IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

HOSPIRA, INC.,	)	
	)	
Plaintiff,	)	Case No. 10-cv-6275
	)	
v.	)	
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Hospira, Inc., by and through its undersigned attorneys, brings this action for a declaratory judgment against Defendant Eli Lilly and Company ("Lilly"), and states as follows:

INTRODUCTION

1. Hospira brings this action for declaratory judgment of patent non-infringement under the federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

2. This action arises out of Hospira's submission of applications seeking regulatory authority from the U.S. Food and Drug Administration ("FDA") to make, sell, and offer for sale a generic version of Lilly's brand-name cancer medication Gemzar®, known generically as gemcitabine.

3. Lilly purports to own U.S. Patent No. 5,606,048 ("the '048 patent"), which claims a process for manufacturing gemcitabine. Hospira seeks to market its generic gemcitabine drug products before the expiration of the '048 patent. In fact, Hospira expects regulatory approval of its gemcitabine applications within a couple of months, and Hospira intends to make, sell, and offer those products for sale as soon as it is permitted to do so. Hospira does not infringe the '048 patent but, as set forth below, is under reasonable apprehension that Lilly will assert the

‘048 patent against Hospira to block the marketing and sale of Hospira’s competing product.

4. Accordingly, Hospira brings this action to seek patent peace—specifically, to resolve the conflict between Lilly and Hospira regarding the ‘048 patent, and to remove any barriers to Hospira’s imminent launch of its competing generic product.

PARTIES

5. Hospira is a Delaware corporation having corporate offices and a principal place of business at 275 Field Dr., Lake Forest, Illinois 60045. Hospira is engaged in the research, development, manufacture, and distribution of pharmaceutical products for sale throughout the world, including in the Northern District of Illinois. Hospira is preparing to offer for sale a generic version of the anti-cancer pharmaceutical drug gemcitabine, which Lilly sells under the trade name Gemzar®.

6. Upon information and belief, Lilly is an Indiana corporation that has its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Upon information and belief, Lilly is engaged in the research, development, manufacture, and sale of pharmaceutical products throughout the world, including in the Northern District of Illinois.

JURISDICTION AND VENUE

PERSONAL JURISDICTION AND VENUE

7. This Court has personal jurisdiction over Lilly: Lilly is registered to do business in Illinois, as shown on the Corporate File Detail Report of the Virginia Secretary of State (http://www.ilsos.gov/corporatellc/). Lilly regularly conducts business in Illinois and in this judicial district, including selling and offering to sell pharmaceutical products to residents of the State and district.

8. Lilly has designated National Registered Agents Inc., located at 200 West Adams Street, Chicago, Illinois 60606, as an agent for service of process in the State of Illinois, as shown on the Corporate File Detail Report of the Virginia Secretary of State.

9. Lilly employs residents of the State of Illinois and operates a research lab in Chicago—the Lilly Research Laboratories Collaborative Access Team (LRL-CAT)—located at 9700 South Cass Avenue, Bldg. 438A Sector 31, Argonne, Illinois 60439.

10. Venue is proper in this district under 28 U.S.C. § 1391(b)(1) and § 1400(b) because Lilly is deemed to reside in this district under 28 U.S.C. § 1391(c).

SUBJECT MATTER JURISDICTION

11. This action arises under the United States Patent Laws, 35 U.S.C. § 101 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

12. As further discussed herein, there now exists a substantial, present, genuine, and justiciable controversy exists between Hospira and Lilly regarding the '048 patent. This Court can and should declare the right and legal relations of the parties concerning the '048 patent because an Article III case or controversy exists between them.

A. Hospira's New Drug Application and Abbreviated New Drug Application

13. The Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended by the Hatch-Waxman Amendments, sets forth the rules that the U.S. Food and Drug Administration ("FDA") follows when considering the approval of applications for both brand-name and generic drugs.

14. Under the Hatch-Waxman Amendments, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA.

See 21 U.S.C. § 355. An NDA must include, among other things, the patent number of any patent that claims the drug or a method of using such drug, for which the applicant submitted the application and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(l), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2). Upon approval of the NDA, the FDA publishes patent information for the approved drug in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluation* ("Orange Book").

