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

ELI LILLY AND COMPANY,

Plaintiff,

v.

SUN PHARMACEUTICAL INDUSTRIES LTD. and SUN PHARMA GLOBAL FZE,

Defendants.

1 : 13 -cv- 1469 TWP -DML

Civil Action No. _____

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 defendants Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE 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. Except where otherwise noted, Sun Pharmaceutical Industries Ltd. and Sun Pharma Global FZE are referred to collectively herein as "Sun."

2. By letter dated August 2, 2013 ("Sun's Notice Letter"), Sun notified Lilly that it had submitted to the FDA ANDA No. 205238 for Sun's Pemetrexed Injection, 100

mg/vial, 500 mg/vial, and 1000 mg/vial products ("Sun's ANDA Products"). Upon information and belief, Sun's ANDA Products will be marketed as 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. Upon information and belief, Sun Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of the Republic of India, having a place of business at 17-B, Mahal Industrial Estate, Mahakali Caves Road, Andheri (E), Mumbai-400093. Upon information and belief, Sun Pharmaceutical Industries Ltd. is in the business of manufacturing, marketing, and selling generic drug products.

5. Upon information and belief, Sun Pharma Global FZE is a corporation organized and existing under the laws of the United Arab Emirates, having a place of business at Executive Suite # 43, Block Y, SAIF Zone, P.O. Box # 122304, Sharjah, U.A.E. Upon information and belief, Sun Pharma Global FZE is a wholly-owned subsidiary of Sun Pharmaceutical Industries Ltd.

JURISDICTION AND VENUE

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

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

8. This Court has personal jurisdiction over Sun Pharmaceutical Industries Ltd. because, upon information and belief, among other things: (1) Sun Pharmaceutical Industries Ltd. is in the business of manufacturing products which it and/or its affiliates or

subsidiaries distribute, sell, and offer to sell throughout the United States, including in Indiana and the Southern District of Indiana; (2) Sun Pharmaceutical Industries Ltd. derives substantial revenue from things sold, used, or consumed within Indiana and the Southern District of Indiana; (3) as part of its ordinary business practice of engaging in U.S. patent litigation, Sun Pharmaceutical Industries Ltd. has litigated ANDA cases in this District, including by asserting counterclaims; (4) following any FDA approval of ANDA No. 205238, Sun Pharmaceutical Industries Ltd. intends to distribute (directly and/or through affiliates or subsidiaries) Sun's ANDA Products within the Southern District of Indiana; (5) if Sun Pharmaceutical Industries Ltd. is permitted to sell Sun's ANDA Products in the United States prior to the expiration of the '209 patent, Sun Pharmaceutical Industries Ltd. will cause substantial injury to Lilly, an Indiana corporation headquartered within the Southern District of Indiana, and Sun Pharmaceutical Industries Ltd. knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana; and (6) directly and/or through its affiliates or subsidiaries, Sun Pharmaceutical Industries Ltd. 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, is engaged in and has maintained systematic and continuous business contacts within the State of Indiana and the Southern District of Indiana, and has purposefully availed itself of the benefits and protections of the laws of Indiana.

9. This Court has personal jurisdiction over Sun Pharma Global FZE because, upon information and belief, among other things: (1) Sun Pharma Global FZE is in the business of manufacturing products which it and/or its affiliates or subsidiaries distribute, sell, and offer to sell throughout the United States, including in Indiana and the Southern District of Indiana; (2) Sun Pharma Global FZE derives substantial revenue from things sold, used, or

consumed within Indiana and the Southern District of Indiana; (3) following any FDA approval of ANDA No. 205238, Sun Pharma Global FZE (directly and/or through affiliates or subsidiaries) intends to distribute Sun's ANDA Products within the Southern District of Indiana; (4) if Sun Pharma Global FZE is permitted to sell Sun's ANDA Products in the United States prior to the expiration of the '209 patent, Sun Pharma Global FZE will cause substantial injury to Lilly, an Indiana corporation headquartered within the Southern District of Indiana, and Sun Pharma Global FZE knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana; and (5) directly and/or through its affiliates or subsidiaries, Sun Pharma Global FZE 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, is engaged in and has maintained systematic and continuous business contacts within the State of Indiana and the Southern District of Indiana, and has purposefully availed itself of the benefits and protections of the laws of Indiana.

10. Upon information and belief, Sun's Notice Letter was signed by Dr. Ratnesh Shrivastava and Dipak Mundra, Esq. on Sun Pharmaceutical Industries Ltd. letterhead. Dr. Shrivastava signed Sun's Notice Letter using the title "Vice President, Intellectual Property Cell, Sun Pharmaceutical Industries Limited." Mr. Mundra signed Sun's Notice Letter using the title "In-house Patent Counsel, Sun Pharmaceutical Industries Limited." Sun's Notice Letter purported to provide notice to Lilly relating to Sun Pharma Global FZE's ANDA No. 205238 on behalf of Sun Pharma Global FZE, and stated that Dr. Shrivastava and Mr. Mundra signed "[o]n behalf and authorization of[] Sun Pharma Global FZE." Upon information and belief, ANDA No. 205238 is in the name of Sun Pharma Global FZE, and for purposes of that ANDA, Sun Pharma Global FZE is acting as the agent and/or alter ego of Sun Pharmaceutical Industries Ltd.

BACKGROUND

11. 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.

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

13. 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.

14. 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}.

15. An actual case or controversy exists between Lilly and Sun with respect to infringement of the '209 patent.

COUNT

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

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

17. Upon information and belief, Sun's ANDA Products contain pemetrexed disodium.

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

19. Upon information and belief, the use of Sun's ANDA Products in accordance with and as directed by Sun's proposed labeling for those products will infringe one or more claims of the '209 patent.

20. Upon information and belief, Sun filed as a part of ANDA No. 205238 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 Sun's ANDA Products.

21. The purpose of ANDA No. 205238 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Sun's ANDA Products prior to the expiration of the '209 patent.

22. Sun's submission of ANDA No. 205238 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Sun'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).

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

the proposed labeling therefor immediately and imminently upon approval of ANDA No. 205238, *i.e.*, prior to the expiration of the '209 patent.

24. Upon information and belief, Sun has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Sun has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 205238.

25. Upon information and belief, Sun 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.

26. Upon information and belief, Sun knows that Sun's ANDA Products are especially made or adapted for use in infringing the '209 patent, and that Sun's ANDA Products are not suitable for substantial noninfringing use. Upon information and belief, Sun plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 205238.

27. The foregoing actions by Sun 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.

28. Upon information and belief, Sun 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.

29. Unless Sun 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 Sun 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 Sun to make, use, offer for sale, sell, market, distribute, or import Sun'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 Sun, and all persons acting in concert with Sun, from making, using, selling, offering for sale, marketing, distributing, or importing Sun'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 Sun'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 other of the '209 patent;

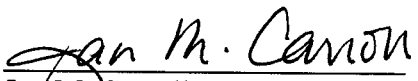
(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(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: September 13, 2013

Respectfully submitted,



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