UNITED STATES DISTRICT COUR
SOUTHERN DISTRICT OF INDIAN
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,

Plaintiff,

v.

SHILPA MEDICARE LIMITED,

Defendant.

Civil Action No. 1:20-cv-3132

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 Shilpa Medicare Limited ("Shilpa") of a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell its Pemetrexed Injection, 100 mg/10mL, 500mg/50mL, and 1g/100mL products ("Shilpa's NDA Products") prior to the expiration of U.S. Patent No. 7,772,209 ("the '209 patent"). By letter dated November 12, 2020 ("Notice Letter"), Shilpa notified Lilly, *inter alia*, that it had submitted to the FDA NDA No. 215179 for Shilpa's NDA Products. Upon information and belief, Shilpa'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 principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

3. Upon information and belief, Shilpa is a corporation organized and existing under the laws of the Republic of India, having a registered office at 12-6-214/A1, Hyderabad Road, Raichur-584102, Karnataka, India, and a place of business at Plot #79, Road #15, Survey #125, IDA Mallapur, Nacharam, Uppal, Hyderabad-500076, India. Upon information and belief, Shilpa is in the business of distributing, marketing and/or selling generic drug products, directly or indirectly, in the Southern District of Indiana and throughout the United States.

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 Shilpa because, upon information and belief and among other things: (1) Shilpa 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. 215179, Shilpa seeks approval to sell a product the use of which 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 Food, Drug & Cosmetic Act ("FDCA") and the Hatch-Waxman Act, Shilpa 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. Shilpa 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, Shilpa knew that other FDCA and/or Hatch-Waxman Act infringement actions relating to the '209 patent had been brought and litigated in Indiana. (3) Following any FDA approval of Shilpa's NDA No. 215179, Shilpa intends to offer to sell and sell, directly or indirectly, Shilpa's NDA Products throughout the United States and within Indiana and the Southern District of Indiana. (4) If Shilpa is permitted to sell its NDA Products in the United States prior to the expiration of the '209 patent, Shilpa will cause substantial injury to Lilly, an Indiana corporation headquartered within the Southern District of Indiana, and Shilpa knows that Lilly will be injured by such actions in Indiana and the Southern District of Indiana. (5) Shilpa derives substantial revenue from things sold, used, or consumed within 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.

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

7. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Shilpa is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

BACKGROUND

8. ALIMTA® is indicated (in combination with cisplatin) for (a) the treatment of patients with malignant pleural mesothelioma, or (b) the initial treatment of locally advanced or

metastatic nonsquamous non-small cell lung cancer. ALIMTA® is also 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® is also indicated as a single-agent for the 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. ALIMTA® is also indicated (in combination with pembrolizumab and platinum chemotherapy) for initial treatment of patients with metastatic non-squamous non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations.

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 Shilpa with respect to infringement of the '209 patent.

13. This action is being filed within 45 days of Lilly's receipt of Shilpa'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, Shilpa's NDA Products contain pemetrexed disodium or its equivalent.

16. Upon information and belief, the proposed labeling for Shilpa's NDA Products involves administration of folic acid and vitamin B_{12}.

17. Upon information and belief, the use of Shilpa's NDA Products in accordance with and as directed by Shilpa's proposed labeling for those products will infringe claims 1-22 of the '209 patent, either literally or under the doctrine of equivalents. In Shilpa's Notice Letter, Shilpa did not assert non-infringement of the '209 patent by Shilpa's NDA Products.

18. Upon information and belief, Shilpa filed, as part of NDA No. 215179, 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 Shilpa's NDA Products.

19. The purpose of NDA No. 215179 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Shilpa's NDA Products prior to the expiration of the '209 patent.

20. Shilpa's submission of NDA No. 215179 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Shilpa'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).

21. Upon information and belief, Shilpa intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Shilpa's NDA Products and the proposed labeling thereto immediately and imminently upon approval of NDA No. 215179, *i.e.*, prior to the expiration of the '209 patent.

22. Upon information and belief, Shilpa has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Shilpa has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Shilpa's

NDA Products and the proposed labeling thereto immediately and imminently upon approval of NDA No. 215179.

23. Upon information and belief, Shilpa 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 of NDA No. 215179.

24. Upon information and belief, Shilpa knows that Shilpa's NDA Products are especially made or adapted for use in infringing the '209 patent, and that Shilpa's NDA Products are not suitable for substantial noninfringing use. Upon information and belief, Shilpa plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of NDA No. 215179.

25. The foregoing actions by Shilpa 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.

26. Unless Shilpa 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 Shilpa has infringed the '209 patent and/or will infringe and/or 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 Shilpa to make, use, offer for sale, sell, market, distribute, or import Shilpa'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 Shilpa, and all persons acting in concert with Shilpa, from making, using, selling, offering for sale, marketing, distributing, or importing Shilpa'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 Shilpa'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 others 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.

Dated: December 4, 2020

Respectfully submitted,

/s/ Deborah Pollack-Milgate

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