UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

SUN PHARMACEUTICAL INDUSTRIES, LTD.,

Plaintiff,

vs.

Case No. 07-CV-15087
HON. GEORGE CARAM STEEH

ELI LILLY AND COMPANY,

Defendant.

_____/

ORDER GRANTING PLAINTIFF SUN PHARMACEUTICALS' MOTION FOR PARTIAL SUMMARY JUDGMENT (# 45)

Plaintiff Sun Pharmaceuticals moves for partial summary judgment of invalidity of the asserted claims of defendant Eli Lilly and Company's U.S. Patent 5,464,826 ("'826 Patent"). A hearing was held on July 24, 2009. For the reasons set forth below, Sun Pharmaceuticals' motion for partial summary judgment will be GRANTED.

I. Background

Sun Pharmaceuticals filed a complaint on November 29, 2007 alleging it has submitted an Abbreviated New Drug Application ("ANDA") with the FDA to market its generic version of Eli Lilly's cancer medication "Gemzar" (gemcitabine). Eli Lilly holds the '826 Patent, a patent listed in the FDA's "Orange Book." Sun Pharmaceuticals wants to market its generic version of the patented drug before Eli Lilly's '826 Patent expires. The Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), required Sun Pharmaceuticals to: (1) certify to the FDA that its generic drug will not

infringe the '826 Patent; and (2) notify Eli Lilly of this certification. Sun Pharmaceuticals seeks declaratory relief that the '826 Patent is invalid, and alternatively, that its generic drug does not infringe the '826 Patent. Eli Lilly filed counterclaims of infringement of its '826 Patent and U.S. Patent 4,808,614 ("'614 Patent") on January 7, 2008.

II. Motion for Partial Summary Judgment

Sun Pharmaceuticals moves for partial summary judgment of its claim that Eli Lilly's '826 Patent is invalid pursuant to the judicially created doctrine of "obviousness-type double patenting," a doctrine that "prohibit[s] a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc., 518 F.3d 1353, 1363 (Fed. Cir. 2008) (quoting Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 967 (Fed Cir. 2001)). The patents at issue here are the commonly owned earlier '614 Patent and the later '826 Patent.

A. '614 Patent

The '614 Patent issued on February 28, 1989 and is titled "DIFLUORO ANTIVIRALS AND INTERMEDIATE THEREFORE." The "ABSTRACT" reads "A 2,2-difluoro-2-deoxycarbohydrate is used to prepare antiviral nucleosides." The "SUMMARY OF THE INVENTION" provides in part:

> Pharmaceutical compositions comprising a nucleoside of the above formula and a pharmaceutically acceptable carrier, diluent or excipient therefor are provided as yet another aspect of the present invention, as is a method of treating viral infections in mammals employing a present novel compound.

(emphasis added). Within the "DESCRIPTION OF THE PREFERRED EMBODIMENTS," the '614 Patent describes the "specific nucleosides . . . to assure that every reader

understands the type of antivirals which this invention makes available." (emphasis added). After giving eleven examples of compounds, the '614 Patent continues:

> In addition to the antiviral utility of the present compounds, certain of the compounds of the present invention have also demonstrated excellent oncolytic activity in standard cancer screens. A particularly preferred compound with this utility is the compound of Example 8 [gemcitabine] . . . . This compound demonstrated activity in tumor systems L1210V lymphocytic leukemia, 6C3HED lymphosarcoma, CA-755 adenocarcinoma, P1534J lymphatic leukemia and X5563 plasma cell myeloma. When used for cancer chemotherapy, dosages per day of the active compounds will be in the range of about 0.1 to about 1200 mg./kg. of body weight. In the treatment of adult humans, the range of about 0.1 to about 50 mg./kg., in single or divided doses, is preferred.

