

LITE DEPALMA GREENBERG, LLC

Michael E. Patunas
Mayra V. Tarantino
Two Gateway Center, Suite 1201
Newark, NJ 07102
(973) 623-3000
mpatunas@litedepalma.com
mtarantino@litedepalma.com

Attorneys for Plaintiff Fresenius Kabi USA, LLC

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

FRESENIUS KABI USA, LLC,

Plaintiff,

v.

EMCURE PHARMACEUTICALS USA,
INC. and EMCURE
PHARMACEUTICALS, LTD.,

Defendants.

Civil Action No.:

COMPLAINT

Fresenius Kabi USA, LLC (“Fresenius”) brings this action for patent infringement against Defendants Emcure Pharmaceuticals USA, Inc. and Emcure Pharmaceuticals, Ltd. (collectively “Emcure”).

1. This is an action by Fresenius against Emcure for infringement of United States Patent No. 8,476,010 (“the ’010 patent”). This action arises out of Emcure’s filing of an Abbreviated New Drug Application (“ANDA”) seeking approval by the United States Food and Drug Administration (“FDA”) to sell generic versions of Diprivan[®], an innovative intravenously administered sedative and anesthetic, prior to the expiration of the ’010 patent.

THE PARTIES

Fresenius

2. Fresenius is a Delaware limited liability company with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047. Fresenius Kabi USA, LLC was formerly known as APP Pharmaceuticals, LLC.

Emcure

3. Upon information and belief, Defendant Emcure Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, with its principal place of business at Emcure House, T 184, M.I.D.C., Bhosari, Pune, India 411 026.

4. Upon information and belief, Defendant Emcure Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in 21/B Cotters Lane, East Brunswick, New Jersey 08816.

5. Upon information and belief, Defendant Emcure Pharmaceuticals USA, Inc. is a subsidiary of and is controlled by Emcure Pharmaceuticals Ltd.

6. Upon information and belief, both Emcure Pharmaceuticals Ltd. and Emcure Pharmaceuticals USA, Inc. submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 206408 (“the Emcure ANDA”).

JURISDICTION AND VENUE

Subject Matter Jurisdiction

7. This action for patent infringement arises under 35 U.S.C. § 271.

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

Personal Jurisdiction Over Emcure

9. Upon information and belief, this Court has personal jurisdiction over Defendant Emcure Pharmaceuticals Ltd. because Emcure Pharmaceuticals Ltd., through its subsidiaries, affiliates and/or agents, including Defendant Emcure Pharmaceuticals USA, Inc., (1) conducts business in this Judicial District; (2) has engaged in continuous and systematic contacts with New Jersey and/or purposefully availed itself of this forum by, among other things, marketing, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Emcure pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities and (3) has sought approval from the FDA to market and sell its proposed generic Diprivan product throughout the United States, including in New Jersey. Upon information and belief, Emcure Pharmaceuticals Ltd. uses its subsidiaries Heritage Pharma Holdings, Inc. and Heritage Pharmaceuticals Inc. as its sales and marketing infrastructure in the United States. Upon information and belief, Heritage Pharma Holdings, Inc., a wholly-owned subsidiary of Emcure Pharmaceuticals Ltd., maintains a principal place of business in Eatontown, New Jersey. Upon information and belief, Heritage Pharmaceuticals Inc., an indirect subsidiary of Emcure Pharmaceuticals Ltd. and a wholly-owned subsidiary of Heritage Pharma Holdings, Inc., maintains a principal place of business in Eatontown, New Jersey. Upon information and belief, Defendant Emcure Pharmaceuticals Ltd. also has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Fresenius, which manufactures Diprivan[®] for sale and use throughout the United States, including the State of New Jersey.

10. Upon information and belief, this Court has personal jurisdiction over Defendant Emcure Pharmaceuticals USA, Inc. because Emcure Pharmaceuticals USA, Inc. (1) is incorporated in and has its principal place of business in this Judicial District; (2) conducts business in this Judicial District; (3) has engaged in continuous and systematic contacts with New Jersey and/or purposefully availed itself of this forum by, among other things, marketing, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, Emcure pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities and (4) has sought approval from the FDA to market and sell its proposed generic Diprivan® product throughout the United States, including in New Jersey. Upon information and belief, Defendant Emcure Pharmaceuticals USA, Inc. also has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Fresenius, which manufactures Diprivan® for sale and use throughout the United States, including the State of New Jersey.

11. Additionally, Emcure has been previously sued for patent infringement in this district and did not contest personal jurisdiction. *See Cephalon, Inc. v. Emcure Pharmaceuticals, Ltd.*, C.A. No. 14-335-GMS, D. I. 9. Emcure has also purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in lawsuits filed in this Court. *See Id.*

Venue

12. Venue is proper in this Judicial District under 28 U.S.C. § 1391 and 1400(b).

BACKGROUND

The Patent-in-Suit: United States Patent No. 8,476,010

13. The '010 patent, entitled "Propofol Formulations with Non-Reactive Container Closures," was duly and lawfully issued on July 2, 2013 to inventors Neil P. Desai, Andrew

Yang, and Sherry Xiaopei Ci. The named inventors assigned the '010 patent to APP Pharmaceuticals, LLC, which later changed its name to Fresenius Kabi USA, LLC.

Accordingly, Fresenius is the owner of all rights, title, and interest in the '010 patent. The '010 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as "The Orange Book" ("Orange Book") with respect to Diprivan[®]. The '010 patent will expire on June 1, 2025. A true and accurate copy of the '010 patent is attached hereto as Exhibit A.

The Diprivan[®] Drug Product

14. Fresenius currently sells, promotes, distributes, and markets Diprivan[®] (propofol) injectable emulsion in the United States.

15. Diprivan[®] is indicated, generally speaking, for the induction and maintenance of general anesthesia and sedation in certain patient populations.

16. Fresenius holds an approved New Drug Application ("NDA") No. 19627 under Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a) in connection with the Diprivan[®] 1% (propofol) injectable emulsion product containing 10 mg propofol per 1 ml of emulsion.

The Emcure ANDA

17. Emcure filed with the FDA an ANDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use, offer for sale, sell in and import into the United States a propofol injectable emulsion containing 10mg propofol per 1 ml of emulsion formulation, in 20 mL, 50 mL and 100 mL vials, that Emcure asserts is a generic copy of Diprivan[®] ("Emcure's generic Diprivan[®] products") prior to the expiration of the '010 patent.

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