UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff v. APOTEX, INC., Defendant.	Civil Action No. 1:17-cv-2865

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 Apotex Inc. ("Apotex") 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 and 500 mg/vial products ("Apotex's NDA Products") prior to the expiration of U.S. Patent No. 7,772,209 ("the '209 patent"). Apotex notified Lilly that it had submitted to the FDA NDA No. 210661 for Apotex's NDA Products by letter dated July 31, 2017 ("Apotex's Notice Letter" or "Notice Letter"). Upon information and belief, Apotex's NDA Products 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, Apotex is a corporation organized and existing under the laws of Canada, having a place of business at 150 Signet Dr., Toronto, Ontario M9L 1T9, Canada. Upon information and belief, Apotex 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. This Court has personal jurisdiction over Apotex because, upon information and belief, among other things: (1) Apotex is in the business of manufacturing drug products which it distributes, sells, and offers to sell, throughout the United States, including in Indiana and the Southern District of Indiana, and through the filing of NDA No. 210661, Apotex seeks approval to sell a product that infringes the '209 patent throughout the United States, including in Indiana and the Southern District of Indiana. (2) With knowledge of the processes described in the FDCA and the Hatch-Waxman Act, Apotex 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, thereby deliberately challenging intellectual property developed and held by Lilly, an Indiana company, in Indiana. Apotex 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, Apotex knew that other FDCA and/or Hatch-Waxman Act infringement actions relating to the '209 patent had been brought and litigated in Indiana. (3) Apotex ships products from Canada to a distribution and operation center located in Indianapolis, Indiana, which is within the Southern District of Indiana. (4) Following any FDA approval of Apotex's NDA No. 210661, Apotex intends to offer to sell and sell, directly or indirectly, Apotex's NDA Products throughout the United States and within Indiana and the Southern District of Indiana. (5) Following any FDA approval of Apotex's NDA No. 210661, Apotex intends to distribute Apotex's NDA Products from the distribution and operation center within the Southern District of Indiana. (6) If Apotex is permitted to sell Apotex's NDA Products in the United States prior to the expiration of the '209 patent, Apotex will cause substantial injury to Lilly, an Indiana corporation headquartered within the Southern District of Indiana, and Apotex knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana. (7) Apotex derives substantial revenue from things it ships to the distribution and operation center within the Southern District of Indiana as well as from things sold, used, or consumed within Indiana and the Southern District of Indiana. (8) Apotex regularly does and solicits business in Indiana and the Southern District of Indiana, including the distribution and sale of drug products in Indiana and the Southern District of Indiana, and is engaged in a persistent, continuous, and systematic course of conduct in Indiana and the Southern District of Indiana. (9) As part of its ordinary business practice of engaging in U.S. patent litigation, Apotex has repeatedly litigated Hatch-Waxman cases in this District, including by asserting counterclaims.

6. For the reasons described above, among others, the filing of NDA No. 210661 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 Apotex. Apotex was already involved in litigation over the '209 patent with Lilly in this District and did not challenge personal jurisdiction in that suit.

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 hereto.

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

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

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

13. Apotex has previously filed an ANDA seeking approval to market generic versions of Lilly's ALIMTA® cancer chemotherapy product. Apotex notified Lilly that it had

submitted to the FDA ANDA No. 203774 by letter dated March 7, 2012, and Lilly filed suit against Apotex on April 17, 2012 alleging that Apotex's ANDA filing infringed the '209 patent. *See Eli Lilly and Company v. Accord Healthcare, Inc. et al.*, Case No. 1:12-cv-86-TWP-MPB (S.D. Ind.). On October 4, 2013, Lilly and Apotex jointly moved to stay Lilly's suit against Apotex and for an order that Lilly and Apotex be bound by the outcome of the then-pending litigation in *Eli Lilly and Company v. Teva Parenteral Medicines, Inc., et al.*, Case No. 1:10-cv-1376-TWP-MPB (S.D. Ind.) ("the Teva/APP Litigation"). This Court granted the motion on October 7, 2013. The Teva/APP Litigation involved a claim that other generic versions of ALIMTA® infringed the '209 patent, and it presented substantially the same issues of infringement and invalidity as Lilly's suit against Apotex.

14. This Court found in the Teva/APP Litigation that the defendants in that litigation failed to prove that the asserted claims of the '209 patent were invalid and that the defendants' ANDA products indirectly infringed the asserted claims of the '209 patent, and this Court entered final judgment in favor of Lilly in the Teva/APP Litigation on August 25, 2015. That decision was appealed to the United States Court of Appeals for the Federal Circuit as Case No. 15-2067, and on January 12, 2017, the Federal Circuit entered judgment affirming this Court's decision. The time for a petition for writ of certiorari to the Supreme Court of the United States expired on April 12, 2017 and no petition was filed.

15. Pursuant to Lilly's agreement with Apotex to be bound by the outcome of the Teva/APP Litigation, Lilly moved for entry of judgment against Apotex on May 5, 2017. This Court granted Lilly's motion—finding that the filing of Apotex's ANDA No. 203774 infringed the asserted claims of the '209 patent, which were not proved invalid—and entered final judgment in favor of Lilly on August 11, 2017. Apotex is barred by the doctrines of res judicata

and/or collateral estoppel from challenging the validity of any claim of the '209 patent that was adjudicated in the prior litigation. Apotex is also collaterally estopped from contesting infringement under any theory that was adjudicated in the prior litigation.

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

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

17. Upon information and belief, Apotex's NDA Products contain pemetrexed disodium or its equivalent.

18. Upon information and belief, the proposed labeling for Apotex's NDA Products involves administration of folic acid and vitamins B_{12}.

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

20. Upon information and belief, Apotex filed as part of NDA No. 210661 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 Apotex's NDA Products.

21. The purpose of NDA No. 210661 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Apotex's NDA Products prior to the expiration of the '209 patent.

22. Apotex's submission of NDA No. 210661 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Apotex'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).

23. Upon information and belief, Apotex intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's NDA Products and the proposed labeling therefor immediately and imminently upon approval of NDA No. 210661, *i.e.*, prior to the expiration of the '209 patent.

24. Upon information and belief, Apotex has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Apotex has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's NDA Products and the proposed labeling therefor immediately and imminently upon approval of NDA No. 210661.

25. Upon information and belief, Apotex 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.

26. Upon information and belief, Apotex knows that Apotex's NDA Products are especially made or adapted for use in infringing the '209 patent, and that Apotex's NDA Products are not suitable for substantial noninfringing use. Upon information and belief, Apotex plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of NDA No. 210661.

27. The foregoing actions by Apotex 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.

28. Unless Apotex 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 Apotex 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 Apotex to make, use, offer for sale, sell, market, distribute, or import Apotex'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 Apotex, and all persons acting in concert with Apotex, from making, using, selling, offering for sale, marketing, distributing, or importing Apotex'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 Apotex'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.

(h)

Respectfully submitted,

/s/ Anne N. DePrez

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