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

ELI LILLY AND COMPANY

Plaintiff,

v.

SICOR PHARMACEUTICALS, INC., SICOR, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., AND TEVA PHARMACEUTICALS USA, INC.

Defendants.

Civil Action No.:

1:06-cv-0238-SEB-VSS

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Eli Lilly and Company ("Lilly") brings this action for patent infringement against SICOR Pharmaceuticals, Inc. ("Sicor Pharma"), SICOR, Inc. ("Sicor Inc."), Teva Pharmaceutical Industries Ltd. ("Teva Industries"), and Teva Pharmaceuticals USA, Inc. ("Teva USA"). This action involves two patents. The first concerns the pharmaceutical drug product, Gemzar®. The second concerns the use of this drug product as a treatment for susceptible neoplasms.

JURISDICTION AND PARTIES

1. Lilly is an Indiana corporation, having its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is engaged in the business of research, development, manufacture, and sale of pharmaceutical drug products throughout the world.

2. Upon information and belief, Sicor Pharma is a Delaware corporation having its principal place of business at 19 Hughes, Irvine, California 92618. Upon information and belief, Sicor Pharma is a wholly owned and directly controlled subsidiary of Teva USA. Upon information and belief, Sicor Pharma develops and markets generic injectable drug products, which constitute Teva USA's line of injectable products.

3. Upon information and belief, Sicor Inc. is a Delaware corporation having a principal place of business at 19 Hughes, Irvine, California 92618. Upon information and belief, Sicor Inc. is another wholly owned and directly controlled subsidiary of Teva USA. Upon information and belief, Sicor Inc. is a generic pharmaceutical company specializing in injectable drug products and active pharmaceutical ingredients.

4. Upon information and belief, Teva USA is a Delaware corporation having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454, and is a wholly owned and directly controlled subsidiary of Teva Industries. Upon information and belief, Teva USA markets a wide range of generic drug products, and specifically markets injectable drug products through Sicor Pharma.

5. Upon information and belief, Teva Industries is an Israeli corporation and maintains an office at 5 Basel St., Patach, Tikva 49131 Israel. Upon information and belief, Teva Industries is a global pharmaceutical company specializing in the development, production, and marketing of generic drug products, as well as bulk active pharmaceutical ingredients. Upon information and belief, Teva Industries expanded its business into the area of generic injectable drug products through its acquisition of Sicor Pharma and Sicor Inc.

6. Upon information and belief, Teva Industries markets generic drug products in the Southern District of Indiana and throughout the United States through its wholly owned and directly controlled subsidiary Teva USA.

7. Upon information and belief, Teva Industries, by and through Teva USA, uses Sicor Inc. and Sicor Pharma to carry out its business of importing, manufacturing, formulating, filling, labeling, and packaging finished dosage forms of injectable generic drug products for distribution in the Southern District of Indiana and throughout the United States.

8. Upon information and belief, Teva Industries acquired Sicor Pharma and Sicor Inc. in January 2004, and since then has endeavored to completely integrate Sicor Pharma and Sicor Inc.'s business into the operations of Teva Industries and Teva USA.

9. The Court has personal jurisdiction over the defendants because they have maintained continuous and systematic contacts with Indiana, and have purposefully availed themselves of the benefits and protections of the laws of Indiana by, among other things, placing goods in the stream of commerce with the intent that the goods would be marketed and distributed to residents of Indiana, have received substantial revenue for pharmaceutical sales in Indiana, and have since at least 1999 entered into or attempted to enter into agreements with Indiana residents.

10. This patent infringement action arises under the United States Patent Laws, Title 35, United States Code, including 35 U.S.C. § 271(e)(2). Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue in this Court is proper under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I FOR PATENT INFRINGEMENT

11. United States Patent No. 4,808,614 ("the '614 patent"), entitled "Difluoro Antivirals and Intermediate Therefor," was duly and legally issued to Lilly by the United States Patent and Trademark Office on February 28, 1989, and expires on May 15, 2010, followed by the six-month period of market exclusivity granted by the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355a, ending on November 15, 2010. A true and correct copy of the '614 patent is attached as Exhibit A. Since its date of issue, Lilly has been, and still is, the owner of that patent.

12. United States Patent No. 5,464,826 ("the '826 patent"), entitled "Method of Treating Tumors in Mammals with 2',2'-Difluoronucleosides," was duly and legally issued to Lilly by the United States Patent and Trademark Office on November 7, 1995, and expires on November 7, 2012, followed by the six-month period of market exclusivity granted by the FDA under 21 U.S.C. § 355a, ending on May 7, 2013. A true and correct copy of the '826 patent is attached as Exhibit B. Since its date of issue, Lilly has been, and still is, the owner of that patent.

13. Lilly is the holder of approved New Drug Application No. 20-509 for the use of Gemzar® as a treatment for non-small cell lung cancer, pancreatic cancer, and breast cancer.

14. Upon information and belief, Sicor Pharma filed with the FDA, in Rockville, Maryland, Abbreviated New Drug Applications ("ANDAs") under 21 U.S.C. § 355(j), to obtain approval for the commercial manufacture, use, and sale of Gemcitabine for Injection, 200 mg base/mL and 1g base/mL. Upon information and belief, Sicor Pharma filed the ANDAs, assigned ANDA Nos. 77-961 and 77-983, to obtain approval to market generic versions of gemcitabine before the expiration date of the '614 or '826 patent. Upon information and belief,

those ANDAs contained certifications, pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), alleging that the claims of the '614 and '826 patents are invalid or would not be infringed.