(emphasis added). The pertinent claims of the '614 Patent read:

> 1. A nucleoside of the formula [formula diagram] wherein R is a base selected from the group consisting of [formula diagrams] wherein
> R1 is hydrogen, methyl, bromo, fluoro, chloro or iodo;
> R2 is hydroxy;
> R3 is hydrogen, bromo, chloro or iodo.
>
> 2. A nucleoside of claim 1 wherein the carbohydrate moiety is in the ribose form.
>
> * * *
>
> 8. A nucleoside of claim 2 wherein the base is of the formula [formula diagram].
>
> * * *
>
> 12. A nucleoside of claim 8 wherein R1 is hydrogen [i.e. gemcitabine].
>
> 13. A method of treating Herpes viral infections in mammals comprising administering to a mammal in need of such treatment an anti-Herpes viral effective amount of a compound of claim 1.
>
> 14. A pharmaceutical composition useful for treating Herpes viral infections comprising an anti-Herpes viral effective amount of a compound of claim 1 and a pharmaceutically-acceptable carrier, diluent or excipient therefor.

(emphasis added).

B. '826 Patent

The '826 Patent issued on November 7, 1995 and is titled "METHOD OF TREATING

TUMORS IN MAMMALS WITH 2', 2'DIFLUORNUCLEOSIDES." The "ABSTRACT" reads "A method of treating susceptible neoplasms [cancers] in mammals comprising administering to a mammal in need of such treatment a pharmaceutically effective amount of the compound of the formula [formula diagram] . . . ." The "SUMMARY OF THE INVENTION" states "The present invention provides a method of treating susceptible neoplasms [cancers] in mammals comprising administering to a mammal in need of such treatment a pharmaceutically effective amount of a compound of the formula [formula diagram]." After giving seven examples of compounds, the '826 Patent continues:

> The term "pharmaceutically effective amount", as defined herein, refers to an appropriate amount of a compound of formula I which is capable of providing chemotherapy to mammals. The active compounds are effective over a wide dosage range. For example, dosages per day will normally fall within the range of about 0.1 to about 1200 mg/kg of body weight. In the treatment of adult humans, the range of about 0.1 to about 50 mg/kg, in single or divided doses is preferred. . . . .

The pertinent claims of the '826 Patent read:

> 1. A method of treating susceptible neoplasms [cancers] in mammals comprising administering to a mammal in need of such treatment a therapeutically effective amount of a compound of the formula [formula diagram] wherein:
>
> R1 is hydrogen;
> R2 is a base defined by one of the formulae [formula diagrams];
> X is C-R4
> R3 is hydrogen;
> R4 is hydrogen, C1-C4 alkyl, bromo, fluoro, chloro or iodo; and the pharmaceutically-acceptable salts thereof.
>
> 2. The method of claim 1 in which the compound is 1-(4-amino-2-oxo-1H-pyrimidin-1-yl)-2-desoxy-2,2-difluororibose [i.e. gemcitabine] or a pharmaceutically acceptable salt thereof.
>
> * * *
>
> 6. The method of claim 1 wherein the susceptible neoplasm [cancer] is selected from the group consisting of leukemias, sarcomas, carcinomas, and myelomas.

> 7. The method of claim 6 employing 1-(4 amino-2-oxo-1H-pyrimidin-1-yl)-2-desoxy-2,2-difluororibose [i.e. gemcitabine] or a pharmaceutically acceptable salt thereof.

(emphasis added).

On March 10, 1983, Lilly filed U.S. Patent Application No. 473,883 ("'883 Application"). On December 4, 1984, Lilly filed a "continuation-in-part" of the '883 Application, which ultimately lead to the '614 Patent. On December 4, 1984, Lilly also filed U.S. Patent Application No. 677,783, which ultimately lead to the '826 Patent. Lilly advanced gemcitabine into clinical development as an anti-cancer agent on January 28, 1985. The '614 Patent issued on February 28, 1989, while the '826 Patent issued on November 7, 1995.

II. Argument

Sun Pharmaceuticals argues Lilly obtained the '614 Patent for the compound gemcitabine as an anti-viral and anti-cancer drug, then improperly extended its monopoly over the compound by obtaining the '826 Patent claiming a method of using gemcitabine to treat cancer. Sun Pharmaceuticals argues that, if a compound claim fails to adequately disclose the patentable bounds of the invention, the court may look to the patent specifications of both patents to determine if there is an overlap of claim scope. Sun Pharmaceuticals relies primarily on Pfizer, supra, and Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373 (Fed. Cir. 2003).

