IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BELCHER PHARMACEUTICALS, LLC,	)	
Plaintiffs,	)	
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. Plaintiff 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 Dairy Road, Suite 210, Largo, Florida 33777.

2. Defendant 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 develops, manufactures, markets, sells and/or distributes 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, 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. 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 judicial 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, the Defendant and/or its affiliates or agents will market and sell Hospira's Epinephrine Injection USP, Abboject™ Syringe 1mg/10mL (the "NDA Product") in Delaware and throughout the United States and will derive substantial revenue therefrom. Upon approval of Hospira's NDA, the Defendant 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, the Defendant 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 purchased and used by consumers in this judicial District.

10. This Court further has personal jurisdiction over the Defendant because the Defendant 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 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 Plaintiff Belcher.

11. This Court has personal jurisdiction over the Defendant by virtue of, inter alia, the above-mentioned facts.

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

THE PATENT-IN-SUIT

13. Belcher holds approved New Drug Application ("NDA") No. 205029 for Epinephrine Injection USP, 1 mg/ml which is prescribed and sold in the United States.

14. 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.

15. United States Patent No. 9,283,197 ("the '197 patent," copy attached as Exhibit A) is titled "More Potent And Less Toxic Formulations Of Epinephrine And

Methods Of Medical Use" and was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on March 15, 2016. The '197 patent claims, inter alia, liquid pharmaceutical formulations of l-epinephrine. In accordance with 21 U.S.C. § 355(b)(2), the '197 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Epinephrine solution (NDA No. 205029).

16. The named inventor of the '197 patent is Jugal K. Taneja. The '197 patent is assigned to Belcher.

CLAIMS FOR RELIEF - PATENT INFRINGEMENT

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

18. By letter dated May 3, 2017 ("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 submitted NDA No. 209359 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the NDA Product before the expiration of the '197 patent.

19. In the May 3, 2017 Notice Letter, Defendant notified Plaintiff that, as a part of Hospira's NDA, they had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") with respect to the '197 patent.

20. The manufacture of Hospira's NDA Product is covered by one or more claims of the '197 patent, including but not limited to Claim 6.

21. This action is being commenced before the expiration of forty-five days from the date the Plaintiff received the Notice letter, which the Plaintiff received on or about May 4, 2017.

COUNT I

Infringement of U.S. Patent No. 9,283,197 Under 35 U.S.C. § 271

22. Plaintiff repeats and realleges paragraphs 1 through 21 as if fully set forth herein.

23. By submitting 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, sale, and/or importation of the NDA Product throughout the United States prior to the expiration of the '197 patent, Defendant committed an act of infringement of the '197 patent under 35 U.S.C. § 271(e)(2).

24. The commercial manufacture, use, offer for sale, sale, and/or importation of the NDA Product, for which Hospira seeks approval of NDA No. 209359, will infringe, induce infringement, and/or contributorily infringe one or more claims of the '197 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

25. The Defendant was aware of the '197 patent at the time the NDA was submitted and deliberately and intentionally submitted the NDA with knowledge that one or more claims of the '197 patent covered the NDA Product or its use or manufacture.

26. The Plaintiff will be irreparably harmed by Defendant's infringing activities and does not have an adequate remedy at law.

PRAYER FOR RELIEF

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

(A) A judgment that under 35 U.S.C. § 271(e)(2)(A), Defendant has infringed one or more claims of the '197 patent by submitting NDA No. 209359 seeking FDA approval for

the commercial manufacture, use, offer for sale, sale, and/or importation of the NDA Product before the expiration of the '197 patent;

(B) A judgment that the manufacture, use, offer for sale, sale, and/or importation of the NDA Product will infringe the '197 patent under 35 U.S.C. §§ 271(a), 271(b), and/or 271(c);

(C) A judgment declaring that the '197 patent remains valid and enforceable;

(D) A permanent injunction restraining and enjoining the Defendant 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 the '197 patent or any later date of exclusivity to which the Plaintiff is or become 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 the '197 Patent or any later date of exclusivity to which the Plaintiff and/or this patent 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: June 16, 2017

PRICKETT, JONES & ELLIOTT, P.A.

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