UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

2013 FEB 28 PM 12:33
SOUTHERN DISTRICT
OF INDIANA
LAURA A. BRIGGS
CLERK

ELI LILLY AND COMPANY,

Plaintiff,

v.

ACCORD HEALTHCARE INC., USA,

Defendant.

1:13-cv-0335 WTL-DKL

Civil Action No. _____

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 Accord Healthcare Inc., USA ("Accord") of an amendment to an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a 1000 mg/vial generic version of ALIMTA® prior to the expiration of U.S. Patent No. 7,772,209 ("the '209 patent").

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 Accord is a wholly owned subsidiary of Intas Pharmaceuticals Ltd.

4. Upon information and belief, defendant Accord is a corporation organized and existing under the laws of the State of North Carolina, having a place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

JURISDICTION AND VENUE

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

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

7. Upon information and belief, Accord is subject to personal jurisdiction in this District because, among other things, Accord 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, Accord 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.

8. Upon information and belief, and consistent with its practice with respect to other generic products, following any FDA approval of Accord's ANDA No. 203485 for a generic version of ALIMTA®, Accord 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. 203485, Accord 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.

9. Accord has also acquiesced to personal jurisdiction and asserted counterclaims in related case no. 1:12-cv-0086-TWP-DKL in this District, in which Lilly has asserted claims of infringement of the '209 patent arising from the filing by Accord of ANDA No. 203485 seeking approval to manufacture and sell 100 mg/vial and 500 mg/vial generic versions of ALIMTA®.

BACKGROUND

10. ALIMTA® is a chemotherapy agent 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 whose disease is unresectable or who are not otherwise candidates for curative surgery, and (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.

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

12. The '209 patent, entitled "Antifolate Combination Therapies," was duly and legally issued on August 10, 2010. The '209 patent is attached as Exhibit A hereto, and is incorporated herein by reference.

13. 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 cover a method of administering pemetrexed disodium to a patient in need thereof that also involves administration of folic acid and vitamin B_{12}.

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

COUNT

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

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

16. By letter dated January 14, 2013 ("Accord's 2013 Notice Letter"), Accord notified Lilly that it had submitted to the FDA an amendment to ANDA No. 203485 for Accord's Pemetrexed Disodium for Injection, 1000 mg/vial product ("Accord's ANDA Product").

17. Accord's ANDA Product is a generic version of ALIMTA®.

18. Accord's ANDA Product contains pemetrexed disodium.

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

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

21. Upon information and belief, Accord filed as a part of ANDA No. 203485 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 and/or not infringed by the manufacture, use, offer for sale, or sale of Accord's ANDA Product.

22. The purpose of ANDA No. 203485 and the amendment(s) thereto was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Accord's ANDA Product prior to the expiration of the '209 patent.

23. Accord's submission and amendment of ANDA No. 203485 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Accord's ANDA 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).

24. Upon information and belief, Accord intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 203485, *i.e.*, prior to the expiration of the '209 patent.

25. Upon information and belief, Accord has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Accord has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Accord's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 203485.

26. Upon information and belief, Accord 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.

27. Upon information and belief, Accord knows that Accord's ANDA Product is especially made or adapted for use in infringing the '209 patent, and that Accord's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Accord plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 203485.

28. The foregoing actions by Accord 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.

29. Upon information and belief, Accord 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.

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

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

(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: February 28, 2013

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