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

ELI LILLY AND COMPANY,

Plaintiff,

v.

ACCORD HEALTHCARE, INC., USA,

Defendant.

Civil Action No. _____

1 : 12 -cv- 0086 RLY -DKL

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 Abbreviated New Drug Application ("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 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, NC, 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 generic versions of ALIMTA®, Accord will market, distribute, and sell its generic products 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 products 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

9. 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, 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.

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

11. 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.

12. 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}.

13. 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)

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

15. By letter dated December 8, 2011 ("Accord's Notice Letter"), Accord notified Lilly that it had submitted to the FDA ANDA No. 203485 for Accord's Pemetrexed Disodium for Injection, 100 mg/vial and 500 mg/vial products ("Accord's ANDA Products").

16. Accord's ANDA Products are generic versions of ALIMTA®.

17. Accord's ANDA Products contain pemetrexed disodium.

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

19. Upon information and belief, the use of Accord's ANDA Products in accordance with and as directed by Accord's proposed labeling for those products will infringe one or more claims of the '209 patent.

20. 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, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Accord's ANDA Products.

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

22. Accord's submission 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 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).

23. 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 Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 203485, *i.e.*, prior to the expiration of the '209 patent.

24. 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 Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 203485.

25. 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.

26. Upon information and belief, Accord knows that Accord's ANDA Products are especially made or adapted for use in infringing the '209 patent, and that Accord's ANDA Products are 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.

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