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. 1:19-cv-1246

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 an amendment to New Drug Application ("NDA") No. 208297 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a Pemetrexed for Injection 1g/vial product ("DRL's NDA Product") prior to the expiration of U.S. Patent No. 7,772,209 ("the '209 patent"). DRL notified Lilly that it had submitted this amendment by letter dated February 11, 2019 (the "Notice Letter"). Upon information and belief, DRL's NDA Product 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.

2. In *Eli Lilly and Company v. Dr. Reddy's Laboratories, Ltd. et al.*, No. 1:16-cv-308-TWP-MPB (S.D. Ind.), this Court concluded—after a two-day bench trial—that the sale of

the 100 mg/vial and 500 mg/vial Pemetrexed for Injection products that are the subject of NDA No. 208297 would indirectly infringe the '209 patent. Specifically, the Court held that the administration of these products according to the labeling proposed by DRL would infringe certain claims of the '209 patent under the doctrine of equivalents, and that DRL would induce and contribute to that infringement. Accordingly, the Court entered final judgment in favor of Lilly and against DRL, finding that the "filing of NDA No. 208297 infringed at least claims 9, 10, 12, 13, 14, 15, 18, 19, 21, and 22 of U.S. Patent No. 7,772,209" and ordering that "the effective date of any approval of any product that is the subject of NDA No. 208297 shall not be earlier than the latest date of expiration of U.S. Patent No. 7,772,209, including any period of pediatric exclusivity." No. 1:16-cv-308-TWP-MPB, ECF 259 (S.D. Ind. Jul. 27, 2018).

3. Upon information and belief, the only difference between DRL's NDA Product at issue in this case and the 100 mg/vial and 500 mg/vial Pemetrexed for Injection products found to infringe under the doctrine of equivalents, is the quantity of DRL's product in each vial. In terms of the method of administration claimed in the '209 patent, the 1g/vial product that is the subject of this action is identical to the 100 mg/vial and 500 mg/vial Pemetrexed for Injection products already adjudicated. Thus, all of the factual and legal questions at issue in this case have already been litigated between the parties and decided in favor of Lilly, and Lilly is entitled to entry of judgment.

PARTIES

4. 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.

5. 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-500034, Telangana, India.

6. 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.

7. Upon information and belief, Dr. Reddy's Laboratories, Inc. is an indirect 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 Product.

JURISDICTION

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

9. Upon information and belief, Dr. Reddy's Laboratories, Ltd. is engaged in developing, manufacturing, marketing, selling, and distributing a broad range of generic 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.

10. Upon information and belief, Dr. Reddy's Laboratories, Inc. performs functions relating to Dr. Reddy's Laboratories, Ltd., including manufacturing, marketing, and sales. Anjum Swaroom, 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 and the amendments thereto.

11. Upon information and belief, Dr. Reddy's Laboratories, Inc. is engaged in the manufacturing, marketing, and sale of generic pharmaceutical products for the United States 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. and/or its affiliates will distribute DRL's NDA Product in the United States, including in Indiana, upon approval of NDA No. 208297 and the amendments thereto.

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, including *Eli Lilly and Company v. Dr. Reddy's Laboratories, Ltd. et al.*, 1:16-cv-308-TWP-MPB (S.D. Ind.). In that case DRL affirmatively filed a counterclaim, asking this Court to adjudicate the infringement issues with respect to the same NDA No. 208297 that

has now been amended. Thus, upon information and belief, DRL has consented to the jurisdiction of this Court with respect to adjudicating the infringement of DRL's NDA Product.

13. Upon information and belief, DRL regularly does business in Indiana and has engaged in a persistent course of conduct within Indiana by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Indiana, and/or by directly selling pharmaceutical products in Indiana.

14. Upon information and belief, DRL has sought approval in its amendment to NDA No. 208297 to distribute DRL's NDA Product in the United States, including in Indiana (and in this District) and will do so upon approval of the amendment to NDA No. 208297. The filing of NDA No. 208297 and the amendments thereto is therefore tightly tied, in purpose and planned effect, to the deliberate making of sales in Indiana and this District, and reliably indicates that DRL plans to engage in the marketing of DRL's NDA Product in this State and District.

15. Upon information and belief, with knowledge of the processes described in the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(b) and the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (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, including the prior infringement action against DRL with respect to the same NDA.

16. 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 and the amendments thereto, 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.

17. Upon information and belief, if the amendment to NDA No. 208297 is approved, DRL will directly or indirectly market and/or sell DRL's NDA Product 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.

18. 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 Abbreviated New Drug Applications ("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.

19. Upon information and belief, if NDA No. 208297 is approved, DRL's NDA Product, 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 Product, would have a substantial effect within Indiana and would constitute infringement of Lilly's patent in the event that DRL's NDA Product is approved before the '209 patent expires.

