UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff, v. EMCURE PHARMACEUTICALS LTD., HERITAGE PHARMA LABS INC. (f/k/a EMCURE PHARMACEUTICALS USA, INC.), and HERITAGE PHARMACEUTICALS, INC., Defendants.	)	Civil Action No. 1:15-CV-1244

COMPLAINT

Plaintiff Eli Lilly and Company ("Lilly"), by its attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by defendant Emcure Pharmaceuticals Ltd. of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell its pemetrexed for injection, 500 mg/vial product ("Emcure's ANDA Product") prior to the expiration of U.S. Patent No. 7,772,209 ("the '209 patent").

2. By letter dated July 10, 2015 ("Emcure's Notice Letter"), Emcure Pharmaceuticals Ltd. notified Lilly that it had submitted to the FDA ANDA No. 208439 for Emcure's ANDA Product. Upon information and belief, Emcure's ANDA Product will be

marketed as a generic version of ALIMTA®, a chemotherapy agent developed and distributed by Lilly and used for the treatment of various types of cancer.

PARTIES

3. Lilly is a corporation organized and existing under the laws of the State of Indiana, having its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

4. Upon information and belief, Emcure Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Emcure House, T184, M.I.D.C., Bhosari, Pune, India 411 026.

5. Upon information and belief, Heritage Pharma Labs, Inc. ("Heritage Labs") is a corporation organized and existing under the laws of the State of New Jersey and has a principal place of business at 21-B Cotters Lane, East Brunswick, New Jersey 08816. Upon information and belief, Heritage Labs was formerly known as Emcure Pharmaceuticals USA, Inc., and is the same entity referred to in Emcure's Notice Letter as Emcure Pharmaceuticals USA, Inc.

6. Upon information and belief, Heritage Pharmaceuticals, Inc. ("Heritage Pharmaceuticals") is a corporation organized under the laws of the State of Delaware and has a principal place of business at 12 Christopher Way, Eatontown, NJ 07724.

7. Upon information and belief, Heritage Labs and Heritage Pharmaceuticals are wholly-owned subsidiaries of Heritage Pharma Holdings, Inc., which itself is a wholly-owned subsidiary of Emcure Pharmaceuticals Ltd. Upon information and belief, Emcure Pharmaceuticals Ltd., Heritage Labs, and Heritage Pharmaceuticals (collectively, "Emcure") are agents and/or alter egos of one another, operate in concert as integrated parts of the same

business group, and enter or have entered into agreements with each other that are nearer than arm's length, including with respect to the manufacture, importation, marketing, sale, and distribution of Emcure's ANDA Product.

JURISDICTION AND VENUE

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

9. Upon information and belief, Emcure Pharmaceuticals Ltd. is a generic pharmaceutical company in India engaged in developing, manufacturing and marketing a broad range of pharmaceutical products globally. Upon information and belief, a substantial number of these products are marketed throughout the United States, including in the State of Indiana. Upon information and belief, Emcure Pharmaceuticals Ltd. operates its sales, marketing, and distribution infrastructure in the United States through Heritage Labs and Heritage Pharmaceuticals.

10. Upon information and belief, Heritage Labs performs functions relating to Emcure's active pharmaceutical ingredient (API) and formulation research and development, API and formulation manufacturing, as well as marketing. Pankaj Dave, Ph.D., who is listed in Emcure's Notice Letter as the Senior Vice President, Regulatory Affairs, of Emcure Pharmaceuticals USA, Inc. (*i.e.*, of Heritage Labs), is designated in Emcure's Notice Letter as the agent of Emcure for service of process with respect to this litigation. Upon information and belief, Heritage Labs participated with Emcure in the preparation, review, and/or submission of ANDA No. 208439.

11. Upon information and belief, Heritage Pharmaceuticals is engaged in the acquisition, licensing, development, marketing, sale, and distribution of generic pharmaceutical

products for the U.S. prescription drug market on behalf of Emcure Pharmaceuticals Ltd. Upon information and belief, Emcure Pharmaceuticals Ltd. provides Heritage Pharmaceuticals with products for sale in the United States. Upon information and belief, those products are then marketed, sold, and distributed directly to retailers, including in Indiana, as well as to wholesalers who sell, with Emcure Pharmaceuticals Ltd.'s knowledge, Emcure Pharmaceuticals Ltd.'s products, including in Indiana. Upon information and belief, Heritage Pharmaceuticals will distribute Emcure's ANDA Product in the United States, including in Indiana, upon approval of ANDA No. 208439.

