

**UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

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

Delaware 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 Delaware. 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., is a corporation organized and existing under the laws of Delaware. Upon information and belief, Heritage Pharmaceuticals Inc., an indirect subsidiary of Emcure Pharmaceuticals Ltd. and a wholly-owned subsidiary of Heritage Pharma Holdings, Inc., is a corporation organized and existing under the laws of Delaware. 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 Delaware.

10. Upon information and belief, this Court has personal jurisdiction over Defendant Emcure Pharmaceuticals USA, Inc. because Emcure Pharmaceuticals USA, Inc. (1) conducts business in this Judicial District; (2) has engaged in continuous and systematic contacts with Delaware 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 Delaware. 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 Delaware.

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.

18. The FDA assigned the Emcure ANDA the number 206408.

19. Upon information and belief, Emcure filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III), a certification that Emcure would not launch its generic Diprivan[®] products until after the expiration of U.S. Patents Nos. 5,714,520; 5,731,355; 5,731,356 and 5,908,869 (“the ’520, ’355, ’356, and ’869 patents”).

20. The ’520, ’355, ’356, and ’869 patents have an expiration date of March 22, 2015 and have pediatric exclusivity with the FDA through September 22, 2015.

21. Emcure filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '010 patent are invalid, unenforceable and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Emcure's generic Diprivan[®] products ("Emcure's Paragraph IV Certification"). Emcure notified Fresenius of this certification, in a letter dated July 23, 2014 sent by U.S. Mail ("Emcure Notice Letter").

22. In the Emcure Notice Letter, Emcure offered Fresenius confidential access to ANDA No. 206408 on terms and conditions set forth in an attached "Offer of Confidential Access" ("OCA"). The initial OCA provided by Emcure contained various terms and conditions, several of which went above and beyond protections typically afforded in a protective order. For instance, the initial Emcure OCA barred Fresenius in-house counsel from access to the Emcure ANDA.

23. Fresenius and Emcure proceeded to negotiate the provisions of the OCA, and a final version of the OCA was executed by both parties on August 18, 2014 which allowed certain Fresenius in-house counsel access to ANDA No. 206408.

24. On August 25, 2014, Fresenius received certain abbreviated portions of ANDA No. 206408 from Emcure, pursuant to the OCA.

25. On September 4, 2014, after reviewing the sections of ANDA No. 206408 that were provided by Emcure, Fresenius requested further documents and information concerning Emcure's proposed generic Diprivan[®] product, including a complete production of the Emcure ANDA. As of the filing of this Complaint, Emcure has begun producing responsive documents, including a production of its voluminous ANDA which was not received until September 5, 2014. Fresenius's counsel has not yet had sufficient time to review all of these documents and other relevant information remains unproduced.

26. Given the 45-day statutory deadline to file suit set forth in 21 U.S.C. § 355(j)(5)(B)(iii) and due to the limited information Fresenius has received from Emcure to date, Fresenius turns to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to further confirm their allegations of infringement and to present to the Court evidence that Emcure's generic Diprivan[®] products fall within the scope of one or more claims of the '010 patent.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,476,010 BY EMCURE

27. The allegations of paragraphs 1-26 are realleged and incorporated herein by reference.

28. The use of Emcure's generic Diprivan[®] products is covered by one or more claims of the '010 patent.

29. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Emcure's generic Diprivan[®] products would infringe one or more claims of the '010 patent.

30. Emcure has infringed the '010 patent by submitting and maintaining the Emcure ANDA before the FDA seeking approval to market Emcure's generic Diprivan[®] products containing propofol before the expiration of the '010 patent.

31. Upon information and belief, Defendants Emcure Pharmaceuticals USA, Inc. and Emcure Pharmaceuticals Ltd. acted in concert and actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the submission and maintenance of the Emcure ANDA to the FDA.

32. Defendants Emcure Pharmaceuticals USA, Inc. and Emcure Pharmaceuticals Ltd. induced the infringement of the '010 patent by actively and knowingly aiding and abetting the preparation, submission, and maintenance of Emcure's ANDA with the Paragraph IV Certification and in the preparation to sell Emcure's generic Diprivan[®] product in the United States.