15. The Hatch-Waxman Amendments also permit subsequent applicants to seek approval of new drug products by relying on data that was submitted with the NDA showing that the drug is safe for use and effective in use. There are two kinds of such applications: (a) a "B2" application (submitted under 21 U.S.C. § 355(b)(2)), and (b) an Abbreviated New Drug Application, or "ANDA" (submitted under 21 U.S.C. § 355(j)).

16. In 2007, Hospira's predecessor-in-interest filed with the FDA its ANDA No. 79-183 ("Hospira's ANDA") seeking approval for the commercial manufacture, use, and sale of a gemcitabine 2g/vial drug product. These products will compete with Lilly's Gemzar® product.

17. In late 2009, Hospira filed with the FDA its B2 Application No. 200-795 ("Hospira's B2") seeking approval for the commercial manufacture, use, and sale of gemcitabine 200 mg/5.3 ml, 1g/26.3ml, and 2g/52.6 ml drug products. These products will compete with Lilly's Gemzar® product.

18. Hospira expects FDA approval of at least one of its products on or about November 15, 2010, and is making preparations to launch its product immediately upon such approval.

B. The ‘048 Patent

19. According to the records of the U.S. Patent and Trademark Office (“USPTO”), Lilly is the owner of the ‘048 patent, entitled “Stereoselective glycosylation process for preparing 2'-Deoxy-2',2'-difluoronucleosides and 2'-deoxy-2'-fluoronucleosides,” which expires on February 25, 2014. A copy of the ‘048 patent is attached as Exhibit A to this Complaint.

20. Furthermore, the ‘048 patent is the U.S. equivalent to the patents in several other countries, including the following:

(a) Danish Patent No. DK/EP 0577303 T3 (“the Danish ‘303 patent”), entitled “Stereoselective Glycosylation Process”;

(b) Canadian Letters Patent 2,098,881 (“the Canada ‘881 patent”), entitled “Stereoselective Glycosylation Process”;

(c) European Patent (UK) No. EP 0 577 303 (“the UK ‘303 patent”), entitled “Stereoselective Glycosylation Process”; and

(d) Singapore Patent No. SG94686 (“the Singapore ‘686 patent”), entitled “Stereoselective Glycosylation Process.”

21. In each of these jurisdictions, Lilly and Hospira have been involved in judicial proceedings in which Lilly has claimed that Hospira’s sale of a generic version of gemcitabine would infringe these patents that are the foreign equivalents of the ‘048 patent.

DANISH ACTION

22. In August 2007, Lilly and Eli Lilly Danmark A/S (“Lilly Denmark”) sought an interim prohibitory injunction against Hospira’s subsidiaries Hospira Nordic AB and Hospira UK Limited (then known as Mayne Pharma (Nordic) AB and Mayne Pharma Plc) in the Copenhagen Maritime and Commercial Court. In the suit, Lilly and Lilly Denmark claimed that

the Danish '303 patent would be infringed by Hospira's offer for sale, sale, and marketing in Denmark of Hospira's gemcitabine drug products.

23. In the Danish action, Lilly and Lilly Denmark alleged that the process described in the Danish '303 patent is the only possible preparation process that may form the basis of a commercially and financially viable large-scale preparation of gemcitabine. This process is the same process that is claimed in the '048 patent.

24. Hospira has argued in the Danish action that its gemcitabine drug products are not manufactured using the process that is claimed in the Danish '303 patent and thus do not infringe the Danish '303 patent. Similarly, Hospira's gemcitabine drug products do not infringe the '048 patent.

25. In February 2008, Lilly and Lilly Denmark obtained an injunction against the distribution and sale of Hospira's gemcitabine drug product in Denmark. That injunction was subsequently lifted by an appeals court, which found that there was an alternative, non-patented process for making gemcitabine, that Hospira's regulatory filings reflected the non-patented process, and that Hospira's expert had witnessed the non-patented process being used to manufacture gemcitabine. The appeals court therefore concluded that there was no basis for excluding the non-patented process as a commercially viable method for manufacturing gemcitabine, and therefore that it had not been shown sufficiently likely that Hospira uses the patented process to manufacture gemcitabine.

26. Although the Danish appeal court lifted the injunction, Lilly continues to litigate in its claims that Hospira's gemcitabine drug product violates the Danish '303 patent.

