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

ELI LILLY AND COMPANY,	)	
	)	
Plaintiff,	)	
v.	)	Civil Action No. 1:16-cv-3460
	)	
HOSPIRA, 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 Hospira, Inc. ("Hospira") of a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell its Pemetrexed for Injection 100 mg/vial, 500 mg/vial, and 1 g/vial products ("Hospira's NDA Products") prior to the expiration of U.S. Patent No. 7,772,209 ("the '209 patent"). Hospira notified Lilly that it had submitted to the FDA NDA No. 208746 for Hospira's NDA Products by letter dated December 1, 2016 ("Hospira's Notice Letter" or "Notice Letter"). Upon information and belief, Hospira's NDA Products will be marketed as competing products to 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 place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

3. Upon information and belief, Hospira, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045. Upon information and belief, Hospira, Inc. 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 Hospira because, upon information and belief: (1) Hospira has filed an NDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Hospira's NDA Products in the United States, including in Indiana and the Southern District of Indiana; (2) Hospira 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; (3) Hospira derives substantial revenue from things sold, used, or consumed within Indiana and the Southern District of Indiana; (4) following any FDA approval of NDA No. 208746 Hospira intends to distribute (directly and/or through affiliates or subsidiaries) Hospira's NDA Products within Indiana and this District; (5) Hospira knowingly and purposefully directed Hospira'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 Hospira is permitted to sell Hospira's NDA Products in the United States prior to the expiration of the '209 patent, Hospira will cause substantial injury to Lilly, an Indiana corporation headquartered within the Southern District of Indiana, and Hospira knows that Lilly will be injured by such actions in Indiana and this District; and (7) directly and/or through its affiliates or subsidiaries, Hospira 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. In addition, Lilly was in litigation in this Court with Hospira regarding NDA No. 200-795, in Case No. 1:10-cv-00346-SEB-DML, and Hospira did not challenge personal jurisdiction in that action.

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

10. Lilly is the assignee of the ’209 patent.

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

12. This action is being filed within 45 days of Lilly’s receipt of Hospira’s Notice Letter.

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. Upon information and belief, Hospira’s NDA Products contain pemetrexed disodium or its equivalent.

15. Upon information and belief, the proposed labeling for Hospira’s NDA Products involves administration of folic acid and vitamins B_{12}.

16. Upon information and belief, the use of Hospira’s NDA Products in accordance with and as directed by Hospira’s proposed labeling for those products will infringe claims 1-22 of the ’209 patent, either literally or under the doctrine of equivalents.

17. Upon information and belief, Hospira filed as part of NDA No. 208746 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), 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 Hospira’s NDA Products.

18. The purpose of NDA No. 208746 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Hospira's NDA Products prior to the expiration of the '209 patent.

19. Hospira's submission of NDA No. 208746 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Hospira's NDA 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. Upon information and belief, Hospira intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Hospira's NDA Products and the proposed labeling therefor immediately and imminently upon approval of NDA No. 208746, *i.e.*, prior to the expiration of the '209 patent.

21. Upon information and belief, Hospira has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Hospira has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Hospira's NDA Products and the proposed labeling therefor immediately and imminently upon approval of NDA No. 208746.

22. Upon information and belief, Hospira plans and intends to, and will, actively induce infringement of the '209 patent when its NDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

23. Upon information and belief, Hospira knows that Hospira's NDA Products are especially made or adapted for use in infringing the '209 patent, and that Hospira's NDA Products are not suitable for substantial noninfringing use. Upon information and belief, Hospira

plans and intends to, and will, contribute to infringement of the ’209 patent immediately and imminently upon approval of NDA No. 208746.

24. The foregoing actions by Hospira 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. Unless Hospira 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 Hospira 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 Hospira to make, use, offer for sale, sell, market, distribute, or import Hospira’s NDA 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 Hospira, and all persons acting in concert with Hospira, from making, using, selling, offering for sale, marketing, distributing, or importing Hospira’s NDA 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 Hospira’s NDA 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: December 21, 2016

Respectfully submitted,

/s/ *Jan M. Carroll*

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