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

ELI LILLY AND COMPANY

Plaintiff,

v.

MAYNE PHARMA LIMITED and MAYNE PHARMA (USA) INC.

Defendants.

Civil Action No.:

1:08-cv-0037-LJM-JMS

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Eli Lilly and Company ("Lilly") brings this action for patent infringement against Mayne Pharma Limited and Mayne Pharma (USA) Inc. (collectively, "Mayne"). This action involves two patents. The first patent concerns the pharmaceutical product, GEMZAR®. The second patent concerns the use of this pharmaceutical 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 products throughout the world.

2. Upon information and belief, Defendant Mayne Pharma Limited is an Australian corporation conducting business from facilities at Level 3, 390 St. Kilda Rd., Melbourne, Victoria, 3004, Australia.

3. On information and belief, Mayne Pharma Limited is a wholly owned subsidiary of Hospira, Inc., which is a Delaware corporation having its principal place of business at 275 N. Field Drive, Lake Forest, Illinois, 60045.

4. Upon information and belief, Defendant Mayne Pharma (USA) Inc. is a Delaware corporation having its principal place of business at Mack-Cali Centre II, 650 From Road, Second Floor, Paramus, New Jersey 07652. Upon information and belief, Mayne Pharma (USA) Inc. is a wholly owned subsidiary of Mayne Pharma Limited.

5. Upon information and belief, Mayne Pharma Limited, Mayne Pharma (USA) Inc., and Hospira, Inc. develop and market generic and specialty injectable drug products.

6. Upon information and belief, Mayne Pharma Limited, Mayne Pharma (USA) Inc., and Hospira, Inc. formulate, manufacture, package, and market injectable generic and specialty pharmaceutical products for distribution in the Southern District of Indiana and throughout the United States.

7. The Court has personal jurisdiction over Mayne Pharma Limited and Mayne Pharma (USA) Inc. (collectively, "Mayne") 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.

8. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(e)(2), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper under 28 U.S.C. §§ 1391 and 1400(b).

COUNT I FOR PATENT INFRINGEMENT

9. 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. The '614 patent expires on May 15, 2010, followed by a six-month period of market exclusivity granted by the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(a), ending on November 15, 2010. A true and correct copy of the '614 patent is attached as Exhibit A. Lilly has owned of the '614 patent since it issued.

10. 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. The '826 patent expires on November 7, 2012, followed by a six-month period of market exclusivity granted by the FDA under 21 U.S.C. § 355(a), ending on May 7, 2013. A true and correct copy of the '826 patent is attached as Exhibit B. Lilly has owned of the '826 patent since it issued.

11. 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, breast cancer, and ovarian cancer.

12. Upon information and belief, Mayne Pharma Limited filed or caused to be filed with the FDA, in Rockville, Maryland, an Abbreviated New Drug Application ("ANDA") No. 79-183 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of gemcitabine hydrochloride (2g base/vial). Upon information and belief, Mayne Pharma Limited filed or caused to be filed ANDA No. 79-183 to obtain approval to market its generic

product before the expiration dates of the '614 or '826 patents. Upon information and belief, ANDA No. 79-183 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification"), alleging that the claims of the '614 and '826 patents are invalid or would not be infringed.

13. On information and belief, Mayne Pharma (USA) Inc. participated in the submission of ANDA No. 79-183 or otherwise acted in concert with Mayne Pharma Limited in the submission of ANDA No. 79-183.

14. On information and belief, Mayne Pharma Limited exercises control over Mayne Pharma (USA) Inc. and conducts its U.S. operations through Mayne Pharma (USA) Inc.

15. On information and belief, if ANDA No. 79-183 is approved, it is the intention of Mayne Pharma Limited, Mayne Pharma (USA) Inc., and Hospira, Inc. that the product will be distributed in the United States by or through Mayne Pharma (USA) Inc.

16. Mayne Pharma Limited caused to be sent to Lilly a letter ("Notice Letter") dated December 5, 2007, notifying Lilly that Mayne Pharma Limited filed ANDA No. 79-183 for Gemcitabine Hydrochloride for Injection (2g base/vial) and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Lilly received the Notice Letter via facsimile on or about December 5, 2007. The Notice Letter alleges that claims 1, 2, 7, 8, 11, 12, 13, and 14 of the '614 patent and claims 1, 2, 6, and 7 of the '826 patent are invalid over the prior art. The Notice Letter further states that claims 3-6, 9, 10, and 13 of the '614 patent and claims 3, 4, and 5 of the '826 patent are not infringed literally or under the doctrine of equivalents. Mayne Pharma Limited also asserts that ANDA No. 79-183 does not induce infringement of the method of use claim 13 in the '614 patent.

