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

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| ELI LILLY AND COMPANY and THE TRUSTEES OF PRINCETON UNIVERSITY<br><br>Plaintiffs,<br>v.<br><br>NANG KUANG PHARMACEUTICAL CO., LTD., and CANDA NX-2, LLC<br><br>Defendants. | ) | Civil Action No. 1:14-cv-1647 |

**COMPLAINT**

Plaintiffs Eli Lilly and Company ("Lilly") and The Trustees of Princeton University ("Princeton"), by their attorneys, for their Complaint, hereby allege 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 Nang Kuang Pharmaceutical Co., Ltd. ("Nang Kuang") 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 Lilly's ALIMTA® products prior to the expiration of U.S. Patent Nos. 5,344,932 ("the '932 patent") and 7,772,209 ("the '209 patent"). ALIMTA® is a chemotherapy agent used for the treatment of various types of cancer.

## PARTIES

2. Plaintiff Eli Lilly and Company 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. Plaintiff The Trustees of Princeton University is a not-for-profit educational institution organized and existing under the laws of the State of New Jersey, having a place of business at One Nassau Hall, Princeton, New Jersey 08540.

4. Defendant Nang Kuang Pharmaceutical Co., Ltd. is a Taiwanese company having its offices at No. 1001, Zhongshan Rd, Xinhua Dist., Tainan City, Taiwan. Nang Kuang is in the business of distributing, marketing and/or selling generic pharmaceutical products, directly or indirectly, in the Southern District of Indiana and throughout the United States.

5. Defendant CANDA NK-2, LLC ("CANDA") is a Texas limited liability company having its offices at 1404 S. New Road, Waco, Texas 76711. CANDA holds rights to ANDA No. 207352, which was filed by Nang Kuang. CANDA is in the business of distributing, marketing and/or selling generic pharmaceutical products, directly or indirectly, in the Southern District of Indiana and throughout the United States.

## JURISDICTION AND VENUE

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

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

8. This Court has personal jurisdiction over Nang Kuang because, among other things, following any FDA approval of ANDA No. 207352, Nang Kuang intends to distribute (directly and/or through affiliates or subsidiaries) Defendants' ANDA Products

throughout the United States and within Indiana and the Southern District of Indiana; if Nang Kuang is permitted to sell Defendants' ANDA Products in the United States prior to the expiration of the '932 and '209 patents, Nang Kuang will cause substantial injury to Lilly, an Indiana corporation headquartered within the Southern District of Indiana, and Nang Kuang knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana.

9. In the alternative, this Court has personal jurisdiction over Nang Kuang under Fed. R. Civ. P. 4(k)(2) because this action arises under federal law, Nang Kuang is not subject to jurisdiction in any state's courts of general jurisdiction, and the exercise of jurisdiction over Nang Kuang is consistent with the Constitution and the laws of the United States.

10. This Court has personal jurisdiction over CANDA because, among other things, following any FDA approval of ANDA No. 207352, CANDA intends to offer to sell and sell (directly and/or through affiliates or subsidiaries) Defendants' ANDA Products throughout the United States and within Indiana and the Southern District of Indiana; if CANDA is permitted to sell Defendants' ANDA Products in the United States prior to the expiration of the '932 and '209 patents, CANDA will cause substantial injury to Lilly, an Indiana corporation headquartered within the Southern District of Indiana, and CANDA knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana.

## BACKGROUND

11. ALIMTA®, in combination with cisplatin, is indicated (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.

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

13. The ’932 patent, titled “N-(pyrrolo(2,3-d)pyrimidin-3-ylacyl)-Glutamic Acid Derivatives,” was duly and legally issued on September 6, 1994. The ’932 patent is attached as Exhibit A hereto.

14. The ’209 patent, titled “Antifolate Combination Therapies,” was duly and legally issued on August 10, 2010. The ’209 patent is attached as Exhibit B hereto.

15. The ’932 and ’209 patents have been listed in connection with ALIMTA® in the FDA’s publication *Approved Drug Products with Therapeutic Equivalence Evaluations*.

16. By letter dated August 25, 2014 (“Defendants’ Notice Letter”), Defendants notified Plaintiffs that Nang Kuang had submitted to the FDA ANDA No. 207352 for Defendants’ pemetrexed disodium, 100 mg base/vial and 500 mg base/vial for intravenous infusion (“Defendants’ ANDA Products”). Defendants’ ANDA Products are generic versions of ALIMTA®.

17. The purpose of the ANDA is to obtain approval under the Federal Food, Drug, and Cosmetic Act (“FDCA”) to engage in the commercial manufacture, use, offer for sale, and/or sale of Defendants’ ANDA Products prior to the expiration of the ’932 and ’209 patents.

