA Product to patients for indications listed in the above-referenced claims of the ’700 Patent, including but not limited to, reactions to drugs and other allergens (a/k/a allergic reactions or anaphylaxis) as demonstrated by Hospira’s package insert, found both in Hospira’s NDA[1] and available online in association with Hospira’s

[1] Previously received October 4, 2017 in association with *Belcher Pharmaceuticals, LLC v. Hospira, Inc.*, Civil Action No. 17-cv-00775 (D. Del.)

unapproved epinephrine product which is advertised for sale but currently unavailable,[2] distributed with its NDA Product to medical treatment facilities, specifically directing the medical personnel to administer the NDA Product to patients, resulting in an infringing use of the NDA Product.

34. Upon information and belief, Hospira's NDA Product, apart from the use described above, has no substantial noninfringing uses.

35. Belcher will be irreparably harmed by Hospira's infringing activities and does not have an adequate remedy at law.

COUNT II
(Infringement of U.S. Patent No. 10,039,728 Under 35 U.S.C. § 271)

36. Belcher repeats and realleges paragraphs 1-35 as if fully set forth herein.

37. By amending NDA No. 209359 to the FDA to obtain approval under the Federal Food, Drug and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, and/or importation of the NDA Product throughout the United States prior to the expiration of the '728 Patent, Hospira committed an act of infringement of the '728 Patent under 35 U.S.C. § 271(e)(2).

38. Hospira is liable for indirectly infringing the above-identified claims of the '728 Patent in this judicial district and elsewhere in the United States by inducing direct infringement in violation of 35 U.S.C. § 271(b) and by contributing to direct infringement in violation of 35 U.S.C. § 271(c).

39. By submitting its Paragraph IV Certification, Hospira is and has been aware of the '728 Patent and deliberately and intentionally submitted the NDA with knowledge that one or more claims of the '728 Patent were covered by the use of the NDA Product.

[2] http://labeling.pfizer.com/ShowLabeling.aspx?id=7373 (last visited October 2, 2013).

40. The direct infringement induced or contributed to by Hospira will include at least the use of the NDA Product by medical personnel at medical treatment facilities, including but not limited to, physicians and nurses administering the NDA Product to patients for indications listed in the above-referenced claims of the ’728 Patent, including but not limited to, reactions to drugs and other allergens (a/k/a septic or anaphylactic shock) as demonstrated by Hospira’s package insert, distributed with its NDA Product to medical treatment facilities, specifically directing the medical personnel to administer the NDA Product to patients suffering from allergic reactions, resulting in an infringing use of the NDA Product.

41. Upon information and belief, Hospira’s NDA Product, apart from the use described above, has no substantial noninfringing uses.

42. Belcher will be irreparably harmed by Hospira’s infringing activities and does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Belcher prays for a judgment in its favor and against Hospira and respectfully requests the following relief:

(A) A judgment that under 35 U.S.C. § 271(e)(2)(A), Hospira has infringed one or more claims of both the ’700 Patent and the ’728 Patent by amending NDA No. 209359 seeking FDA approval for the commercial manufacture, use, offer for sale, and/or importation of the NDA Product before the expiration dates of both the ’700 Patent and the ’728 Patent.

(B) A judgment that the manufacture, use, offer for sale, sale, and/or importation of the NDA Product will infringe both the ’700 Patent and the ’728 Patent under 35 U.S.C. §§ 271(b) and/or 271(c);

(C) A judgment declaring that both the ’700 Patent and the ’728 Patent are valid and enforceable;

(D) A permanent injunction restraining and enjoining Hospira and its officers, agents, attorneys, and employees, and those acting in privity or concert therewith, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of the NDA Product until the expiration of both the ’700 Patent and the ’728 Patent or any later date of exclusivity to which Belcher is or becomes entitled;

(E) An order that the effective date of any approval of Hospira’s NDA No. 209359, under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)) shall be a date that is not earlier than the expiration of both the ’700 Patent and the ’728 Patent or any later date of exclusivity to which Belcher and/or these patents are or become entitled;

(F) A determination that this case is “exceptional” under 35 U.S.C. § 285 and an award of attorneys’ fees;

(G) Costs and expenses in this action; and

(H) Such other and further relief as the Court may deem just and proper.

Dated: October 2, 2019

BAYARD, P.A.

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