12. Upon information and belief, Emcure has previously used the process contemplated by the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

13. Upon information and belief, with knowledge of the Hatch-Waxman Act process, Emcure directed the Notice Letter to Lilly, an entity incorporated in Indiana, at its corporate headquarters in Indiana, and alleged in the Notice Letter that Lilly's '209 patent is invalid. Upon information and belief, Emcure knowingly and deliberately challenged Lilly's patent rights, and knew when it did so that it was triggering a forty-five-day period for Lilly to bring an action for patent infringement under the Hatch-Waxman Act. Moreover, upon information and belief, Emcure knew that other Hatch-Waxman Act infringement actions relating to the '209 patent had been brought and litigated in Indiana.

14. Because Lilly is incorporated in Indiana, the injury and consequences from Emcure's filing of ANDA No. 208439, challenging Lilly's patent rights, are suffered in Indiana. Upon information and belief, Emcure knew that it was deliberately challenging the patent rights of an Indiana entity and seeking to invalidate intellectual property held in Indiana and that the effects of any invalidation of the '209 patent would be felt by Lilly in Indiana.

15. Upon information and belief, if ANDA No. 208439 is approved, Emcure will directly or indirectly market and/or sell Emcure's ANDA Product within the United States, including in Indiana, consistent with Emcure's practices for the marketing and distribution of other generic pharmaceutical products on its own or through its affiliates. Upon information and belief, Emcure and/or its affiliates regularly do business in Indiana, and their practices with other generic pharmaceutical products have involved placing Emcure products into the stream of commerce for distribution throughout the United States, including in Indiana. Upon information and belief, Emcure's generic pharmaceutical products are used and/or consumed within and throughout the United States, including Indiana.

16. Upon information and belief, Emcure and its affiliates derive substantial revenue from generic pharmaceutical products that are used and/or consumed within Indiana, and which are manufactured by Emcure or its affiliates and/or for which Emcure is the named applicant on approved ANDAs. Upon information and belief, various products for which Emcure, or its affiliates, is the named applicant on approved ANDAs are available at pharmacies in Indiana.

17. Upon information and belief, if ANDA No. 208439 is approved, Emcure's ANDA Product, under the direction and control of physicians practicing in Indiana, will be administered to patients in Indiana. These activities, as well as Emcure's marketing, selling,

and/or distributing of Emcure's ANDA Product, would have a substantial effect within Indiana and would constitute infringement of Lilly's patent in the event that Emcure's ANDA Product is approved before the '209 patent expires.

18. For the reasons described above, among others, this Court may properly exercise personal jurisdiction over Emcure Pharmaceuticals Ltd., Heritage Labs, and Heritage Pharmaceuticals.

19. Alternatively, if the exercise of personal jurisdiction over Emcure Pharmaceuticals Ltd. in this Court is not held to be proper, then, upon information and belief, Emcure Pharmaceuticals Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and there is therefore personal jurisdiction over Emcure Pharmaceuticals Ltd. in this Court pursuant to Fed. R. Civ. P. 4(k)(2).

20. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

21. ALIMTA® is indicated (in combination with cisplatin) (a) for the treatment of patients with malignant pleural mesothelioma, or (b) for the initial treatment of locally advanced or metastatic nonsquamous non-small cell lung cancer. ALIMTA® also is indicated as a single-agent for the treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer after prior chemotherapy. ALIMTA® also is indicated for maintenance treatment of patients with locally advanced or metastatic nonsquamous non-small cell lung cancer whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.

22. Lilly sells ALIMTA® in the United States pursuant to a New Drug Application that has been approved by the FDA.

23. The ’209 patent, titled “Novel Antifolate Combination Therapies,” was duly and legally issued on August 10, 2010. The ’209 patent is attached as Exhibit A.