**COUNT I**

(Infringement of U.S. Patent No. 5,344,932)

18. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

19. As set forth in greater detail in the '932 patent, one or more claims of the '932 patent, incorporated by reference herein, cover ALIMTA®.

20. Princeton owns the '932 patent. Princeton will be substantially and irreparably damaged by infringement of the '932 patent.

21. Lilly has been granted an exclusive license under the '932 patent. Lilly will be substantially and irreparably damaged by infringement of the '932 patent.

22. Defendants' ANDA Products contain pemetrexed disodium.

23. Defendants' ANDA Products are covered by one or more claims of the '932 patent.

24. In Defendants' Notice Letter, Defendants notified Plaintiffs that, as part of their ANDA, Defendants filed 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), with respect to the '932 patent, asserting that the claims of the '932 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Defendants' ANDA Products.

25. Defendants' submission of ANDA No. 207352 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Defendants' ANDA Products prior to the expiration of the '932 patent is an act of infringement of the '932 patent under 35 U.S.C. § 271(e)(2)(A).

26. Defendants intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' ANDA Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 207352, i.e., prior to the expiration of the '932 patent.

27. Defendants have knowledge of the claims of the '932 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' ANDA Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 207352.

28. Defendants plan and intend to, and will, actively induce infringement of the '932 patent when their ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

29. The foregoing actions by Defendants constitute and/or will constitute infringement of the '932 patent and active inducement of infringement of the '932 patent.

30. An actual case or controversy exists between Plaintiffs and Defendants with respect to infringement of the '932 patent.

31. Defendants are without a reasonable basis for believing that they will not be liable for infringing the '932 patent and/or actively inducing infringement of the '932 patent.

32. Unless Defendants are enjoined from infringing the '932 patent and actively inducing infringement of the '932 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT II**

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

33. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

34. 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 $B_{12}$.

35. Lilly owns the '209 patent. Lilly will be substantially and irreparably damaged by infringement of the '209 patent.

36. Defendants' ANDA Products contain pemetrexed disodium.

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

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

39. In Defendants' Notice Letter, Defendants notified Plaintiffs that, as part of their ANDA, Defendants filed 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), 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 Defendants' ANDA Products.

40. Defendants' submission of ANDA No. 207352 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Defendants' 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).

41. Defendants intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' ANDA Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 207352, i.e., prior to the expiration of the '209 patent.

42. Defendants have knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' ANDA Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 207352.

43. Defendants plan and intend 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.

44. Defendants know that Defendants' ANDA Products are especially made or adapted for use in infringing the '209 patent, and that Defendants' ANDA Products are not suitable for substantial noninfringing use. Defendants plan and intend to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 207352.

45. The foregoing actions by Defendants 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.

46. An actual case or controversy exists between Plaintiffs and Defendants with respect to infringement of the ’209 patent.

47. Defendants are without a reasonable basis for believing that they 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.

48. Unless Defendants are 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, Plaintiffs request the following relief:

(a) A judgment that Defendants have infringed the ’932 patent and/or will infringe and/or actively induce infringement of the ’932 patent;

(b) A judgment ordering that the effective date of any FDA approval for Defendants to make, use, offer for sale, sell, market, distribute, or import Defendants’ ANDA Products, or any product the use of which infringes the ’932 patent, be not earlier than the expiration date of the ’932 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Defendants, and all persons acting in concert with Defendants, from making, using, selling, offering for sale, marketing, distributing, or importing Defendants’ ANDA Products, or any product the use of

which infringes the ’932 patent, or the inducement of any of the foregoing, prior to the expiration date of the ’932 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 Defendants’ ANDA Products, or any product the use of which infringes the ’932 patent, prior to the expiration date of the ’932 patent, infringes, will infringe and/or will actively induce infringement of the ’932 patent;

(e) A judgment that Defendants have infringed the ’209 patent and/or will infringe, actively induce infringement of, and/or contribute to infringement by others of the ’209 patent;

(f) A judgment ordering that the effective date of any FDA approval for Defendants to make, use, offer for sale, sell, market, distribute, or import Defendants’ 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;

(g) A preliminary and permanent injunction enjoining Defendants, and all persons acting in concert with Defendants, from making, using, selling, offering for sale, marketing, distributing, or importing Defendants’ 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;

(h) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing of Defendants’ 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 others of the '209 patent;

(i) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(j) An award of Plaintiffs' costs and expenses in this action; and

(k) Such further and other relief as this Court may deem just and proper.

Dated: October 8, 2014

Respectfully submitted,

*/s/ Jan M. Carroll*

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