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

ELI LILLY AND COMPANY,

Plaintiff,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

Civil Action No. _____

1:12-cv-0499 JMS-MJD

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 Apotex Inc. and Apotex Corp. 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, Apotex Inc. and Apotex Corp. are referred to collectively herein as "Apotex."

2. By letter dated March 7, 2012 ("Apotex's Notice Letter"), Apotex notified Lilly that it had submitted to the FDA ANDA No. 203774 for Apotex's pemetrexed disodium for injection, 100 mg/vial and 500 mg/vial products ("Apotex's ANDA Products"). Apotex'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. Upon information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 150 Signet Dr., Toronto, Ontario M9L 1T9, Canada. Upon information and belief, Apotex Inc. is in the business of manufacturing, marketing, and selling generic drug products.

5. Upon information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc. that serves as Apotex Inc.'s United States sales agent or distributor and sells and offers for sale Apotex Inc.'s drug products throughout the United States, including in the Southern District of Indiana.

6. Upon information and belief, Apotex Inc. and Apotex Corp. are two arms of the same business group, operate in concert with each other, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc. that serves as Apotex Inc.'s United States sales agent and distributor and sells and offers for sale Apotex Inc.'s drug products throughout the United States, including in Indiana and the Southern District of Indiana. Apotex Inc. has stated on its web site that "Apotex Inc. serves a marketplace of over 115 countries, and is committed to growth on a global basis through affiliates such as Apotex Corp. in the United States of America." Apotex Inc. has also stated on its web site that Apotex is "a vertically integrated

company" with a "preference . . . to develop, manufacture and market our own products—from API to finished dosage form to marketing and distribution."

7. Upon information and belief, the web site of Apotex Corp. is http://www.apotexcorp.com. Upon information and belief, apotexcorp.com is registered to "Apotex" at the Toronto, Ontario address of Apotex Inc., and the administrative and technical contact listed by the Internet domain registrar for apotexcorp.com is an employee of Apotex Inc. Upon information and belief, visitors to http://www.apotexcorp.com are redirected to a web page on the web site of Apotex Inc., http://www.apotex.com, that is directed towards and is accessible to residents of the United States, including Indiana and the Southern District of Indiana, and that makes available a product catalog describing products made by Apotex Inc. and sold, through Apotex Corp., in the United States, including Indiana and the Southern District of Indiana.

JURISDICTION AND VENUE

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

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

10. This Court has personal jurisdiction over Apotex Inc. because, upon information and belief, among other things, Apotex Inc. ships products from Canada to a distribution and operation center located in Indianapolis, Indiana, which is within the Southern District of Indiana; Apotex Inc. is in the business of manufacturing drug products which it distributes, sells, and offers to sell, primarily through Apotex Corp., throughout the United States, including in Indiana and the Southern District of Indiana; Apotex Inc. derives substantial revenue from things it ships to the distribution and operation center within the Southern District of Indiana as well as from things sold, used, or consumed within Indiana and the Southern

District of Indiana; as part of its ordinary business practice of engaging in U.S. patent litigation, Apotex Inc. has repeatedly litigated ANDA cases in this District, including by asserting counterclaims; following any FDA approval of Apotex's ANDA No. 203774, Apotex Inc. intends to offer to sell and sell, primarily through Apotex Corp., Apotex's ANDA Products throughout the United States and within Indiana and the Southern District of Indiana; following any FDA approval of Apotex's ANDA No. 203774, Apotex Inc. intends to distribute Apotex's ANDA Products from the distribution and operation center within the Southern District of Indiana; if Apotex Inc. is permitted to sell Apotex's ANDA Products in the United States prior to the expiration of the '209 patent, Apotex Inc. will cause substantial injury to Lilly, an Indiana corporation headquartered within the Southern District of Indiana, and Apotex Inc. knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana; and, through its agent and/or alter ego Apotex Corp., Apotex Inc. 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.

11. This Court has personal jurisdiction over Apotex Corp. because, upon information and belief, among other things, Apotex Corp. operates the operations and distribution center in Indianapolis through which Apotex distributes its products for sale throughout the United States including in Indiana and the Southern District of Indiana; Apotex Corp. 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; Apotex Corp. derives substantial revenue from things it distributes from the distribution and operation center within the Southern District of Indiana as well as from things sold, used, or consumed within Indiana

and the Southern District of Indiana; as part of its ordinary business practice of engaging in U.S. patent litigation, Apotex Corp. has repeatedly litigated ANDA cases in this District, including by asserting counterclaims; following any FDA approval of Apotex's ANDA No. 203774, Apotex Corp. intends to offer to sell and sell Apotex's ANDA Products throughout the United States and within Indiana and the Southern District of Indiana; following any FDA approval of Apotex's ANDA No. 203774, Apotex Corp. intends to distribute Apotex's ANDA Products from the distribution and operation center within the Southern District of Indiana; if Apotex Corp. is permitted to sell Apotex's ANDA Products in the United States prior to the expiration of the '209 patent, Apotex Corp. will cause substantial injury to Lilly, an Indiana corporation headquartered within the Southern District of Indiana, and Apotex Inc. knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana; and Apotex Corp. 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.

12. Upon information and belief, Apotex's Notice Letter was signed by Kiran Krishnan. Upon information and belief, Mr. Krishnan signed Apotex's Notice Letter using the title of "Director-Regulatory Affairs, Apotex Corp., U.S. Agent for Apotex Inc." Apotex's Notice Letter purported to provide notice to Lilly relating to Apotex's ANDA No. 203774 on behalf of Apotex Inc., and stated that Mr. Krishnan is the "agent in the United States authorized to accept service of process for Apotex, limited to commencement of a patent infringement suit based on this notification of certification." Upon information and belief, and consistent with its

regular practices with respect to other ANDAs, Apotex Corp. is acting as the agent and/or alter ego of Apotex Inc. for purposes of ANDA No. 203774.

BACKGROUND

13. 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.

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

15. 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.

16. 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}.

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

COUNT

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

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

19. Apotex's ANDA Products contain pemetrexed disodium.

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

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

22. Upon information and belief, Apotex filed as a part of ANDA No. 203774 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 Apotex's ANDA Products.

23. The purpose of ANDA No. 203774 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Apotex's ANDA Products prior to the expiration of the '209 patent.

24. Apotex's submission of ANDA No. 203774 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Apotex'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).

25. Upon information and belief, Apotex intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 203774, *i.e.*, prior to the expiration of the '209 patent.

26. Upon information and belief, Apotex has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Apotex has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 203774.

27. Upon information and belief, Apotex 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.

28. Upon information and belief, Apotex knows that Apotex's ANDA Products are especially made or adapted for use in infringing the '209 patent, and that Apotex's ANDA Products are not suitable for substantial noninfringing use. Upon information and belief, Apotex plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 203774.

29. The foregoing actions by Apotex 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.

30. Upon information and belief, Apotex 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.

31. Unless Apotex 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 Apotex 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 Apotex to make, use, offer for sale, sell, market, distribute, or import Apotex'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 Apotex, and all persons acting in concert with Apotex, from making, using, selling, offering for sale, marketing, distributing, or importing Apotex'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 Apotex'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: April 17, 2012

Respectfully submitted,

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