UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,

Plaintiff

v.

AMNEAL PHARMACEUTICALS LLC,

Defendant.

Civil Action No. 1:17-cv-986

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 Amneal Pharmaceuticals LLC ("Amneal") of an Abbreviated New Drug Application ("ANDA") 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 ("Amneal's ANDA Products") prior to the expiration of U.S. Patent No. 7,772,209 ("the '209 patent"). Amneal notified Lilly that it had submitted to the FDA NDA No. 210047 for Amneal's ANDA Products by letter dated February 28, 2017 ("Amneal's Notice Letter" or "Notice Letter"). Upon information and belief, Amneal'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, Amneal Pharmaceuticals LLC is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807.

JURISDICTION AND VENUE

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

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

6. Upon information and belief, Amneal 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 website, "Amneal ranks as the seventh largest generic manufacturer in the United States, by prescription volume." Amneal further states on its website that "primary distribution & sales operations facilities in the United States are centrally situated in Glasgow, Kentucky. With over 215,000 square feet of space, they are strategically located in close proximity to the UPS hub and within the Central time zone, enabling it provide one-day ground delivery to more than 75% of the American population."

7. Upon information and belief, those products are then marketed, sold, and distributed to oncologists, clinics, and hospitals throughout the United States, including in Indiana, as well as to wholesalers, including in Indiana.

8. Upon information and belief, Amneal has directly entered into a distribution agreement with an Indiana wholesale distributor. According to the website for Amneal, Amneal

lists A.F. Hauser, Inc. as one of its authorized distributors of record of its products. Upon information and belief, A.F. Hauser, Inc. is located at 4401 East U.S. Hwy. 30, Valparaiso, Indiana 46383.

9. Upon information and belief, Amneal has sought approval in ANDA No. 210047 to distribute its ANDA Products in the United States, including in Indiana (and in this District), and will do so upon approval of ANDA No. 210047. The filing of ANDA No. 210047 is therefore tightly tied, in purpose and planned effect, to the deliberate making of sales in Indiana and this District, and reliably indicates plans to engage in marketing of Amneal's ANDA Products in this State and District.

10. Upon information and belief, Amneal has availed itself of the legal protections of the state of Indiana by filing claims or counterclaims affirmatively seeking relief in other prior actions in this Court.

11. Upon information and belief, with knowledge of the processes described in the FDCA and the Hatch-Waxman Act, Amneal 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. Upon information and belief, Amneal deliberately challenged Lilly's patent rights, and 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, Amneal knew that other FDCA and/or Hatch-Waxman Act infringement actions relating to the '209 patent had been brought and litigated in Indiana.

12. Because Lilly is incorporated and has its principal place of business in Indiana, the injury and consequences of Amneal's filing of ANDA No. 210047, challenging Lilly's patent

rights, are suffered in Indiana. Upon information and belief, Amneal knew that it was deliberately challenging the patent rights of an Indiana entity and seeking to challenge intellectual property held in Indiana and that the effects of any successful challenge of the '209 patent would be felt by Lilly in Indiana.

13. Upon information and belief, Amneal derives substantial revenue from pharmaceutical products that are used and/or consumed within Indiana, and which are manufactured by Amneal or its affiliates and/or for which Amneal is the named applicant on approved NDAs or ANDAs. Upon information and belief, various products for which Amneal, or its affiliates, is the named applicant on approved NDAs and ANDAs are available at pharmacies in Indiana.

14. Upon information and belief, if ANDA No. 210047 is approved, Amneal's ANDA Products, under the direction and control of physicians practicing in Indiana, will be administered to patients of Indiana. These activities, as well as Amneal's marketing, selling, and/or distributing of Amneal's ANDA Products, would have a substantial effect within Indiana and would constitute infringement of Lilly's patent in the event that Amneal's ANDA Products are approved before the '209 patent expires.

15. For the reasons described above, among others, the filing of ANDA No. 210047 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 Amneal.

BACKGROUND

16. 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.

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

18. 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.

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

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

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

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

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

23. Upon information and belief, Amneal's ANDA Products contain pemetrexed disodium.

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

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

26. Upon information and belief, Amenal filed as part of ANDA No. 210047 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 Amneal's ANDA Products.

27. The purpose of ANDA No. 210047 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Amneal's ANDA Products prior to the expiration of the '209 patent.

28. Amneal's submission of ANDA No. 210047 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Amneal'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).

29. Upon information and belief, Amneal intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Amneal's ANDA Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 210047, *i.e.*, prior to the expiration of the '209 patent.

30. Upon information and belief, Amneal has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Amneal has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Amneal's ANDA Products and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 210047.

31. Upon information and belief, Amneal 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.

32. Upon information and belief, Amenal knows that Amneal's ANDA Products are especially made or adapted for use in infringing the '209 patent, and that Amneal's ANDA Products are not suitable for substantial noninfringing use. Upon information and belief, Amneal plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 210047.

33. The foregoing actions by Amneal 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.

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

(h)

Respectfully submitted,

/s/ Anne N. DePrez

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