UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff v. JIANGSU HANSOH PHARMACEUTICAL GROUP CO., LTD., Defendant.	Civil Action No. 1:17-cv-2864

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 Jiangsu Hansoh Pharmaceutical Group Co., Ltd. ("Hansoh") of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell their Pemetrexed Disodium injectable 100 mg/vial and 500 mg/vial products ("Hansoh's ANDA Products") prior to the expiration of U.S. Patent No. 7,772,209 ("the '209 patent"). Hansoh notified Lilly that it had submitted to the FDA ANDA No. 208696 for Hansoh's ANDA Products by letter dated July 28, 2017 ("Hansoh's Notice Letter" or "Notice Letter"). Upon information and belief, Hansoh's ANDA Products will be marketed as competing products 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, Hansoh is a corporation organized and existing under the laws of China, having a place of business at 9 Dongjin Road, Economic and Technical Development Zone, Lianyungang City, Jiangsu, 222069, China.

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, Hansoh 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 English website, Hansoh "has developed into a new pharmaceutical group featuring R&D, manufacture, sales and pharmaceutical investment of drugs," is "a flagship enterprise for R&D and production in China," and is "a Top 30 enterprise of China's Pharmaceutical Industry." Upon information and belief, Hansoh currently manufactures, markets, and/or sells generic pharmaceutical products in the United States, including, for example, gemcitabine hydrochloride.

6. This Court has personal jurisdiction over Hansoh because, upon information and belief, among other things: (1) Hansoh 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 ANDA No. 2008696, Hansoh 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, Hansoh 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. Hansoh 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, Hansoh knew that other FDCA and/or Hatch-Waxman Act infringement actions relating to the '209 patent had been brought and litigated in Indiana. (3) Hansoh 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 Hansoh's ANDA No. 208696, Hansoh intends to offer to sell and sell, directly or indirectly, Hansoh's NDA Products throughout the United States and within Indiana and the Southern District of Indiana. (5) Following any FDA approval of Hansoh's ANDA No. 208696, Hansoh intends to distribute Hansoh's NDA Products from the distribution and operation center within the Southern District of Indiana. (6) If Hansoh is permitted to sell Hansoh's NDA Products in the United States prior to the expiration of the '209 patent, Hansoh will cause substantial injury to Lilly, an Indiana corporation headquartered within the Southern District of Indiana, and Hansoh knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana. (7) Hansoh 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) Hansoh 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.

7. For the reasons described above, among others, the filing of ANDA No. 2008696 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 Hansoh.

BACKGROUND

8. 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. 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.

11. Lilly is the assignee of the ’209 patent.

12. An actual case or controversy exists between Lilly and Hansoh with respect to infringement of the ’209 patent.

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

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

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

15. Upon information and belief, Hansoh's ANDA Products contain pemetrexed disodium.

16. Upon information and belief, the proposed labeling for Hansoh's ANDA Products involves administration of folic acid and vitamins B_{12}.

17. Upon information and belief, the use of Hansoh's ANDA Products in accordance with and as directed by Hansoh's proposed labeling for those products will infringe claims 1-22 of the '209 patent.

18. Upon information and belief, Hansoh filed as part of ANDA No. 208696 a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(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 Hansoh's ANDA Products.

19. The purpose of ANDA No. 208696 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Hansoh's ANDA Products prior to the expiration of the '209 patent.

20. Hansoh's submission of ANDA No. 208696 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Hansoh'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).

21. Upon information and belief, Hansoh intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Hansoh's ANDA Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 208696, *i.e.*, prior to the expiration of the '209 patent.

22. Upon information and belief, Hansoh has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Hansoh has continued to assert their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Hansoh's ANDA Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 208696.

23. Upon information and belief, Hansoh plans and intends to, and will, actively induce infringement of the '209 patent when their ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

24. Upon information and belief, Hansoh knows that Hansoh's ANDA Products are especially made or adapted for use in infringing the '209 patent, and that Hansoh's ANDA Products are not suitable for substantial noninfringing use. Upon information and belief, Hansoh plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 208696.

25. The foregoing actions by Hansoh constitutes 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. Unless Hansoh 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 Hansoh 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 Hansoh to make, use, offer for sale, sell, market, distribute, or import Hansoh’s ANDA 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 Hansoh, and all persons acting in concert with Hansoh, from making, using, selling, offering for sale, marketing, distributing, or importing Hansoh’s ANDA 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 Hansoh’s ANDA 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.

Respectfully submitted,

/s/ Anne N. DePrez

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