UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,

Plaintiff

v.

EAGLE PHARMACEUTICALS, INC.,

Defendant.

Civil Action No. 1:17-cv-2772

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 Eagle Pharmaceuticals, Inc. ("Eagle") of a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell its Pemetrexed Injection, 25mg/mL, 500 mg vial product ("Eagle's NDA Product") prior to the expiration of U.S. Patent No. 7,772,209 ("the '209 patent"). Eagle notified Lilly that it had submitted to the FDA NDA No. 209472 for Eagle's NDA Product by letter dated August 7, 2017 ("Eagle's Notice Letter" or "Notice Letter"). Upon information and belief, Eagle's NDA Product will be marketed as a competing product 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, Eagle is a corporation organized and existing under the laws of the State of Delaware having a place of business at 50 Tice Blvd., Suite 315, Woodcliff Lake, New Jersey 07677.

JURISDICTION AND VENUE

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

5. Upon information and belief, Eagle is engaged in the manufacturing, marketing, and sale of generic pharmaceutical products for the U.S. prescription drug market with products for sale in the United States. According to its S-1 SEC Registration Statement, Eagle is a "specialty pharmaceutical company focused on developing and commercializing injectable products utilizing the FDA's 505(b)(2) regulatory pathway." Eagle states on its website that it "estimate[s] that the current annual revenue of the overall U.S. market [it] target[s] is approximately $4 billion," and Eagle reported in its S-1 Registration Statement that three of the drugs in its "currently disclosed product portfolio," including Eagle's NDA Product, "represent $3.4 billion in U.S. peak branded drug sales." In its 10-K filing to the SEC for the year 2016, Eagle reported that it "ha[s] established a small, contract specialty sales force focusing on GPOs, hospital systems and key stakeholders in acute care settings, primarily hospitals," and "[i]n an effort to expand on [its] commercial strategy," Eagle "plan[s] to grow [its] internal sales force by 20 during 2017 and ha[s] partnered with Spectrum [Pharmaceuticals, Inc.] to commercialize some of [its] products." Eagle further reported that its "intent is to commercialize [its] product

portfolio in the United States with our commercial organization." Eagle recently reported to the SEC in its August 9, 2017 10-Q report that it "plan[s] to continue to market and/or commercialize our products through marketing partners and/or through our growing internal direct sales force."

6. Upon information and belief, Eagle regularly does business in Indiana and has engaged in a persistent course of conduct within Indiana by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Indiana, and/or by directly selling pharmaceutical products in Indiana.

7. Upon information and belief, Eagle has sought approval in NDA No. 209472 to distribute Eagle's NDA Product in the United States, including in Indiana (and in this District), and will do so upon approval of NDA No. 209472. The filing of NDA No. 209472 is therefore tightly tied, in purpose and planned effect, to the deliberate making of sales in Indiana and this District, and reliably indicates plans to engage in marketing of Eagle's NDA Product in this State and District.

8. Upon information and belief, with knowledge of the processes described in the FDCA and the Hatch-Waxman Act, Eagle directed its Notice Letter to Lilly, an entity incorporated in Indiana, at its corporate headquarters in Indiana, and alleged in the Notice Letter the invalidity, unenforceability, and/or non-infringement of Lilly's '209 patent. Upon information and belief, Eagle deliberately challenged Lilly's patent rights, and knew when it did so that it was triggering a forty-five-day period for Lilly to bring an action for patent infringement under the FDCA. Moreover, upon information and belief, Eagle knew that other FDCA and/or Hatch-Waxman Act infringement actions relating to the '209 patent had been brought and litigated in Indiana.

9. Because Lilly is incorporated and has its principal place of business in Indiana, the injury and consequences of Eagle's filing of NDA No. 209472, challenging Lilly's patent rights, are suffered in Indiana. Upon information and belief, Eagle knew that it was deliberately challenging the patent rights of an Indiana entity and seeking to challenge intellectual property held in Indiana and that the effects of any successful challenge of the '209 patent would be felt by Lilly in Indiana.

10. Upon information and belief, Eagle derives substantial revenue from pharmaceutical products that are used and/or consumed within Indiana, and which are manufactured by Eagle or its affiliates and/or for which Eagle is the named applicant on approved NDAs or ANDAs. Upon information and belief, various products for which Eagle, or its affiliates, is the named applicant on approved NDAs and ANDAs are available at pharmacies in Indiana.

11. Upon information and belief, if NDA No. 209472 is approved, Eagle's NDA Product, under the direction and control of physicians practicing in Indiana, will be administered to patients of Indiana. These activities, as well as Eagle's marketing, selling, and/or distributing of Eagle's NDA Product, would have a substantial effect within Indiana and would constitute infringement of Lilly's patent in the event that Eagle's NDA Product is approved before the '209 patent expires.

12. For the reasons described above, among others, the filing of NDA No. 209472 was suit-related conduct with a substantial connection to Indiana and this District, the exercise of personal jurisdiction in this Court does not offend traditional notions of fair play and substantial justice, and this Court may properly exercise personal jurisdiction over Eagle.

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 "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.

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

18. This action is being filed within 45 days of Lilly's receipt of Eagle's Notice Letter.

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

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

20. Upon information and belief, Eagle's NDA Product contains pemetrexed disodium or its equivalent.

21. Upon information and belief, the proposed labeling for Eagle's NDA Product involves administration of folic acid and vitamins B_{12}.

22. Upon information and belief, the use of Eagle's NDA Product in accordance with and as directed by Eagle's proposed labeling for that product will infringe claims 1-22 of the '209 patent, either literally or under the doctrine of equivalents.

23. Upon information and belief, Eagle filed as part of NDA No. 209472 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 Eagle's NDA Product.

24. The purpose of NDA No. 209472 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Eagle's NDA Product prior to the expiration of the '209 patent.

25. Eagle's submission of NDA No. 209472 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Eagle's NDA Product 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).

26. Upon information and belief, Eagle intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Eagle's NDA Product and the proposed labeling therefor immediately and imminently upon approval of NDA No. 209472, *i.e.*, prior to the expiration of the '209 patent.

27. Upon information and belief, Eagle has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Eagle has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Eagle's NDA Product and the proposed labeling therefor immediately and imminently upon approval of NDA No. 209472.

28. Upon information and belief, Eagle 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.

29. Upon information and belief, Eagle knows that Eagle's NDA Product is especially made or adapted for use in infringing the '209 patent, and that Eagle's NDA Product is not suitable for substantial noninfringing use. Upon information and belief, Eagle plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of NDA No. 209472.

30. The foregoing actions by Eagle 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.

31. Unless Eagle 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 Eagle 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 Eagle to make, use, offer for sale, sell, market, distribute, or import Eagle's NDA 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 preliminary and permanent injunction enjoining Eagle, and all persons acting in concert with Eagle, from making, using, selling, offering for sale, marketing,

distributing, or importing Eagle's NDA 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;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing of Eagle's NDA 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 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,

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