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

ELI LILLY AND COMPANY,

Plaintiff,

v.

APP PHARMACEUTICALS, LLC,

Defendant.

Civil Action No. 1:11-cv-0942 TWP-TAB

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 APP Pharmaceuticals, LLC ("APP") of an Abbreviated New Drug Applications ("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.

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, defendant APP is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173-5837.

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. Upon information and belief, APP is subject to personal jurisdiction in this District because, among other things, APP markets, sells, and distributes generic drugs throughout the United States, including within the State of Indiana and the Southern District of Indiana. Upon information and belief, APP has engaged in and 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.

7. Upon information and belief, and consistent with its practice with respect to other generic products, following any FDA approval of APP's ANDA No. 90-384 for a generic version of ALIMTA®, APP will market, distribute, and sell its generic product throughout the United States and within Indiana and the Southern District of Indiana, and knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana. Upon information and belief, following any FDA approval of ANDA No. 90-384, APP knows and intends that its generic product will be marketed, distributed, and sold in the United States and within the State of Indiana and the Southern District of Indiana, and knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana.

BACKGROUND

8. ALIMTA® is a chemotherapy drug used for the treatment of various types of cancer. 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. United States Patent No.7,772,209 ("the '209 patent"), entitled "Novel 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 APP with respect to infringement of the '209 patent.

COUNT I

(Patent Infringement – 500 mg)

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

14. By letters dated June 10, 2008 ("APP's 2008 Notice Letter") and June 2, 2011 ("APP's 500 mg Notice Letter"), APP notified Lilly that it had submitted to the FDA ANDA No. 90-384 for APP's Pemetrexed Disodium Injectable, Eq. 500 mg Base/Vial product.

15. APP's 500 mg ANDA Product is a generic version of ALIMTA®.

16. The purpose of ANDA No. 90-384 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of APP's 500 mg ANDA Product prior to the expiration of the '209 patent.

17. In APP's 2008 Notice Letter and APP's 500 mg Notice Letter, APP notified Lilly that APP's 500 mg ANDA Product contains pemetrexed disodium.

18. Upon information and belief, the use of APP's 500 mg ANDA Product in accordance with APP's proposed labeling for APP's 500 mg ANDA Product involves administration of folic acid and vitamin B_{12}.

19. Upon information and belief, the use of APP's 500 mg ANDA Product in accordance with and as directed by APP's proposed labeling for that product will infringe one or more claims of the '209 patent.

20. APP's submission of ANDA No. 90-384 is for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of APP's 500 mg ANDA Product prior to the expiration of the '209 patent.

21. Upon information and belief, APP intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's 500 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-384, *i.e.*, prior to the expiration of the '209 patent.

22. Upon information and belief, APP has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, APP has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's

500 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-384.

23. Upon information and belief, APP 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.

24. Upon information and belief, APP knows that APP's 500 mg ANDA Product is especially made or adapted for use in infringing the '209 patent, and that APP's 500 mg ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, APP plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 90-384.

25. The foregoing actions by APP 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.

26. Upon information and belief, APP 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.

27. Unless APP 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.

COUNT II

(Patent Infringement – 100 mg)

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

29. By a letter dated June 2, 2011 ("APP's 100 mg Notice Letter"), APP notified Lilly that it had submitted to the FDA a Supplement to ANDA No. 90-384 for APP's Pemetrexed Disodium Injectable, Eq. 100 mg Base/Vial product.

30. APP's 100 mg ANDA Product is a generic version of ALIMTA®.

31. The purpose of ANDA No. 90-384 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of APP's 100 mg ANDA Product prior to the expiration of the '209 patent.

32. In APP's 100 mg Notice Letter, APP notified Lilly that APP's 100 mg ANDA Product contains pemetrexed disodium.

33. Upon information and belief, the use of APP's 100 mg ANDA Product in accordance with APP's proposed labeling for APP's 100 mg ANDA Product involves administration of folic acid and vitamin B_{12}.

34. Upon information and belief, the use of APP's 100 mg ANDA Product in accordance with and as directed by APP's proposed labeling for that product will infringe one or more claims of the '209 patent.

35. APP's submission of ANDA No. 90-384 is for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of APP's 100 mg ANDA Product prior to the expiration of the '209 patent.

36. Upon information and belief, APP intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's 100 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-384, *i.e.*, prior to the expiration of the '209 patent.

37. Upon information and belief, APP has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, APP has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's 100 mg ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-384.

38. Upon information and belief, APP 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.

39. Upon information and belief, APP knows that APP's 100 mg ANDA Product is especially made or adapted for use in infringing the '209 patent, and that APP's 100 mg ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, APP plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 90-384.

40. The foregoing actions by APP 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.

41. Upon information and belief, APP 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.

42. Unless APP 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 APP 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 APP to make, use, offer for sale, sell, market, distribute, or import APP's 500 mg ANDA Product, 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 judgment ordering that the effective date of any FDA approval for APP to make, use, offer for sale, sell, market, distribute, or import APP's 100 mg ANDA Product, 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;

(d) A preliminary and permanent injunction enjoining APP, and all persons acting in concert with APP, from making, using, selling, offering for sale, marketing, distributing, or importing APP's 500 mg ANDA Product, 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;

(e) A preliminary and permanent injunction enjoining APP, and all persons acting in concert with APP, from making, using, selling, offering for sale, marketing, distributing, or importing APP's 100 mg ANDA Product, 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;

(f) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing of APP's 500 mg ANDA Product, 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;

(g) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing of APP's 100 mg ANDA Product, 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;

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

(i) An award of Lilly's costs and expenses in this action; and

(j) Such further and other relief as this Court may deem just and proper.

Dated: July 15, 2011

Respectfully submitted,

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