

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-2960
)
 FRESENIUS KABI USA, LLC,)
)
 Defendant.)
 _____)

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 Fresenius Kabi USA, LLC (“Fresenius”) of an Abbreviated New Drug Application (“ANDA”) with the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell its Pemetrexed Disodium for Injection, Eq. 750 mg Base/Vial product (“Fresenius’s ANDA Product”) prior to the expiration of U.S. Patent No. 7,772,209 (“the ’209 patent”). Fresenius notified Lilly that it had submitted to the FDA an amendment to ANDA No. 90-384, seeking approval for Fresenius’s ANDA Product, by letter dated October 6, 2016 (“Fresenius’s Notice Letter” or “Notice Letter”). Upon information and belief, Fresenius’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

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, Fresenius is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3 Corporate Drive, Lake Zurich, Illinois 60047. Upon information and belief, Fresenius is in the business of manufacturing, marketing, and selling generic drug products. Upon information and belief, Fresenius was formerly known as APP Pharmaceuticals, LLC.

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. This Court has personal jurisdiction over Fresenius because, upon information and belief: (1) Fresenius is in the business of manufacturing products which it and/or its affiliates or subsidiaries distribute, sell, and offer to sell throughout the United States, including Indiana and the Southern District of Indiana; (2) Fresenius derives substantial revenue from things sold, used, or consumed within Indiana and the Southern District of Indiana; (3) as part of its ordinary business practice of engaging in U.S. patent litigation, Fresenius litigated ANDA cases in this District, including by asserting counterclaims; (4) following any FDA approval of ANDA No. 90-384 Fresenius intends to distribute (directly and/or through affiliates or subsidiaries) Fresenius's ANDA Product within Indiana and this District; (5) Fresenius knowingly and purposefully directed Fresenius's Notice Letter to Lilly at its principal place of

business within this District, thus intentionally challenging the intellectual property rights held by an Indiana corporation in this District; (6) if Fresenius is permitted to sell Fresenius's ANDA Product in the United States prior to the expiration of the '209 patent, Fresenius will cause substantial injury to Lilly, an Indiana corporation headquartered within the Southern District of Indiana, and Fresenius knows that Lilly will be injured by such actions in Indiana and this District; and (7) directly and/or through its affiliates or subsidiaries, Fresenius regularly does and solicits business in Indiana and this District, including the distribution and sale of drug products in Indiana and this District; is engaged in and has maintained systematic and continuous business contacts within the State of Indiana and this District; and has purposefully availed itself of the benefits and protections of the laws of Indiana. In addition, Lilly was in litigation in this Court with Fresenius (including under its former name of APP Pharmaceuticals, LLC) regarding the same ANDA No. 90-384, in Case Nos. 1:10-cv-1376-TWP-DKL and 1:15-cv-96-TWP-DKL (now consolidated with Case No. 1:10-cv-1376), and Fresenius did not challenge personal jurisdiction in those actions. Case No. 1:10-cv-1376 is currently on appeal to the Federal Circuit, Case No. 2015-2067.

BACKGROUND

7. 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.

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

9. The '209 patent, titled "Antifolate Combination Therapies," was duly and legally issued on August 10, 2010. The '209 patent is attached as Exhibit A.

10. 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 B₁₂.

11. Lilly has previously asserted the '209 patent against Fresenius (including under its former name of APP Pharmaceuticals, LLC) in this Court, alleging, *inter alia*, that the filing of ANDA No. 90-384, seeking FDA approval for 100 mg Base/Vial, 500 mg Base/Vial, and 1000 mg Base/Vial ANDA products, infringed the '209 patent. These actions were before this Court as Case Nos. 10-cv-1376-TWP-DKL and 1:15-cv-96-TWP-DKL (now consolidated with Case No. 1:10-cv-1376), and Case No. 1:10-cv-1376 is currently on appeal to the Federal Circuit, Case No. 2015-2067. The instant action concerns an amendment to the same ANDA No. 90-384, seeking FDA approval for a 750 mg Base/Vial product.

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

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

COUNT

(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, Fresenius's ANDA Product contains pemetrexed disodium.

16. Upon information and belief, the use of Fresenius's ANDA Product in accordance with Fresenius's proposed labeling for Fresenius's ANDA Product involves administration of folic acid and vitamin B₁₂.

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

18. Upon information and belief, Fresenius filed as a part of ANDA No. 90-384 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 and/or not infringed by the manufacture, use, offer for sale, or sale of Fresenius's ANDA Product.

19. The purpose of ANDA No. 90-384 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Fresenius's ANDA Product prior to the expiration of the '209 patent.

20. Fresenius's submission of ANDA No. 90-384 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Fresenius'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).

21. Upon information and belief, Fresenius intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-384, *i.e.*, prior to the expiration of the '209 patent.

22. Upon information and belief, Fresenius has knowledge of the claims of the '209 patent. Notwithstanding this knowledge, Fresenius has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius's ANDA Product and the proposed labeling therefor immediately and imminently upon approval of ANDA No. 90-384.

23. Upon information and belief, Fresenius 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.

24. Upon information and belief, Fresenius knows that Fresenius's ANDA Product is especially made or adapted for use in infringing the '209 patent, and that Fresenius's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Fresenius plans and intends to, and will, contribute to infringement of the '209 patent immediately and imminently upon approval of ANDA No. 90-384.

25. The foregoing actions by Fresenius 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. In Case No. 10-cv-1376-TWP-DKL, this Court rejected Fresenius's challenges to the validity of certain claims of the '209 patent as well as its non-infringement defenses. Accordingly, Fresenius is estopped from challenging the validity of those claims of the

'209 patent in this case. In addition, because, on information and belief, Fresenius's ANDA Product is the substantially same as the products that were the subject of Case No. 10-cv-1376-TWP-DKL other than the quantity of pemetrexed disodium in each vial, which is irrelevant to whether Fresenius has infringed or will infringe the '209 patent, Fresenius also is estopped from contesting infringement.

27. Upon information and belief, Fresenius 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.

28. Unless Fresenius 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 Fresenius 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 Fresenius to make, use, offer for sale, sell, market, distribute, or import Fresenius'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 Fresenius, and all persons acting in concert with Fresenius, from making, using, selling, offering for sale, marketing, distributing, or importing Fresenius'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 Fresenius'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 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: November 1, 2016

Respectfully submitted,

/s/ Jan M. Carroll

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