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

ELI LILLY AND COMPANY,	)	
	)	
Plaintiff,	)	
v.	)	Civil Action No. 1:16-cv-469
	)	
BIOCON LIMITED,	)	
	)	
Defendants.	)	

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 Biocon Limited ("Biocon") 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 (collectively, "Biocon's ANDA Product") prior to the expiration of U.S. Patent No. 7,772,209 ("the '209 patent").

2. By letter dated February 4, 2016 ("Notice Letter"), Biocon notified Lilly that it had submitted to the FDA ANDA No. 20-8927 for Biocon's ANDA Product. Upon information and belief, Biocon's ANDA Product will be marketed as a generic version of ALIMTA®, a chemotherapy agent developed and distributed by Lilly and used for the treatment of various types of cancer.

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. Upon information and belief, Biocon is a corporation organized and existing under the laws of India, having a place of business at 20th KM, Hosur Road, Electronic City, Bangalore, India 560100.

JURISDICTION AND VENUE

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

6. Upon information and belief, Biocon is a generic pharmaceutical company that develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Indiana, either directly or through its affiliates.

7. Upon information and belief, Biocon and/or its affiliates maintain a broad distribution network within Indiana and will utilize this network to market, sell, and/or distribute Biocon's ANDA Product in Indiana, if ANDA No. 20-8927 is approved.

8. Upon information and belief, with knowledge of the Hatch-Waxman Act process, Biocon directed the Notice Letter to Lilly, an entity incorporated in Indiana, at its corporate headquarters in Indiana, and alleged in the Notice Letter that Lilly's '209 patent is invalid, unenforceable, and/or not infringed by Biocon's ANDA Product. Upon information and belief, Biocon knowingly and 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 Hatch-Waxman Act. Moreover, upon information and belief, Biocon knew that other Hatch-Waxman Act infringement actions relating to the '209 patent had been brought and litigated in Indiana.

9. Because Lilly is incorporated in Indiana, the injury and consequences from Biocon's filing of ANDA No. 20-8927, challenging Lilly's patent rights, are suffered in Indiana. Upon information and belief, Biocon knew that it was deliberately challenging the patent rights of an Indiana entity and seeking to invalidate intellectual property held in Indiana and that the effects of any invalidation of the '209 patent would be felt by Lilly in Indiana.

10. Upon information and belief, if ANDA No. 20-8927 is approved, Biocon will directly or indirectly manufacture, market, and/or sell Biocon's ANDA Product within the United States, including in Indiana, consistent with Biocon's practices for the marketing and distribution of other generic pharmaceutical products on its own or through its affiliates. Upon information and belief, Biocon and/or its affiliates regularly do business in Indiana, and their practices with other generic pharmaceutical products have involved distribution of Biocon products, directly or indirectly, throughout the United States, including in Indiana. Upon information and belief, Biocon's generic pharmaceutical products are used and/or consumed within and throughout the United States, including Indiana.

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

12. Upon information and belief, if ANDA No. 20-8927 is approved, Biocon's ANDA Product will be prescribed by physicians practicing in Indiana, dispensed by pharmacies located within Indiana, and used by patients in Indiana. These activities, as well as Biocon's marketing, selling, and/or distributing of Biocon's ANDA Product, would have a substantial effect within Indiana and would constitute infringement of Lilly's patent in the event that Biocon's ANDA Product is approved before the '209 patent expires.

13. For the reasons described above, among others, this Court may properly exercise personal jurisdiction over Biocon.

14. In the alternative, this Court has personal jurisdiction over Biocon under Fed. R. Civ. P. 4(k)(2) because this action arises under federal law, the action arises out of Biocon's submission of an ANDA with the FDA in the United States in an effort to obtain U.S. regulatory approval, Biocon is not subject to jurisdiction in any state's courts of general jurisdiction, and the exercise of jurisdiction over Biocon is consistent with the Constitution and the laws of the United States.

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

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***.

19. Lilly is the assignee of the ’209 patent. As set forth in greater detail in the ’209 patent, one or more claims of the ’209 patent, incorporated by reference herein, cover a method of administering pemetrexed disodium to a patient in need thereof that also involves administration of folic acid and vitamin B_{12}.

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

COUNT

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

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

22. Upon information and belief, Biocon’s ANDA Product contains pemetrexed disodium.

23. Upon information and belief, the use of Biocon’s ANDA Product in accordance with Biocon’s proposed labeling for Biocon’s ANDA Product involves administration of folic acid and vitamin B_{12}.

24. Upon information and belief, the use of Biocon's ANDA Product in accordance with and as directed by Biocon's proposed labeling for that product will infringe one or more claims of the '209 patent.

25. Upon information and belief, Biocon filed as a part of ANDA No. 20-8927 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), with respect to the '209 patent, 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 Biocon's ANDA Product.

26. The purpose of ANDA No. 20-8927 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Biocon's ANDA Product prior to the expiration of the '209 patent.

27. Biocon's submission of ANDA No. 20-8927 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Biocon's ANDA 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).

28. Upon information and belief, Biocon intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Biocon's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 20-8927, *i.e.*, prior to the expiration of the '209 patent.

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

Biocon's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 20-8927.

30. Upon information and belief, Biocon plans and intends to, and will, actively induce infringement of the '209 patent when Biocon's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

31. Upon information and belief, Biocon knows that Biocon's ANDA Product is especially made or adapted for use in infringing the '209 patent, and that Biocon's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Biocon plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 20-8927.

32. The foregoing actions by Biocon 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.

33. Upon information and belief, Biocon is without a reasonable basis for believing that it will not be liable for infringing the '209 patent, actively inducing infringement of the '209 patent, and/or contributing to the infringement by others of the '209 patent.

34. Unless Biocon 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 Biocon 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 Biocon to make, use, offer for sale, sell, market, distribute, or import Biocon's ANDA 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 Biocon, and all persons acting in concert with Biocon, from making, using, selling, offering for sale, marketing, distributing, or importing Biocon's ANDA Product, 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 Biocon's ANDA 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 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 26, 2016

Respectfully submitted,

/s/ *Jan M. Carroll*

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