15. Sicor Pharma caused to be sent to Lilly letters ("the Notice Letters"), dated January 3, 2006, and January 16, 2006, notifying Lilly that Sicor Pharma had filed ANDAs for Gemcitabine for Injection 200 mg base/mL and 1g base/mL, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The letters allege noninfringement of claims 3-6, 9, 10, 13, and 14 of the '614 patent and claims 3-5 of the '826 patent. The letters further allege that claims 1, 2, 7, 8, 11, and 12 of the '614 patent are invalid for one reason, and that claims 1, 2, 6, and 7 of the '826 patent are invalid for two reasons. Lilly received the Notice Letters on or about January 4, 2006, and January 17, 2006.

16. Under 35 U.S.C. § 271(e)(2)(A), Sicor Pharma's submissions to the FDA of its ANDAs to obtain approval for the manufacture, use, or sale of gemcitabine before the expiration of the '614 and '826 patents constitute acts of infringement of these patents, and if approved, Sicor Pharma's commercial manufacture, use, offer to sell, sale, or importation of gemcitabine would infringe one or more claims of the '614 and '826 patents under 35 U.S.C. § 271(a)-(c).

17. Upon information and belief, the Defendants have filed or caused to be filed an application with the FDA, seeking authorization to import, market, use, offer for sale, and sell the gemcitabine drug product. On information and belief, doctors prescribing or using gemcitabine according to the indications sought by the Defendants will be using such gemcitabine in a manner that would infringe one or more claims of the '614 patent and the '826 patent.

18. Under 35 U.S.C. § 271(b), Sicor Inc., Teva USA, and Teva Industries have acted in concert, actively supporting, participating in, encouraging, and inducing Sicor Pharma's filing of ANDAs Nos. 77-961 and 77-983 for Gemcitabine for Injection, USP, and in the preparation to sell, in the United States, pharmaceutical products containing gemcitabine.

19. Upon information and belief, Teva Industries, Teva USA, and Sicor Inc. will actively aid, abet, encourage, and induce Sicor Pharma and others in the production, importation, sale, and use of gemcitabine.

20. Upon information and belief, Teva Industries, Teva USA, and Sicor Inc. will actively participate in the production, importation, sale, and use of gemcitabine.

21. Upon information and belief, Sicor Pharma had actual notice of the '614 and '826 patents prior to filing its ANDAs, and Sicor Pharma's infringement of the '614 and '826 patents has been, and continues to be, willful.

COUNT II FOR DECLARATORY JUDGMENT

22. Lilly realleges and incorporates by reference paragraphs 1-21.

23. Defendants have filed or caused to be filed applications with the FDA, seeking authorization to import, market, use, offer for sale, and sell the gemcitabine drug product. On information and belief, doctors prescribing or using gemcitabine according to the indications sought by defendants will be using such gemcitabine in a manner that would infringe one or more claims of the '614 and '826 patents.

24. On information and belief, defendants seek approval of at least one indication for the gemcitabine drug product.

25. On information and belief, defendants plan to begin marketing, selling, and offering to sell the gemcitabine drug product soon after the FDA has approved such indications.

26. Such conduct will constitute direct infringement of one or more claims of the '614 and '826 patents under 35 U.S.C. § 271(a), inducement of infringement of the '614 and '826 patents under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c).

27. Defendants' infringing activity has been and will continue to be done in willful disregard of Plaintiff's patent rights.

28. Defendants' infringing activity complained of herein is imminent and will begin following FDA approval of the ANDAs.

29. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Lilly and defendants as to liability for the infringement of the '614 and '826 patents. Defendants' actions have created in Lilly a reasonable apprehension of irreparable harm and loss resulting from defendants' threatened imminent actions.

WHEREFORE, Plaintiff demands judgment against the Defendants as follows:

(a) declaring United States Patent Nos. 4,808,614 and 5,464,826 are valid and enforceable;

(b) declaring that defendants would infringe one or more claims of United States Patent No. 4,808,614 by the threatened acts of importation, use, offering to sell, and sale of the gemcitabine drug product prior to the expiration of said patents;

(c) declaring that defendants would infringe one or more claims of United States Patent No. 5,464,826 by the threatened acts of importation, use, offering to sell, and sale of the gemcitabine drug product prior to the expiration of said patents;

(d) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of Sicor Pharma's Gemcitabine for Injection before the expiration of the six-month periods of market exclusivity for the '614 and '826 patents, granted under 21 U.S.C. § 355a, which follow the expiration of the '614 and '826 patents;

(e) enjoining defendants from the commercial manufacture, use, offer to sell, sale, or importation of the gemcitabine product, in accordance with 35 U.S.C. § 271(e)(4)(B);

(f) declaring this to be an exceptional case and awarding Lilly attorney's fees under 35 U.S.C. §§ 285 and 271(e)(4); and

(g) awarding Lilly any further and additional relief as this Court deems just and proper.

Respectfully submitted,

Dated: February 15, 2006 By: Jan M. Carroll

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