33. Emcure was aware of the '010 patent when engaging in these knowing and purposeful activities and was aware that filing Emcure's ANDA with the Paragraph IV Certification with respect to the '010 patent constituted an act of infringement of the '010 patent.

34. Use of Emcure's generic Diprivan[®] products in accordance with and as directed by Emcure's proposed labeling for that product would infringe one or more claims of the '010 patent.

35. Upon information and belief, Emcure intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Emcure's generic Diprivan[®] products with its proposed labeling immediately and imminently upon approval of the Emcure ANDA.

36. Upon information and belief, Emcure plans and intends to, and will, actively induce infringement of the '010 patent when the Emcure ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

37. Upon information and belief, Emcure knows that Emcure's generic Diprivan[®] product and the proposed labeling for Emcure's generic Diprivan[®] product is especially made or adapted for use in infringing the '010 patent and that Emcure's generic Diprivan[®] product and the proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Emcure plans and intends to, and will, contribute to the infringement of the '010 patent immediately and imminently upon approval of the Emcure ANDA.

38. The foregoing actions by Emcure constitute and/or would constitute infringement of the '010 patent, active inducement of infringement of the '010 patent and/or contribution to the infringement by others of the '010 patent.

39. Upon information and belief, Emcure acted without a reasonable basis for believing that it would not be liable for infringing the '010 patent, actively inducing infringement of the '010 patent, and/or contributing to the infringement by others of the '010 patent.

40. Fresenius will be substantially and irreparably harmed by Emcure's infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Emcure is not enjoined from the commercial manufacture, use, offer to sell, sale in, and importation into the United States of Emcure's generic Diprivan[®] products.

41. Emcure's activities render this case an exceptional one, and Fresenius is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Fresenius respectfully requests the following relief:

- a. A judgment that Emcure's submission of the Emcure ANDA No. 206408 infringes one or more claims of the '010 patent and that the making, using, offering to sell, or selling in the United States, or importing into the United States of Emcure's generic Diprivan[®] products prior to the expiration of the '010 patent will infringe, actively induce infringement, and/or contribute to the infringement of one or more claims of the patent;
- b. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Emcure ANDA No. 206408 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, or any product or compound the use of which infringes the '010 patent, shall be a date that is not earlier than the expiration of the patent;
- c. An Order permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Emcure's generic Diprivan[®] products, or any other product or compound the use of which infringes the '010 patent, or inducing or contributing to the infringement of the '010 patent until after the expiration of the patent;
- d. An Order enjoining Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of the Emcure ANDA No. 206408 before the expiration of the '010 patent;

e. An award of Plaintiff's damages or other monetary relief to compensate Plaintiff if Defendants engage in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Defendants' generic Diprivan[®] products, or any product or compound the use of which infringes the '010 patent, or the inducement or contribution of the foregoing, prior to the expiration of the patent in accordance with 35 U.S.C. § 271(e)(4)(C);

f. A judgment that this is an exceptional case and awarding Plaintiff its attorneys' fees under 35 U.S.C. § 285;

g. An award of Plaintiff's reasonable costs and expenses in this action; and

h. An award of any further and additional relief to Plaintiff as this Court deems just and proper.

Dated: September 8, 2014

Respectfully submitted,

FARNAN LLP

/s/ Brian E. Farnan

Brian E. Farnan(Bar No. 4089)

919 North Market Street

12th Floor

Wilmington, DE 19801

Phone: 302-777-0300

Fax: 302-777-0301

bfarnan@farnanlaw.com

Of Counsel:

Daryl L. Wiesen

John T. Bennett

Sundar Subramanyam

Srikanth Reddy

Jennifer L. Ford

Todd Marabella

GOODWIN PROCTER LLP

Exchange Place

53 State Street

Boston, MA 02109

(617) 570-1000

(617) 523-1231 (fax)

DWiesen@goodwinprocter.com

JBennett@goodwinprocter.com

SSubramanyam@goodwinprocter.com

SReddy@goodwinprocter.com

JFord@goodwinprocter.com

TMarabella@goodwinprocter.com

Attorneys for Plaintiff

Fresenius Kabi USA, LLC