CANADIAN ACTION

27. In October 2007, Lilly and its wholly owned subsidiary, Eli Lilly Canada Inc.

("Lilly Canada"), filed a patent infringement lawsuit against Hospira's Canadian subsidiary, Hospira Healthcare Corporation ("Hospira Canada") in the Federal Court of Canada in Ottawa, Court File No. T-1773-07. In the suit, Lilly and Lilly Canada claimed that the Canada '881 patent, which Lilly stated "relates to processes that can be used in making the valuable anticancer drug gemcitabine," was infringed by Hospira Canada's manufacture, importation, and sale of gemcitabine products.

28. In the Canadian action, Lilly and Lilly Canada alleged that the only process that is commercially viable for making gemcitabine is the process claimed in the Canadian '881 patent. This process is the same process that is claimed in the '048 patent.

29. Hospira has argued in the Canadian action that its gemcitabine drug products are not manufactured using the process that is claimed in the Canadian '881 patent and thus do not infringe the Canadian '881 patent. Similarly, Hospira's gemcitabine drug products do not infringe the '048 patent.

UK ACTION

30. In September 2007 correspondence to Hospira's UK subsidiary, Hospira UK Limited, counsel for Lilly in the United Kingdom threatened to bring proceedings against Hospira UK for infringement of the UK '303 patent.

31. As of September 2007, Lilly had already commenced proceedings against Hospira in Denmark on the Danish equivalent to the UK '303 patent. Immediately afterwards, in October 2007, Lilly commenced infringement proceedings against Hospira in Canada on the corresponding Canadian patent.

32. Because of the Danish and Canadian proceedings, and Lilly's September 2007 correspondence regarding UK '303 patent, Hospira UK understood there to be a real and present

dispute about whether Hospira's gemcitabine drug product infringed the UK '303 patent. Hospira UK also believed that Lilly would assert the UK '303 patent to block the distribution and sale of Hospira's gemcitabine drug product in the UK. Accordingly, to clear the way for an expected March 2009 launch of its gemcitabine drug product, Hospira UK filed suit against Lilly in October 2007, seeking a declaration from the UK Patents Court that its product did not infringe the UK '303 patent.

33. Although Lilly did not counterclaim for infringement of the UK '303 patent, it also refused to admit that Hospira's gemcitabine drug product was manufactured using a non-patented process, in accordance with the information set forth in Hospira's regulatory documents. Indeed, in its written defense to Hospira's claim, Lilly "admitted that there is an issue between the parties as to whether [Hospira's] products containing gemcitabine will infringe the patent if they are imported and/or sold in the United Kingdom."

34. After over a year of litigating in the UK proceedings, Lilly eventually acknowledged that "if" Hospira's product was manufactured according to the process described in Hospira's documents, then it would not infringe the UK '303 patent. However, Lilly refused to accept that any gemcitabine product that Hospira eventually imported into and sold in the UK would actually be manufactured according to the non-infringing process. In other words, as in the Canadian action and the Danish action, Lilly maintained that Hospira does not actually use the non-infringing process to manufacture its gemcitabine.

35. Throughout the UK proceedings, Lilly reserved its right to bring future proceedings alleging infringement of the UK '303 patent based on Hospira's importation and sale of its gemcitabine drug product.

SINGAPORE ACTION

36. In February 2010, Lilly filed a patent infringement lawsuit in the High Court of the Republic of Singapore against Hospira's Singaporean subsidiary Hospira Singapore PTE Ltd. ("Hospira Singapore"). In the suit, Lilly alleged that Hospira Singapore's acts of disposing, using, or importing gemcitabine products would infringe the Singapore '686 patent.

37. The Singapore '686 patent also claims a process for manufacturing gemcitabine. The processes claimed in the Singapore '686 patent are the same processes claimed in the '048 patent.

38. Hospira Singapore has argued in the Singapore action that its gemcitabine drug products are not manufactured using the process that is claimed in the Singapore '686 patent and thus do not infringe the Singapore '686 patent. Similarly, Hospira's gemcitabine drug products do not infringe the '048 patent.

* * *

39. As these lawsuits demonstrate, Lilly has the willingness and desire to enforce foreign equivalents of the '048 patent against Hospira to protect its Gemzar® products from competition from Hospira's generic gemcitabine products.