24. Lilly is the assignee of the ’209 patent. As set forth in greater detail in the ’209 patent, one or more claims of the ’209 patent, incorporated by reference herein, cover a method of administering pemetrexed disodium to a patient in need thereof that also involves administration of folic acid and vitamin B_{12}.

25. An actual case or controversy exists between Lilly and Emcure with respect to infringement of the ’209 patent.

COUNT

(Infringement of U.S. Patent No. 7,772,209)

26. Lilly incorporates each of the preceding paragraphs as if fully set forth herein.

27. Upon information and belief, Emcure’s ANDA Product contains pemetrexed disodium.

28. Upon information and belief, the use of Emcure’s ANDA Product in accordance with Emcure’s proposed labeling for Emcure’s ANDA Product involves administration of folic acid and vitamin B_{12}.

29. Upon information and belief, the use of Emcure’s ANDA Product in accordance with and as directed by Emcure’s proposed labeling for that product will infringe one or more claims of the ’209 patent.

30. Upon information and belief, Emcure filed as a part of ANDA No. 208439 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the ’209 patent, asserting that the claims of the ’209

patent are invalid and/or not infringed by the manufacture, use, offer for sale, or sale of Emcure's ANDA Product.

31. The purpose of ANDA No. 208439 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Emcure's ANDA Product prior to the expiration of the '209 patent.

32. Emcure's submission of ANDA No. 208439 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Emcure's ANDA Product prior to the expiration of the '209 patent is an act of infringement of the '209 patent under 35 U.S.C. § 271(e)(2)(A).

33. Upon information and belief, Emcure intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Emcure's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 208439, *i.e.*, prior to the expiration of the '209 patent.

34. Upon information and belief, Emcure has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Emcure has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Emcure's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 208439.

35. Upon information and belief, Emcure plans and intends to, and will, actively induce infringement of the '209 patent when Emcure's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

36. Upon information and belief, Emcure knows that Emcure's ANDA Product is especially made or adapted for use in infringing the '209 patent, and that Emcure's

ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Emcure plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 208439.

37. The foregoing actions by Emcure constitute and/or will constitute infringement of the '209 patent, active inducement of infringement of the '209 patent, and contribution to the infringement by others of the '209 patent.

38. Upon information and belief, Emcure is without a reasonable basis for believing that it will not be liable for infringing the '209 patent, actively inducing infringement of the '209 patent, and/or contributing to the infringement by others of the '209 patent.

39. Unless Emcure is enjoined from infringing the '209 patent, actively inducing infringement of the '209 patent, and contributing to the infringement by others of the '209 patent, Lilly will suffer irreparable injury. Lilly has no adequate remedy at law.

WHEREFORE, Lilly requests the following relief:

(a) A judgment that Emcure has infringed the '209 patent and/or will infringe, actively induce infringement of, and/or contribute to infringement by others of the '209 patent;

(b) A judgment ordering that the effective date of any FDA approval for Emcure to make, use, offer for sale, sell, market, distribute, or import Emcure's ANDA Product, or any product the use of which infringes the '209 patent, be not earlier than the expiration date of the '209 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Emcure, and all persons acting in concert with Emcure, from making, using, selling, offering for sale, marketing, distributing, or importing Emcure's ANDA Product, or any product the use of which infringes the '209 patent, or the inducement of or contribution to any of the foregoing, prior to the

expiration date of the ’209 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing of Emcure’s ANDA Product, or any product the use of which infringes the ’209 patent, prior to the expiration date of the ’209 patent, infringes, will infringe, will actively induce infringement of, and/or will contribute to the infringement by other of the ’209 patent;

(e) A declaration that this is an exceptional case and an award of attorneys’ fees pursuant to 35 U.S.C. § 285;

(f) An award of Lilly’s costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Dated: August 7, 2015

Respectfully submitted,

/s/ Jan M. Carroll

Jan M. Carroll, No. 4187-49
BARNES & THORNBURG LLP
11 South Meridian Street
Indianapolis, IN 46204
(317) 236-1313
jan.carroll@btlaw.com

Attorney for Plaintiffs
Eli Lilly and Company

OF COUNSEL:
Bruce R. Genderson
Adam L. Perlman
Ellen E. Oberwetter
Dov P. Grossman
David M. Krinsky
Christopher T. Berg

WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
(202) 434-5000