Lilly responds that Pfizer and Geneva are inapplicable because those cases involved initial compound patents that disclosed only a single utility in their specifications, and the subsequent patents claimed the earlier disclosed utility. Lilly argues that its earlier '614 Patent claimed the compound gemcitabine and its essential utility as an anti-viral agent,

and that the '826 patent claimed the new use of gemcitabine as an anti-cancer agent. Lilly asserts it disclosed the anti-cancer use in the '614 Patent specification to avert any "best mode" challenges to the validity of the '614 Patent, but relied on the anti-viral utility of gemcitabine to obtain the '614 Patent. Lilly maintains that, because the anti-cancer use of gemcitabine set forth in the '614 Patent specification was unnecessary to support the '614 Patent, the anti-cancer use was eligible for later patenting in the '826 Patent. Lilly argues that the court may not rely on the earlier patent specification as prior art to determine whether the later patent resulted in double patenting. Lilly maintains that In re Kaplan, 789 F.2d 1574 (Fed. Cir. 1986), is controlling.

III. Analysis

An obviousness-type double patenting analysis involves a two step process: (1) the court construes the claims of the earlier and later patents and determines their differences; and (2) the court determines whether those differences render the claims patentably distinct. Pfizer, 518 F.3d at 1363. Double patenting is an issue of law for the court to decide. Id.

Claim 12 of the '614 Patent claims the compound gemcitabine, a claim that is not dependent upon Claims 13 or 14, which claim, respectively, the method and use of treating Herpes viral infections. Claim 12 is a compound claim that, standing alone, does not adequately disclose the patentable bounds of the invention. Therefore, this court may examine the specifications of both patents to determine any overlap in the claim scope for double patenting purposes. Geneva, 349 F.3d at 1385. Such was not the case in In re Kaplan, where a panel of the Federal Circuit ruled there was adequate support to determine the scope of a patent claim limitation "organic solvent" (as opposed to "organic solvents")

from the claim language itself without resorting to the "mixed solvent" examples disclosed in the patent specification. In re Kaplan, 789 F.2d at 1575, 1580. The Kaplan court reasoned that the United States Trademark and Patenting Office ("PTO") erred in its double patenting analysis by treating the "mixed solvent" specification disclosure as prior art in rejecting a subsequent patent application claiming a process using a "solvent mixture." Id. Reversing the PTO's decision, the Kaplan court cited In re Vogel, 422 F.2d 438 (CCPA 1970) for the rule that treating a patent disclosure as prior art in performing an obviousness-type double patenting analysis "has repeatedly been held in our precedents to be impermissible." In re Kaplan, 789 F.2d at 1580.

Recently, a panel of the Federal Circuit explained the contours of Vogel when rejecting an argument that Kaplan forbids reading limitations from a patent specification into claims for purposes of conducting an obviousness-type double patenting analysis:

> . . . . While we stated in Kaplan that it is impermissible to treat a "patent disclosure as though it were prior art" in a double patenting inquiry, we further reaffirmed the holding in In re Vogel, 57 C.C.P.A. 920, 422 F.2d 438 (CCPA 1970) that certain instances may exist where a patent's disclosure may be used. Kaplan, 789 F.2d at 1580. Indeed, our predecessor court stated that a patent's disclosure may be used to determine whether an application claim is merely an obvious variation of an invention claimed in a patent. Vogel, 422 F.2d at 441-42. The court stated that the disclosure may be used to learn the meaning of terns and in "interpreting the coverage of [a] claim." Id. at 441. It may also be used to answer the question whether claims merely define an obvious variation of what is earlier disclosed and claimed. The court stated that the disclosure "sets forth at least one tangible embodiment within the claim, and it is less difficult and more meaningful to judge whether [something] has been modified in an obvious manner." Id. at 442. The court further stated that "use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. § 103, since only the disclosure of the invention claimed in the patent may be examined." Id. As such, we conclude that the Board did not err in referring to the specification of the '987 Patent when it determined whether the claims were patentably distinct from the claims of the '687 Patent.

In re Basell Poliolefine Italia S.P.A., 547 F.3d 1371, 1378-79 (Fed. Cir. 2008).