20. For the reasons described above, among others, the filing of the amendment to NDA No. 208297 was suit-related conduct with a substantial connection to Indiana and this District, the exercise of personal jurisdiction over DRL does not offend traditional notions of fair play and substantial justice, and this Court may properly exercise personal jurisdiction over Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.

21. 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

22. 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 non-squamous non-small cell lung cancer ("NSCLC"). ALIMTA® is also indicated as a single-agent for the treatment of patients with locally advanced or metastatic non-squamous NSCLC after prior chemotherapy. ALIMTA® is also indicated for maintenance treatment of patients with locally advanced or metastatic non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy. ALIMTA® is also approved for the initial treatment of patients with metastatic non-squamous NSCLC, with no

EGFR or ALK genomic tumor aberrations in combination with pembrolizumab and platinum chemotherapy.

23. Lilly sells ALIMTA® in the United States pursuant to an NDA that has been approved by the FDA.

24. The ’209 patent, titled “Antifolate Combination Therapies,” was duly and legally issued on August 10, 2010. The validity of the ’209 patent was upheld by the Federal Circuit in *Eli Lilly and Company v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357 (Fed. Cir. 2017). The ’209 patent is attached as Exhibit A hereto.

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

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

27. Lilly received DRL’s Notice Letter on February 12, 2019. This action is being filed within 45 days of Lilly’s receipt of DRL’s Notice Letter.

28. Both the ’209 patent and NDA No. 208297 were previously the subject of litigation between Lilly and DRL. DRL notified Lilly that it had filed NDA No. 208297 by letter dated December 22, 2015, and Lilly filed suit against DRL on February 5, 2016, alleging that the filing of DRL’s NDA infringed the ’209 patent. *See* No. 1:16-cv-308-TWP-MPB, ECF 1 (S.D. Ind. Feb. 5, 2016). DRL could have challenged the validity of the ’209 patent as a counterclaim or affirmative defense to Lilly’s claim of patent infringement, but did not do so. *See* No. 1:16-cv-308-TWP-MPB, ECF 17 (S.D. Ind. Mar. 7, 2016). DRL is thus barred by the doctrines of res judicata and/or collateral estoppel from challenging the validity of any claim of the ’209 patent that was adjudicated in the prior litigation. After a two-day bench trial, this Court found that by filing NDA No. 208297, DRL indirectly infringed certain claims of the ’209 patent and entered

final judgment in favor of Lilly on July 27, 2018. Under the doctrines of res judicata and/or collateral estoppel, DRL is further barred from contesting infringement under any theory that was adjudicated in the prior litigation between Lilly and DRL involving NDA No. 208297 and the '209 patent.

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

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

30. Upon information and belief, the administration of DRL's NDA Product, which contains pemetrexed ditromethamine, is equivalent to the administration of pemetrexed disodium.

31. As this Court has found, pemetrexed ditromethamine and pemetrexed disodium both dissociate in the aqueous solutions that are to be infused into patients, and consequently patients receiving DRL's NDA Product will receive exactly the same active pemetrexed moiety as those receiving pemetrexed disodium. Thus, administering DRL's NDA Product and administering pemetrexed disodium are insubstantially different from one another.

32. Upon information and belief, the proposed labeling for DRL's NDA Product involves administration of folic acid and vitamins B_{12}.

33. Upon information and belief, the use of DRL's NDA Product in accordance with and as directed by DRL's proposed labeling for that product will infringe claims 1–22 of the '209 patent under the doctrine of equivalents.

34. In addition, upon information and belief, the administration of DRL's NDA Product will at least under certain circumstances be performed together with the administration of saline solution, thus constituting administration of pemetrexed disodium, and in consequence, the administration of DRL's NDA Product as directed by DRL's proposed labeling will literally

infringe claims 1–22 of the ’209 patent.

35. Upon information and belief, DRL filed as part of its amendment to 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 Product.

36. The purpose of filing the amendment to 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 Product prior to the expiration of the ’209 patent.

37. DRL’s submission of the amendment to 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 Product 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).

38. 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 Product and the proposed labeling therefor immediately and imminently upon the approval of NDA No. 208297 and any amendments thereto, *i.e.*, prior to the expiration of the ’209 patent.

39. Upon information and belief, DRL has knowledge of the claims of the ’209 patent. Notwithstanding this knowledge, DRL continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL’s NDA Product and the proposed labeling therefor immediately and imminently upon the approval of NDA No. 208297 and any amendments thereto.

40. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the ’209 patent when NDA No. 208297 and any amendments thereto are

approved, and plans and intends to, and will, do so immediately and imminently upon approval.

41. Upon information and belief, DRL knows that DRL's NDA Product is especially made or adapted for use in infringing the '209 patent, and that DRL's NDA Product is 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 and any amendments thereto.

42. 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.

43. 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 Product, 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 Product, or any product the use of which infringes the '209 patent, or inducing or contributing 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 Product, 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: March 27, 2019

Respectfully submitted,

/s/*Deborah Pollack-Milgate*
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