17. Under 35 U.S.C. § 271(e)(2)(A), Mayne Pharma Limited's submission to the FDA seeking approval for the commercial manufacture, use, or sale of Gemcitabine Hydrochloride for Injection before the expiration of the '614 and '826 patents, constitutes an act of infringement. If ANDA No. 79-183 is approved by the FDA, Mayne's commercial manufacture, use, offer to sell, sale, or importation of Gemcitabine Hydrochloride for Injection would infringe one or more claims of the '614 and '826 patents under 35 U.S.C. § 271(a)-(c).

18. Upon information and belief, Mayne Pharma Limited has filed ANDA No. 79-183, seeking authorization to commercially manufacture, use, offer for sale, and sell the Gemcitabine Hydrochloride for Injection pharmaceutical product. On information and belief, Mayne knows that physicians will use Gemcitabine Hydrochloride for Injection in accordance with the indications sought by Mayne, and will therefore infringe one or more claims of the '614 patent and the '826 patent.

19. Upon information and belief, Mayne did not exercise due care in analyzing the '614 and '826 patents and presenting arguments in the paragraph IV certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), and Notice Letter, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii).

20. Lilly will be substantially and irreparably harmed by Mayne's infringing activities unless those activities are enjoined by this Court. Lilly has no adequate remedy at law.

COUNT II FOR DECLARATORY JUDGMENT

21. Lilly realleges and incorporates by reference paragraphs 1-20.

22. This declaratory judgment counterclaim arises under the United States Patent Laws, Title 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a)-(c), and the Declaratory

Judgment Act, 28 U.S.C. §§ 2201, 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

23. Upon information and belief, Mayne Pharma Limited has filed an ANDA with the FDA, seeking authorization to commercially manufacture, use, offer for sale, and sell its Gemcitabine Hydrochloride for Injection pharmaceutical product.

24. Upon information and belief, Mayne seeks approval of at least one indication claimed in the '826 patent for the Gemcitabine for Injection pharmaceutical products.

25. Upon information and belief, Mayne knows that physicians will use Gemcitabine Hydrochloride for Injection in accordance with the indications sought by Mayne, and will therefore infringe one or more claims of the '614 and '826 patents, either literally or under the doctrine of equivalents.

26. Upon information and belief, Mayne plans to begin marketing, selling, and offering to sell Gemcitabine Hydrochloride for Injection soon after the FDA approves such indications.

27. Such conduct will constitute direct infringement of one or more claims of the '614 patent 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 of the '826 patent under 35 U.S.C. § 271(c).

28. Mayne's infringing activity complained of herein is imminent and will begin following FDA approval of ANDA No. 79-183.

29. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Lilly and Mayne concerning liability for the infringement of the '614 and '826 patents. Mayne's actions create a reasonable apprehension of irreparable harm and loss resulting from its threatened imminent actions.

WHEREFORE, Lilly demands judgment against Mayne as follows:

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

(b) declaring that Mayne would infringe one or more claims of United States Patent No. 4,808,614 by the threatened acts of commercial manufacture, use, offering to sell, and sale of its Gemcitabine Hydrochloride for Injection pharmaceutical product prior to the expiration of said patent;

(c) declaring that Mayne would infringe one or more claims of United States Patent No. 5,464,826 by the threatened acts of commercial manufacture, use, offer to sell, and sale of its Gemcitabine Hydrochloride for Injection pharmaceutical product prior to the expiration of said patent;

(d) prohibiting, in accordance with 35 U.S.C. § 271(e)(4)(A), the approval of Mayne Pharma Limited's ANDA No. 79-183 relating to Gemcitabine Hydrochloride 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. § 355(a), which follow the expiration of the patents;

(e) enjoining Mayne from the commercial manufacture, use, offer to sell, sale, or importation of its Gemcitabine Hydrochloride for Injection 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: January 10, 2008 By: Jan M. Carroll

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