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

ELI LILLY AND COMPANY, Plaintiff, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	)	Civil Action No. 1:16-cv-308

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 Dr. Reddy's Laboratories, Inc. on behalf of defendant Dr. Reddy's Laboratories, Ltd. (collectively, "DRL") of a New Drug Application ("NDA") 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 ("DRL's NDA Products") prior to the expiration of U.S. Patent No. 7,772,209 ("the '209 patent"). DRL notified Lilly that it had submitted to the FDA NDA No. 208297 for DRL's NDA Products by letter dated December 22, 2015 ("DRL's Notice Letter" or "Notice Letter"). Upon information and belief, DRL's NDA 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, Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India, having a place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, India 500034.

4. Upon information and belief, Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 107 College Road East, Princeton, New Jersey 08540. Upon information and belief, Dr. Reddy's Laboratories, Inc. is in the business of manufacturing, marketing, and selling generic drug products.

5. Upon information and belief, Dr. Reddy's Laboratories, Inc. is a wholly-owned subsidiary of Dr. Reddy's Laboratories, Ltd. Upon information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. are agents and/or alter-egos of one another, operate in concert as integrated parts of the same business group, and enter or have entered into agreements with each other that are nearer than arm's length, including with respect to the manufacture, importation, marketing, sale, and distribution of DRL's NDA Products.

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. Upon information and belief, Dr. Reddy's Laboratories, Ltd. is a generic pharmaceutical company in India engaged in developing, manufacturing, marketing, selling, and distributing a broad range of pharmaceutical products globally. Upon information and belief, a substantial number of these products are marketed throughout the United States, including in the State of Indiana. Upon information and belief, Dr. Reddy's Laboratories, Ltd. operates its manufacturing, marketing, sales, and distribution infrastructure in the United States through Dr. Reddy's Laboratories, Inc. as a vertically-integrated company.

9. Upon information and belief, Dr. Reddy's Laboratories, Inc. performs functions relating to Dr. Reddy's Laboratories, Ltd., including manufacturing, marketing, and sales. Lee Banks, Esq., who is listed in DRL's Notice Letter as the Vice President, Intellectual Property of Dr. Reddy's Laboratories, Inc., is designated as the agent of Dr. Reddy's Laboratories, Ltd. for service of process with respect to this litigation. Upon information and belief, Dr. Reddy's Laboratories, Inc. participated with Dr. Reddy's Laboratories, Ltd. in the preparation, review, and/or submission of NDA No. 208297.

10. Upon information and belief, Dr. Reddy's Laboratories, Inc. is engaged in the manufacturing, marketing, and sale of generic pharmaceutical products for the U.S. prescription drug market on behalf of Dr. Reddy's Laboratories, Ltd. Upon information and belief, Dr. Reddy's Laboratories, Ltd. provides Dr. Reddy's Laboratories, Inc. with products for sale in the United States. 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, who sell, with Dr. Reddy's Laboratories, Ltd.'s knowledge, Dr. Reddy's Laboratories Ltd.'s products, including in Indiana. Upon information and belief,

Dr. Reddy's Laboratories, Inc. or its affiliates will distribute DRL's NDA Products in the United States, including in Indiana, upon approval of NDA No. 208297.

11. Upon information and belief, DRL has previously used the process contemplated by the Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. § 355(b) and the Drug Price Competition Term Restoration Act of 1984, 21. U.S.C. § 355(j) (the "Hatch-Waxman Act"), to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(b)(2)(A)(iv) or 505(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the processes contemplated by those acts. Upon information and belief, as of March 31, 2015, DRL had cumulative filings of 735 Drug Master Files and 220 Abbreviated New Drug Applications ("ANDAs"), of which 68 were pending approval.

12. Upon information and belief, DRL 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.

13. Upon information and belief, with knowledge of the processes described in the FDCA and the Hatch-Waxman Act, DRL 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, DRL 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, DRL knew that other FDCA and/or Hatch-Waxman Act infringement actions relating to the '209 patent had been brought and litigated in Indiana.

14. Because Lilly is incorporated and has its principal place of business in Indiana, the injury and consequences of DRL's filing of NDA No. 208297, challenging Lilly's patent rights, are suffered in Indiana. Upon information and belief, DRL 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.

15. Upon information and belief, if NDA No. 208297 is approved, DRL will directly or indirectly market and/or sell DRL's NDA Products within the United States, including in Indiana, consistent with DRL's practices for the marketing and distribution of other pharmaceutical products on its own or through its affiliates. Upon information and belief, DRL and/or its affiliates regularly do business in Indiana, and their practices with other pharmaceutical products have involved the distribution of DRL products, directly or indirectly, throughout the United States, including in Indiana. Upon information and belief, DRL's pharmaceutical products are used and/or consumed within and throughout the United States, including Indiana.

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

17. Upon information and belief, if NDA No. 208297 is approved, DRL's NDA Products, under the direction and control of physicians practicing in Indiana, will be

administered to patients of Indiana. These activities, as well as DRL's marketing, selling, and/or distributing of DRL's NDA Products, would have a substantial effect within Indiana and would constitute infringement of Lilly's patent in the event that DRL's NDA Products are approved before the '209 patent expires.

18. For the reasons described above, among others, this Court may properly exercise personal jurisdiction over Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.

19. Alternatively, if the exercise of personal jurisdiction over Dr. Reddy's Laboratories Ltd. in this Court is not held to be proper, then, upon information and belief, Dr. Reddy's Laboratories, Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and there is therefore personal jurisdiction over Dr. Reddy's Laboratories, Ltd. in this Court pursuant to Fed. R. Civ. P. 4(k)(2).

BACKGROUND

20. 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.

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

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

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

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

25. This action is being filed within 45 days of Lilly’s receipt of DRL’s Notice Letter.

COUNT

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

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

27. Upon information and belief, DRL’s NDA Products contain pemetrexed disodium or its equivalent.

28. Upon information and belief, the proposed labeling for DRL’s NDA Products involves administration of folic acid and vitamins B_{12}.

29. Upon information and belief, the use of DRL’s NDA Products in accordance with and as directed by DRL’s proposed labeling for those products will infringe claims 1-22 of the ’209 patent, either literally or under the doctrine of equivalents.

30. Upon information and belief, DRL filed as part of NDA No. 208297 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 DRL’s NDA Products.

31. The purpose of NDA No. 208297 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of DRL's NDA Products prior to the expiration of the '209 patent.

32. DRL's submission of NDA No. 208297 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of DRL'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).

33. Upon information and belief, DRL intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's NDA Products and the proposed labeling therefor immediately and imminently upon approval of NDA No. 208297, *i.e.*, prior to the expiration of the '209 patent.

34. Upon information and belief, DRL has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, DRL has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's NDA Products and the proposed labeling therefor immediately and imminently upon approval of NDA No. 208297.

35. Upon information and belief, DRL 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.

36. Upon information and belief, DRL knows that DRL's NDA Products are especially made or adapted for use in infringing the '209 patent, and that DRL's NDA Products are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and

intends to, and will, contribute to infringement of the ’209 patent immediately and imminently upon approval of NDA No. 208297.

37. The foregoing actions by DRL 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.

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

Dated: February 5, 2016

/s/ *Jan M. Carroll*

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