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-2008
	)	
SANDOZ INC.,	)	
	)	
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 Sandoz Inc. ("Sandoz") 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 Injectable; IV (Infusion), 100 mg, 500 mg, and 1 gram base/vial products ("Sandoz's ANDA Products") prior to the expiration of U.S. Patent No. 7,772,209 ("the '209 patent"). Sandoz notified Lilly that it had submitted to the FDA ANDA No. 206638 for Sandoz's ANDA Products by letter dated October 29, 2014 ("Sandoz's Notice Letter"). Upon information and belief, Sandoz's ANDA Products will be marketed as generic versions of ALIMTA®, a chemotherapy agent developed and distributed by Lilly and used for the treatment of various types of cancer.

PARTIES

2. 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.

3. Upon information and belief, Sandoz Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 506 Carnegie Drive, Suite 400, Princeton, New Jersey 08540. Upon information and belief, Sandoz is in the business of manufacturing, marketing, and selling generic drug products.

JURISDICTION AND VENUE

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

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

6. This Court has personal jurisdiction over Sandoz because, upon information and belief: (1) Sandoz 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 Indiana and the Southern District of Indiana; (2) Sandoz 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, Sandoz has litigated ANDA cases in this District, including by asserting counterclaims; (4) following any FDA approval of ANDA No. 206638 Sandoz intends to distribute (directly and/or through affiliates or subsidiaries) Sandoz's ANDA Products within Indiana and this District; (5) Sandoz knowingly and purposefully directed Sandoz's Notice Letter to Lilly at its principal place of business within this District, thus intentionally challenging the intellectual property rights held by an Indiana

corporation in this District; (6) if Sandoz is permitted to sell Sandoz's ANDA Products in the United States prior to the expiration of the '209 patent, Sandoz will cause substantial injury to Lilly, an Indiana corporation headquartered within the Southern District of Indiana, and Sandoz knows that Lilly will be injured by such actions in Indiana and this District; and (7) directly and/or through its affiliates or subsidiaries, Sandoz regularly does and solicits business in Indiana and this District, including the distribution and sale of drug products in Indiana and this District; is engaged in and has maintained systematic and continuous business contacts within the State of Indiana and this District; and has purposefully availed itself of the benefits and protections of the laws of Indiana.

BACKGROUND

7. 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.

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

9. 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.

10. 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}.

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

COUNT

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

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

13. Upon information and belief, Sandoz's ANDA Products contain pemetrexed disodium.

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

15. Upon information and belief, the use of Sandoz's ANDA Products in accordance with and as directed by Sandoz's proposed labeling for those products will infringe one or more claims of the '209 patent. Other than an allegation that the claims of the '209 patent are invalid, Sandoz's Notice Letter did not articulate any factual or legal basis of an opinion that such use will not infringe the '209 patent, even though Sandoz was obligated to articulate such bases under Section 505(j)(2)(B)(iv)(II) of the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(B)(iv)(II), if in Sandoz's opinion the patent will not be infringed.

16. Upon information and belief, Sandoz filed as a part of ANDA No. 206638 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 Sandoz's ANDA Products.

17. The purpose of ANDA No. 206638 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Sandoz's ANDA Products prior to the expiration of the '209 patent.

18. Sandoz's submission of ANDA No. 206638 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Sandoz'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).

19. Upon information and belief, Sandoz intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 206638, *i.e.*, prior to the expiration of the '209 patent.

20. Upon information and belief, Sandoz has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Sandoz has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 206638.

21. Upon information and belief, Sandoz 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.

22. Upon information and belief, Sandoz knows that Sandoz's ANDA Products are especially made or adapted for use in infringing the '209 patent, and that Sandoz's ANDA Products are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 206638.

23. The foregoing actions by Sandoz 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.

24. Upon information and belief, Sandoz 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.

25. Unless Sandoz 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 Sandoz 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 Sandoz to make, use, offer for sale, sell, market, distribute, or import Sandoz'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 Sandoz, and all persons acting in concert with Sandoz, from making, using, selling, offering for sale, marketing, distributing, or importing Sandoz’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 Sandoz’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.

Respectfully submitted,

Dated: December 5, 2014

/s/ Jan M. Carroll

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