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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUMITOMO DAINIPPON PHARMA CO., LTD. and SUNOVION PHARMACEUTICALS INC., Plaintiffs, v. EMCURE PHARMACEUTICALS LIMITED and EMCURE PHARMACEUTICALS USA, INC., Defendants.	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Sumitomo Dainippon Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. (collectively, "Plaintiffs"), for their Complaint against Defendants Emcure Pharmaceuticals Limited (hereinafter "Emcure Ltd.") and Emcure Pharmaceuticals USA, Inc. (hereinafter "Emcure Inc.") (together with Emcure Ltd., "Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff Sumitomo Dainippon Pharma Co., Ltd. is a Japanese corporation, having a primary place of business at 6-8, Doshomachi 2-chome, Chuo-ku, Osaka, Osaka 541-0045, Japan.

2. Plaintiff Sunovion Pharmaceuticals Inc. is a corporation having a principal place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

3. 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.I.D.C. Bhosari, Pune, Maharashtra 411026, Pune, India.

4. 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.

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

6. 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."

7. 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.

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

9. 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.

JURISDICTION AND VENUE

10. This is a civil action for infringement of United States Patent No. 5,532,372 ("the '372 patent"). This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

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

12. Venue is proper in this Court under 28 U.S.C. §§ 1391(b)-(d) and 1400(b).

13. This Court has personal jurisdiction over Defendants because, *inter alia*, they have committed, or aided, abetted, contributed to, or participated in the commission of, tortious acts of patent infringement, including acts in the State of New Jersey, that have led to foreseeable harm and injury to Plaintiffs in the State of New Jersey. Defendants sent two

substantially identical letters to Plaintiffs, one dated December 2, 2014 and one dated December 3, 2014 ("Notice Letters").

14. Defendants' Notice Letters state that Defendants filed Abbreviated New Drug Application ("ANDA") No. 208058 seeking approval from the United States Food and Drug Administration ("FDA") to commercially manufacture, use, market or sell generic lurasidone hydrochloride tablets 20 mg, 40 mg, 60 mg, and 80 mg in the United States (including, upon information and belief, in the State of New Jersey), prior to the expiration of the '372 patent.

15. Defendants' Notice Letters authorized Dr. Pankaj Dave of Emcure Inc. to accept service of process for Emcure Ltd.

16. This Court also has personal jurisdiction over Defendants because, upon information and belief, *inter alia*: (1) Emcure Inc. is a corporation organized and existing under the laws of the State of New Jersey; (2) Emcure Inc. has its principal place of business in the State of New Jersey, and does business in the State of New Jersey; (3) Defendants have affiliations with the State of New Jersey that are pervasive, continuous, and systematic, including the direct marketing, distribution, or sale of generic pharmaceutical drugs within the State of New Jersey and to residents of the State of New Jersey by Emcure Ltd. itself or through its wholly-owned subsidiary and agent Emcure Inc.; and (4) Defendants have previously submitted to the jurisdiction of this Court and have availed themselves of the legal protections of the State of New Jersey, having consented to jurisdiction in this Court, *see, e.g., Genzyme Corporation, et al. v. Emcure Pharmaceuticals USA Inc., et al.*, No. 14-cv-5975 (D.N.J. December 2, 2014).

THE PATENT-IN-SUIT

17. Plaintiff Sunovion Pharmaceuticals Inc. holds approved New Drug Application ("NDA") No. 200603, under which the FDA granted approval for 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg lurasidone HCl tablets marketed in the United States under the trade name LATUDA®.

18. The LATUDA® (lurasidone HCl) tablets approved in NDA No. 200603 are indicated for the treatment of (1) depressive episodes associated with Bipolar I Disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate; and (2) the treatment of schizophrenia.

19. Plaintiff Sumitomo Dainippon Pharma Co., Ltd. owns the '372 patent titled "Imide derivatives, and their production and use." The '372 patent was duly and legally issued on July 2, 1996. A copy of the '372 patent is attached as Exhibit A.

20. The '372 patent is listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for LATUDA®.

DEFENDANTS' ANDA AND NOTICE LETTERS

21. Upon information and belief, Defendants submitted ANDA No. 208058 ("Defendants' ANDA") to the FDA, including a certification with respect to the '372 patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) ("Paragraph IV Certification"), seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of generic lurasidone hydrochloride tablets 20 mg, 40 mg, 60 mg, and 80 mg (collectively, "ANDA Products") prior to expiration of the '372 patent.

22. Upon information and belief, on or about December 2, 2014 and December 3, 2014, Defendants sent the Defendants' Notice Letters to Plaintiffs. In the Notice Letters, Defendants represented that they filed ANDA No. 208058 for the ANDA Products, including their Paragraph IV Certification with respect to the '372 patent, and that Defendants sought approval of ANDA No. 208058 prior to the expiration of the '372 patent. Plaintiffs first received one of the Defendants' Notice Letters on December 4, 2014.

23. Plaintiffs commenced this action within 45 days of the date of receipt of the first of the Defendants' Notice Letters.

DEFENDANTS' INFRINGEMENT OF THE '372 PATENT

24. Plaintiffs repeat and re-allege paragraphs 1-23 as if fully set forth herein.

25. By seeking approval of their ANDA No. 208058 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Products prior to the expiration of the '372 patent, Defendants have infringed the '372 patent under 35 U.S.C. § 271(e)(2)(A).

26. Defendants are jointly and severally liable for infringement of the '372 patent under 35 U.S.C. § 271(e)(2)(A). This is because, upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of Defendants' ANDA seeking to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Products prior to the expiration of the '372 patent.

27. If Defendants manufacture, use, offer to sell, or sell within the United States, or import into the United States, the ANDA Products prior to the expiration of the '372

patent, Defendants will infringe one or more claims of this patent under 35 U.S.C. § 271(a), (b), or (c).

28. Plaintiffs are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Defendants' ANDA be a date that is not earlier than the expiration date of the '372 patent, or any later expiration of any patent term extension or exclusivity for the '372 patent to which Plaintiffs are or become entitled.

29. Plaintiffs are entitled to a declaration that, if Defendants commercially manufacture, use, offer for sale, or sell the ANDA Products within the United States, import the ANDA Products into the United States, or induce or contribute to such conduct, Defendants will infringe the '372 patent under 35 U.S.C. § 271(a), (b), or (c).

30. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

Plaintiffs request that the Court grant the following relief:

A. An Order adjudging and decreeing that Defendants have infringed the '372 patent by submitting Defendants' ANDA to the FDA;

B. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283 restraining and enjoining Defendants, their directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with them, from infringing the '372 patent by the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product claimed in the'372 patent;

C. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of Defendants' ANDA be a date that is not earlier than the expiration date of the '372 patent, or any later expiration of any patent term extension or exclusivity for the'372 patent to which Plaintiffs are or become entitled;

D. That Plaintiffs be awarded monetary relief to the extent Defendants commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States any product that infringes or induces or contributes to the infringement of the '372, patent within the United States prior to the expiration of the '372 patent, including any later expiration of any patent term extension or exclusivity for the patent to which Plaintiffs are or become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest;

E. An Order be entered that this case is exceptional, and that Plaintiffs are entitled to reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

F. Such other and further relief as the Court may deem just and proper.

Dated: January 14, 2015

Respectfully submitted,

By: s/ Charles M. Lizza

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