IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff, v. MYLAN LABORATORIES LIMITED, MYLAN INC., and MYLAN PHARMACEUTICALS INC. Defendants.	)	Civil Action No. 1:15-CV-1083

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 Mylan Laboratories Limited ("Mylan Labs") of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell its pemetrexed disodium for injection, 500 mg/vial product ("Mylan's ANDA Product") prior to the expiration of U.S. Patent No. 7,772,209 ("the '209 patent").

2. By letter dated June 29, 2015 ("Mylan's Notice Letter"), Mylan Labs notified Lilly that it had submitted to the FDA ANDA No. 20-3628 for Mylan's ANDA Product. Upon information and belief, Mylan'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, Mylan Labs is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500034, Hyderabad, India.

5. Upon information and belief, Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") is a corporation organized and existing under the laws of the State of West Virginia and has a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

6. Upon information and belief, Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania and has a principal place of business at Robert J. Coury Global Center, 1000 Mylan Blvd., Canonsburg, Pennsylvania 15317.

JURISDICTION AND VENUE

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

8. Upon information and belief, Mylan Inc. is one of the leading generic and specialty pharmaceutical companies with over 20,000 employees in its family of companies, and markets more than 1,300 separate products in approximately 140 different countries and territories. Upon information and belief, a substantial number of these products are marketed throughout the United States, including in the State of Indiana.

9. Upon information and belief, Mylan Pharmaceuticals is a subsidiary of Mylan Inc. and serves as Mylan Inc.'s primary U.S. pharmaceutical research, development, manufacturing, marketing and distribution subsidiary. Mylan Pharmaceuticals has at least four employees who live in Indiana, including two members of the company's eight-to-ten member National Account Manager group, which manages Mylan Inc.'s national sales relationships. Mylan Pharmaceuticals obtained a wholesaler drug license allowing it to sell its generic products in Indiana, and its Indiana sales include dozens of Mylan Inc.'s products, including at least some products that are manufactured by Mylan Labs. Mylan Pharmaceuticals sells Mylan Inc.'s products directly to retailers in Indiana as well as wholesalers, knowing that the wholesalers sell their products in Indiana. Mylan Pharmaceuticals also makes sales calls and directs promotional materials to residents in Indiana.

10. Upon information and belief, Mylan Labs, Mylan Inc.'s Indian subsidiary, is one of the world's largest manufacturers of active pharmaceutical ingredients (API), and manufactures and supplies low-cost API for Mylan Inc.'s products. Upon information and belief, Mylan Labs provides Mylan Inc. and/or Mylan Pharmaceuticals with products for sale in the United States, which are then sold and distributed directly to retailers in Indiana as well as to wholesalers who sell, with Mylan Labs' knowledge, Mylan Labs' products in Indiana.

11. Upon information and belief, Mylan Labs, Mylan Inc., and Mylan Pharmaceuticals (collectively, "Mylan") are agents of each other and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length. Mylan Inc.'s SEC Form 10-K states that Mylan Labs (which it refers to as "Mylan India") is "included within Rest of World in our Generics segment."

12. Upon information and belief, the agreements among Mylan Labs, Mylan Inc., and Mylan Pharmaceuticals include agreements that relate to the development, regulatory approval, marketing, sale, offer for sale, and distribution of pharmaceutical products throughout the United States, including in Indiana, of generic pharmaceuticals, including the infringing Mylan ANDA Product at issue. Mylan Inc.'s SEC Form 10-K describes Mylan Labs' manufacturing capabilities, including with respect to injectables (the product category to which, upon information and belief, Mylan's ANDA Product belongs). The 10-K further states that Mylan Labs "manufactures . . . FDF [finished dosage form] products that are marketed and sold to third parties by other Mylan operations around the world." Upon information and belief, Mylan and/or its affiliates maintain a broad distributorship network within Indiana and will utilize this network to market, sell, and/or distribute Mylan's ANDA Product in Indiana, if ANDA No. 20-3628 is approved.

13. Based on Mylan Labs' relationship with Mylan Inc. and Mylan Pharmaceuticals, this Court has attributed their contacts with Indiana to Mylan Labs with respect to at least one ANDA seeking approval to make a generic version of a Lilly drug product. *See Eli Lilly and Company v. Mylan Pharmaceuticals, Inc.*, No. 1:14-cv-00389-SEB-TAB, ECF No. 304 (S.D. Ind. Mar. 12, 2015).

14. Upon information and belief, Mylan 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. Indeed, Mylan Inc.'s SEC 10-K form states that "[a]s of December 31, 2014, approximately 120 injectable [Mylan] products have been filed and are pending ANDA approval for the U.S. market."

15. Upon information and belief, with knowledge of the Hatch-Waxman Act process, Mylan Labs 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, Mylan 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, Mylan knew that other Hatch-Waxman Act infringement actions relating to the '209 patent had been brought and litigated in Indiana.

16. Because Lilly is incorporated in Indiana, the injury and consequences from Mylan's filing of ANDA No. 20-3628, challenging Lilly's patent rights, are suffered in Indiana. Upon information and belief, Mylan 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.

17. Upon information and belief, if ANDA No. 20-3628 is approved, Mylan will directly or indirectly manufacture, market, and/or sell Mylan's ANDA Product within the United States, including in Indiana, consistent with Mylan's practices for the marketing and distribution of other generic pharmaceutical products on its own or through its affiliates. Upon information and belief, Mylan and/or its affiliates regularly do business in Indiana, and their practices with other generic pharmaceutical products have involved placing Mylan products into the stream of commerce for distribution throughout the United States, including in Indiana.

Upon information and belief, Mylan's generic pharmaceutical products are used and/or consumed within and throughout the United States, including Indiana.

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

19. Upon information and belief, if ANDA No. 20-3628 is approved, Mylan'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 Mylan's marketing, selling, and/or distributing of Mylan's ANDA Product, would have a substantial effect within Indiana and would constitute infringement of Lilly's patent in the event that Mylan's ANDA Product is approved before the '209 patent expires.

20. For the reasons described above, among others, this Court may properly exercise personal jurisdiction over Mylan Inc., Mylan Pharms, and Mylan Labs.

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

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

BACKGROUND

23. 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.

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

25. 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*** hereto.

26. 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}.

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

COUNT

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

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

29. Upon information and belief, Mylan's ANDA Product contains pemetrexed disodium.

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

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

32. Upon information and belief, Mylan filed as a part of ANDA No. 20-3628 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 Mylan's ANDA Product.

33. The purpose of ANDA No. 20-3628 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Product prior to the expiration of the '209 patent.

34. Mylan's submission of ANDA No. 20-3628 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan'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).

35. Upon information and belief, Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product

and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 20-3628, i.e., prior to the expiration of the '209 patent.

36. Upon information and belief, Mylan has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Mylan has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 20-3628.

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

38. Upon information and belief, Mylan knows that Mylan's ANDA Product is especially made or adapted for use in infringing the '209 patent, and that Mylan's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Mylan plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 20-3628.

39. The foregoing actions by Mylan 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.

40. Upon information and belief, Mylan 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.

41. Unless Mylan 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 Mylan 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 Mylan to make, use, offer for sale, sell, market, distribute, or import Mylan'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 Mylan, and all persons acting in concert with Mylan, from making, using, selling, offering for sale, marketing, distributing, or importing Mylan'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 Mylan'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: July 10, 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 Plaintiff
Eli Lilly and Company

OF COUNSEL:

Bruce R. Genderson
Adam L. Perlman
Ellen E. Oberwetter
Dov P. Grossman
David M. Krinsky
Andrew V. Trask
Christopher T. Berg
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
(202) 434-5000