

BLANK ROME LLP
A Pennsylvania LLP
Stephen M. Orlofsky
Gary J. Ruckelshaus
New Jersey Resident Partners
301 Carnegie Center, 3rd Floor
Princeton, New Jersey 08540
Tel: (609) 750-7700
Fax: (609) 750-7701
gruckelshaus@blankrome.com
*Attorneys for Defendants Emcure Pharmaceuticals
Ltd. and Heritage Pharma Labs Inc.*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

HELSINN HEALTHCARE S.A. and ROCHE
PALO ALTO LLC,

Plaintiffs,

vs.

FRESENIUS KABI USA, LLC, EMCURE
PHARMACEUTICALS LIMITED, and
EMCURE PHARMACEUTICALS USA, INC.,

Defendants.

Civil Action No.: 15-7015 (MLC)(DEA)

**ANSWER AND COUNTERCLAIMS OF
HERITAGE PHARMA LABS INC. (f/k/a
EMCURE PHARMACEUTICALS USA,
INC.) AND EMCURE
PHARMACEUTICALS LTD.**

Filed Electronically

Defendants Emcure Pharmaceuticals Ltd. ("Emcure Ltd.") and Heritage Pharma Labs Inc. (formerly known as Emcure Pharmaceuticals USA, Inc.) ("HPL" and collectively, "Emcure"), by their attorneys, answer the amended complaint (the "Complaint") filed by Plaintiffs Helsinn Healthcare S.A. ("Helsinn") and Roche Palo Alto LLC ("Roche") (collectively "Plaintiffs") as follows:

AS TO THE PARTIES

1. Helsinn is a Swiss corporation having its principal place of business at Via Pian Scairolo, 9, CH-6912 Lugano-Pazzallo, Switzerland.

ANSWER

Emcure is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1 of the Complaint, and therefore, denies same.

2. Roche is a company, organized and existing under the laws of the State of Delaware, having a principal place of business at One DNA Way, South San Francisco, California 94080-4990.

ANSWER

Emcure is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2 of the Complaint, and therefore, denies same.

3. Upon information and belief, Defendant Fresenius is a corporation organized and existing under the laws of Delaware, having a principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

ANSWER

The allegations contained in this paragraph of the Complaint are not directed to Emcure; however, to the extent that any answer is required from these answering defendants, Emcure is without sufficient information to admit or deny such allegations and therefore denies same.

4. Upon information and belief, Defendant Fresenius develops, manufactures, imports, markets, distributes, and/or sells generic pharmaceutical versions of branded products for sale and use throughout the United States, including in the State of New Jersey.

ANSWER

The allegations contained in this paragraph of the Complaint are not directed to Emcure; however, to the extent that any answer is required from these answering defendants, Emcure is without sufficient information to admit or deny such allegations and therefore denies same.

5. Upon information and belief, Defendant Emcure Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at T-184, M.L.D.C. Bhosari, Pune, Maharashtra 411026, Pune, India.

ANSWER

Emcure admits that Emcure Ltd. is a corporation organized and existing under the laws of India and has a place of business located at Emcure House, T 184, M.L.D.C., Bhosari, Pune, 411 026, India, but otherwise denies the allegations of Paragraph 5 of the Complaint.

6. Upon information and belief, Defendant Emcure Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 21-B Cotters Lane, East Brunswick, New Jersey 08816.

ANSWER

Emcure denies the allegations of Paragraph 6 of the Complaint as stated. By way of further response, Emcure states that, in August 2014, Emcure Pharmaceuticals USA, Inc. filed an Amended and Restated Certificate of Incorporation with the New Jersey Secretary of State, which effectively changed its name to “Heritage Pharma Labs Inc.” (“HPL”). By way of further response, Emcure admits that HPL is a corporation organized and existing under the laws of New Jersey with a principal place of business at 21/B Cotters Lane, East Brunswick, New Jersey 08816.

7. Upon information and belief, Emcure Inc. is a wholly-owned subsidiary and agent of Defendant Emcure Ltd.

ANSWER

Emcure admits that Emcure Ltd. is the ultimate parent of HPL. Emcure denies the remaining allegations of Paragraph 7 of the Complaint.

8. Upon information and belief, in August 2014, Emcure Inc. filed an Amended and Restated Certificate of Incorporation with the New Jersey Secretary of State, which effectively changed its name to “Heritage Pharma Labs, Inc.”

ANSWER

Emcure admits the allegations of Paragraph 8 of the Complaint.

9. Upon information and belief, Emcure Ltd. has appointed Dr. Pankaj Dave of Emcure Inc., 21-B Cotters Lane, East Brunswick, New Jersey 08816, as its agent in New Jersey authorized to accept service of process for this action.

ANSWER

Emcure admits that HPL is the United States agent for Emcure Ltd. with respect to ANDA No. 202951. Emcure denies the remaining allegations of Paragraph 9 of the Complaint.

10. Upon information and belief, Emcure Ltd. and Emcure Inc. have common officers and directors.

ANSWER

Emcure admits that Emcure Ltd. is the ultimate parent of HPL and that there are common officers and directors.

11. Upon information and belief, Emcure Ltd., by itself or through its wholly owned subsidiary and agent Emcure Inc., develops, manufactures, and imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in this Judicial District. Upon information and belief, Emcure Ltd., by itself or through its wholly-owned subsidiary and agent Emcure Inc., markets, distributes, and/or sells generic pharmaceutical versions of branded products throughout the United States, including in the State of New Jersey.

ANSWER

Emcure admits that HPL and Emcure Ltd. are in a business that focuses on pharmaceutical products. Emcure denies the remaining allegations of Paragraph 11 of the Complaint.

AS TO THE PATENT-IN-SUIT

12. This is a civil action concerning the infringement of United States Patent No. 7,947,724 (“the ’724 patent”), United States Patent No. 7,947,725 (“the ’725 patent”), United States Patent No. 7,960,424 (“the ’424 patent”), United States Patent No. 8,598,219 (“the ’219 patent”), and United States Patent No. 8,729,094 (“the ’094 patent”). This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 et seq., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER

Paragraph 12 of the Complaint states legal conclusions to which no response is required. To the extent any response is required, Emcure admits that the Complaint purports to assert an action against Emcure based on a technical act of alleged patent infringement pursuant to the Patent Laws of the United States.

AS TO JURISDICTION AND VENUE

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER

Paragraph 13 of the Complaint states legal conclusions to which no response is required. To the extent any response is required, Emcure states that it does not contest subject matter jurisdiction in this District for the limited purpose of this action only.

14. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201-02 because this case is an actual controversy within the Court's jurisdiction.

ANSWER

Paragraph 14 of the Complaint states legal conclusions to which no response is required. To the extent any response is required, Emcure states that it does not contest subject matter jurisdiction in this District for the limited purpose of this action only.

15. Venue is proper in this Court as to each of the Defendants pursuant to 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b).

ANSWER

Paragraph 15 of the Complaint states legal conclusions to which no response is required. To the extent any response is required, Emcure states that it does not contest venue in this District for the limited purpose of this action only.

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