40. Lilly has also asserted against Hospira *in the United States* patents covering gemcitabine and methods of using gemcitabine. With respect to Hospira's ANDA, Lilly sued Hospira's predecessors-in-interest in 2008 in the Southern District of Indiana to prevent competition to its sales of Gemzar®. *See Eli Lilly and Company v. Mayne Pharma (USA) Inc. and Mayne Pharma Ltd.*, Civ. A. No. 1:08-cv-0037 (S.D. Ind.). Similarly, with respect to Hospira's B2, Lilly sued Hospira in 2010 in that same court. *See Eli Lilly and Company v. Hospira, Inc.*, Civ. A. No. 1:10-cv-0346 (S.D. Ind.). Though these lawsuits involved different

patents, they demonstrate that Lilly has acted aggressively to protect its Gemzar® product from competition by Hospira's generic gemcitabine drug products.

41. Lilly did not assert claims for infringement of the '048 patent in the lawsuits filed against Hospira in the Southern District of Indiana. Those lawsuits involved Lilly's "Orange-Book-listed" patents under the Hatch-Waxman Act. As noted above, the Orange Book includes patents that claim a drug or a method of using such drug. The '048 patent claims a process of manufacturing gemcitabine, not the drug gemcitabine or a method of using gemcitabine, and is therefore not listed in the Orange Book. The Hatch-Waxman Act does not address litigation of process patents like the '048 patent; such disputes are handled under general patent law.

42. Because Lilly has systematically asserted the foreign equivalent to patent '048 against Hospira in lawsuits filed outside the United States, as described above, Hospira has an objectively reasonable belief that Lilly intends to and will sue Hospira in the United States for infringement of the '048 patent.

43. In addition, the totality of the circumstances demonstrate that there now exists a substantial controversy between Hospira and Lilly concerning the '048 patent. The adverse legal interests of Hospira and Lilly are of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

CLAIM 1

FOR DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '048 PATENT

44. Hospira realleges and incorporates by reference the allegations in Paragraphs 1 through 43 as if fully set forth herein.

45. A conflict of rights and justiciable controversy exists between Hospira and Lilly concerning the '048 patent.

46. Lilly has previously sued Hospira, or a wholly owned subsidiary of Hospira, for infringement of the foreign equivalent of the ‘048 patent in Canada, Denmark, and Singapore.

47. Lilly has also sued Hospira in the United States District Court for the Southern District of Indiana in an effort to prevent Hospira from selling gemcitabine products that would compete with Lilly’s Gemzar®.

48. Lilly’s conduct has given Hospira an objectively reasonable apprehension that Lilly intends to and will file suit against Hospira in the United States for infringement of the ‘048 patent. In addition, the totality of the circumstances demonstrate that there now exists a substantial controversy between Hospira and Lilly concerning the ‘048 patent that is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

49. Hospira has engaged in, and continues to engage in, meaningful preparations to manufacture, use, and sell gemcitabine drug products in the United States. Hospira intends to launch such products in the United States as soon as it has regulatory authority to do so, which should occur for at least one of its products no later than mid-November 2010.

50. Hospira’s manufacture, use, offer to sell, and/or sale of its gemcitabine drug products does not and will not infringe any valid and enforceable claim of the ‘048 patent, either directly or indirectly, or either literally or under the doctrine of equivalents. Without this Court’s declaration to that effect, Hospira’s manufacture, use, offer to sell, and/or sale of its gemcitabine drug products in the United States could subject Hospira to legal liability and damages.

51. Hospira is entitled to a declaratory judgment that its manufacture, use, offer to sell, and sale of its gemcitabine drug products does not and would not infringe the ‘048 patent.

PRAYER FOR RELIEF

WHEREFORE, Hospira requests that this Court enter judgment in favor of Hospira against Lilly and issue an Order as follows:

A. Declaring that Hospira's manufacture, use, offer to sell and sale of its proposed gemcitabine hydrochloride drug products does not and will not infringe any valid and enforceable claim of the '048 patent;

B. Awarding Hospira its legal fees and costs of this suit; and

C. Awarding Hospira any and all such other relief as the Court determines to be just and proper.

Respectfully submitted,

HOSPIRA, INC.

By: /s/William C. O'Neil
One of its Attorneys

James F. Hurst
William C. O'Neil
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601
(312) 558-5600

Gail Standish
Peter Perkowski
WINSTON & STRAWN LLP
333 S. Grand Avenue, Suite 3800
Los Angeles, California 90071
(213) 615-1700