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

ELI LILLY AND COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 1:14-cv-104-_____
	)	
GLENMARK GENERICS INC., USA,	)	
	)	
Defendant.	)	
	)	

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 Glenmark Generics Inc., USA ("Glenmark") of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of ALIMTA® prior to the expiration of U.S. Patent No. 7,772,209 ("the '209 patent"). ALIMTA® is a chemotherapy agent used for the treatment of various types of cancer.

2. By letter dated December 13, 2013 ("Glenmark's Notice Letter"), Glenmark notified Lilly that it had submitted to the FDA ANDA No. 205526 for Glenmark's pemetrexed disodium, Equivalent (EQ) 100 mg base/vial and Equivalent (EQ) 500 mg base/vial, injectable IV (infusion) products ("Glenmark's ANDA Products"). Glenmark's ANDA Products are generic versions of ALIMTA®.

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. Glenmark is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 750 Corporate Drive, Mahwah, New Jersey, 07430. Glenmark is in the business of offering for sale and selling generic drug products throughout the United States, including in the Southern District of Indiana.

JURISDICTION AND VENUE

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

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

7. This Court has personal jurisdiction over Glenmark because, among other things, Glenmark is in the business of distributing, selling, and offering to sell drug products throughout the United States, including in Indiana and the Southern District of Indiana; Glenmark is licensed as a wholesale drug distributor in Indiana; Glenmark derives substantial revenue from things sold, used, or consumed within Indiana and the Southern District of Indiana; for at least the past five years Glenmark has sold substantial quantities of drug products to Indiana's Medicaid program for use in Indiana and in the Southern District of Indiana; following any FDA approval of Glenmark's ANDA No. 205526, Glenmark intends to offer to sell and sell Glenmark's ANDA Products throughout the United States and within Indiana and the Southern District of Indiana; if Glenmark is permitted to sell Glenmark's ANDA Products in the United States prior to the expiration of the '209 patent, Glenmark will cause substantial injury to Lilly,

an Indiana corporation headquartered within the Southern District of Indiana, and Glenmark knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana; and Glenmark regularly does and solicits business in Indiana and the Southern District of Indiana, including the distribution and sale of drug products in Indiana and the Southern District of Indiana, and is engaged in a persistent, continuous, and systematic course of conduct in Indiana and the Southern District of Indiana.

BACKGROUND

8. 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.

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

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

11. 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}.

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

COUNT

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

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

14. Glenmark’s ANDA Products contain pemetrexed disodium.

15. The use of Glenmark’s ANDA Products in accordance with Glenmark’s proposed labeling for Glenmark’s ANDA Products involves administration of folic acid and vitamin B_{12}.

16. The use of Glenmark’s ANDA Products in accordance with and as directed by Glenmark’s proposed labeling for those products will infringe one or more claims of the ’209 patent.

17. Glenmark filed as a part of ANDA No. 205526 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Food, Drug and Cosmetic Act (“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, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Glenmark’s ANDA Products.

18. The purpose of ANDA No. 205526 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Glenmark’s ANDA Products prior to the expiration of the ’209 patent.

19. Glenmark’s submission of ANDA No. 205526 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of

Glenmark's ANDA Products 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).

20. Glenmark intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Glenmark's ANDA Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 205526, *i.e.*, prior to the expiration of the '209 patent.

21. Glenmark has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Glenmark has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Glenmark's ANDA Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 205526.

22. Glenmark plans and intends to, and will, actively induce infringement of the '209 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

23. Glenmark knows that Glenmark's ANDA Products are especially made or adapted for use in infringing the '209 patent, and that Glenmark's ANDA Products are not suitable for substantial noninfringing use. Glenmark plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 205526.

24. The foregoing actions by Glenmark 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.

25. Glenmark 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.

26. Unless Glenmark 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 Glenmark 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 Glenmark to make, use, offer for sale, sell, market, distribute, or import Glenmark's ANDA Products, 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 Glenmark, and all persons acting in concert with Glenmark, from making, using, selling, offering for sale, marketing, distributing, or importing Glenmark's ANDA Products, 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 Glenmark's ANDA Products, 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 others 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: January 23, 2014

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
Megan A. Hughes
Andrew V. Trask
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 2005
(202) 434-5000