IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELI LILLY AND COMPANY and THE TRUSTEES OF PRINCETON UNIVERSITY,	)	
Plaintiffs,	)	
v.	)	Civil Action No. _____
APP PHARMACEUTICALS, LLC,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Eli Lilly and Company ("Lilly") and The Trustees of Princeton University ("Princeton"), by their attorneys, for their Complaint, allege as follows:

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 APP Pharmaceuticals, LLC ("APP") of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of ALIMTA®, a chemotherapy agent marketed by Lilly, prior to the expiration of U.S. Patent No. 5,344,932 ("the '932 patent").

2. By letter dated June 2, 2011 (the "Notice Letter"), APP notified Lilly and Princeton that APP had submitted to the FDA a Supplement to ANDA No. 90-384, for APP's Pemetrexed Disodium Injectable, Eq. 100 mg Base/Vial ("APP's ANDA Product"), a drug product that is a generic version of ALIMTA®, containing a certification that the '932 patent is invalid, unenforceable, and/or will not be infringed by the sale of APP's ANDA Product.

PARTIES

3. 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.

4. Princeton 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.

5. Upon information and belief, defendant APP is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173-5837. Upon information and belief, APP is a wholly-owned subsidiary of APP Pharmaceuticals, Inc., which is a corporation organized and existing under the laws of the State of Delaware.

JURISDICTION AND VENUE

6. Jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391, and 1400(b). APP is subject to personal jurisdiction in Delaware because, among other things, APP is a resident and citizen of the State of Delaware and has submitted itself to the jurisdiction of courts in Delaware by virtue of its and APP Pharmaceuticals, Inc.'s organization under Delaware law.

BACKGROUND

7. ALIMTA® is a chemotherapy drug 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.

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

9. This action is related to C.A. No. 08-335-GMS (consolidated with C.A. Nos. 08-384-GMS, 08-860-GMS, and 09-272-GMS) in this District, an action for patent infringement of the '932 patent that was tried before Hon. Gregory M. Sleet, Chief Judge, on November 8 through November 15, 2010. APP, a party to C.A. No. 08-335-GMS, stipulated that its proposed generic copy of ALIMTA®, 500 mg Base/Vial, would infringe the '932 patent, and the Court tried the issue of validity of claims 1, 2, 3, and 7 of the '932 patent. At the conclusion of trial, the Court announced that it was ruling in favor of the Plaintiffs.

COUNT I – U.S. PATENT NO. 5,344,932

10. Plaintiffs incorporate each of the preceding paragraphs 1–9 as if fully set forth herein.

11. The '932 patent, entitled "N-(pyrrolo(2,3-d)pyrimidin-3-ylacyl)-Glutamic Acid Derivatives" (Exhibit A hereto), was duly and legally issued on September 6, 1994 to Princeton, as assignee of Edward C. Taylor.

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

13. Lilly has been granted an exclusive license under the '932 patent. Lilly

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

14. ALIMTA® is covered by one or more claims of the '932 patent, and the '932 patent has been listed in connection with that drug product in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*.

15. The purpose of APP's ANDA No. 90-384 was 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 APP's ANDA Product prior to the expiration of the '932 patent.

16. In the Notice Letter, APP notified Lilly and Princeton that, as part of its ANDA, APP had filed certifications 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. Upon information and belief, APP submitted ANDA No. 90-384 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '932 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, or sale of APP's ANDA Product.

17. APP's ANDA Product is covered by one or more claims of the '932 patent.

18. APP has knowledge of the '932 patent.

19. APP's filing of ANDA No. 90-384 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of APP's ANDA Product before the expiration of the '932 patent is an act of infringement of the '932 patent.

20. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's ANDA Product would infringe one or more claims of the '932 patent.

21. Upon information and belief, APP will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's ANDA Product

immediately and imminently upon approval of ANDA No. 90-384.

22. Upon information and belief, use of APP's ANDA Product in accordance with and as directed by APP's proposed labeling for that product would infringe one or more claims of the '932 patent.

23. Upon information and belief, APP will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of APP's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 90-384.

24. Upon information and belief, APP plans and intends to, and will, actively induce infringement of the '932 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

25. Upon information and belief, APP knows that APP's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '932 patent, and that APP's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, APP plans and intends to, and will, contribute to infringement of the '932 patent immediately and imminently upon approval of ANDA No. 90-384.

26. The foregoing actions by APP constitute and/or will constitute infringement of the '932 patent, active inducement of infringement of the '932 patent, and contribution to the infringement by others of the '932 patent.

27. Upon information and belief, APP acted without a reasonable basis for believing that it would not be liable for infringing the '932 patent, actively inducing infringement of the '932 patent, and contributing to the infringement by others of the '932 patent.

28. Unless APP is enjoined from infringing the '932 patent, actively inducing

infringement of the '932 patent, and contributing to the infringement by others of the '932 patent, Lilly and Princeton will suffer irreparable injury. Lilly and Princeton have no adequate remedy at law.

29. In connection with C.A. No. 08-335-GMS, Plaintiffs and APP entered into a stipulation of infringement. C.A. No. 08-335-GMS, D.I. 33. In that stipulation, APP agreed that "[t]he pemetrexed disodium product which is the subject of [APP's] ANDA No. 90-384 (including any amendments or supplements thereto), as well as the active ingredient therein, infringe" claims 1, 2, 3, and 7 of the '932 patent, assuming that those respective claims are valid and enforceable. APP has therefore stipulated to infringement of the '932 patent by APP's ANDA Product.

30. Because all issues of validity and enforceability of the '932 patent that APP might raise in this action are the same as the issues that APP litigated and lost, or declined to raise, in C.A. No. 08-335-GMS, APP is precluded by principles of claim preclusion and issue preclusion from raising them in this action. Plaintiffs are therefore entitled to judgment in their favor.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that APP has infringed the '932 patent;

(b) A judgment ordering that the effective date of any FDA approval for APP to make, use, offer for sale, sell, market, distribute, or import APP's ANDA Product, or any product or compound that 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 APP, and all persons acting in concert with APP, from making, using, selling, offering for sale, marketing,

distributing, or importing APP's ANDA Product, or any product or compound that infringes the '932 patent, or the inducement of or the contribution to 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 APP's ANDA Product, or any product or compound that infringes the '932 patent, prior to the expiration date of the '932 patent, will infringe, actively induce infringement of, and contribute to the infringement by others of the '932 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 Plaintiffs' costs and expenses in this action; and

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

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