Claim 12 of the '614 Patent fails to adequately describe the bounds of the claimed invention, and therefore, this court may use the specification disclosure in the '614 Patent, using gemcitabine for cancer chemotherapy treatment, to interpret the coverage of Claim 12. Id.; Geneva, 349 F.3d at 1385. Clearly, when properly considering the anti-cancer use of gemcitabine expressly disclosed in the '614 Patent specification, there is an overlap of Claim 12 of the '614 Patent and Claims 2, 6 and 7 of the '826 Patent. Indeed, there is an overlap of the identical "pharmaceutically effective amount" for anti-cancer treatment in the '614 Patent is repeated in the '826 Patent. A "claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing the identical use." Pfizer, Inc., 518 F.3d at 1363 (quoting Geneva, 349 F.3d at 1385-86). Construing Claim 12 of the earlier '612 Patent and Claims 2, 6 and 7 of the later '826 Patent, the court finds they are not patentably distinct as a matter of law. Pfizer, 518 F.3d at 1363.

> It would shock one's sense of justice if an inventor could receive a patent upon a composition of matter, setting out at length in the specification the useful purposes of such composition, manufacture and sell it to the public, and then prevent the public from making any beneficial use of such product by securing patents upon each of the uses to which it may be adapted.

Geneva, 349 F.3d at 1386 (quoting In re Byck, 48 F.2d 665, 668 (CCPA 1931)).

The court has limited its non-statutory double patenting analysis to a comparison of the Claims in the earlier '612 Patent to the Claims in the later '826 Patent, and does not rely on Lilly's motivations. Geneva, 349 F.3d at 1377 n.1. The timing of when Lilly discovered gemcitabine's uses for treating viral infections and treating cancer is irrelevant to the instant

double patenting analysis. Lilly's assertion that it included the anti-cancer use of gemcitabine in the '612 Patent to avoid a later "best mode" challenge supports a conclusion that anti-cancer use was "contemplated by the inventor of carrying out [the] invention" set forth in Claim 12. See Pfizer, 518 F.3d at 1364 (quoting 35 U.S.C. § 112). While Lilly may be entitled to patent newly discovered uses of a previously disclosed compound, Ortho Pharm. Corp. v. Smith, 959 F.2d 936 (Fed. Cir. 1992); In re Maxwell, 578 F.2d 479 (CCPA 1951), it may not, as here, claim the same use of a compound in a later patent. Geneva, 349 F.3d at 1386. Lilly's argument that it was unnecessary to disclose the anti-cancer use in the '614 Patent because it relied on the anti-viral utility to secure the '614 Patent does not displace the court's double patenting analysis. Although Lilly may not have been required to disclose the anti-cancer utility in the '614 Patent, it did make such a disclosure under circumstances which allow the court to interpret the coverage of Claim 12 using that disclosure. In re Basell Poliolefine, 547 F.3d at 1378 (quoting Vogel, 422 F.2d at 441-42). The court agrees with the reasoning in Boehringer Ingelheim International GMBH v. Barr Laboratories, Inc., 562 F.Supp.2d 619, 639 (D. Del. 2008), that, although Geneva and Pfizer involved single utility compounds, the rationale of Geneva and Pfizer are not limited to that circumstance. Construing Claim 12 of the '612 Patent along with the other Patent Claims, Lilly claimed two utilities for the compound gemcitabine - anti-viral and anti-cancer - and cannot now claim the same anti-cancer utility for the same compound. Boehringer, 562 F.Supp.2d at 639. Contrary to Lilly's argument, the court has not confused double patenting with "domination." See In re Kaplan, 789 F.2d at 1577. As opposed to a broad or "generic" claim, Claim 12 of the '612 Patent covers the specific anti-cancer use of gemcitabine as is also claimed in Claims 2, 6 and 7 of the '826 Patent. Based on clear and

convincing evidence, these claims are not patentably distinct as a matter of law. Pfizer, 518 F.3d at 1363. Accordingly,

Sun Pharmaceuticals motion for partial summary judgment of invalidity of Eli Lilly's '826 Patent is hereby GRANTED to the extent the '826 Patent claims the method of treating susceptible neoplasms [cancers] employing gemcitabine or a pharmaceutically acceptable salt thereof. Such claims are invalid as a matter of law under the doctrine of obviousness-type double patenting. Judgment shall enter in favor of Sun Pharmaceuticals on its claim that the '826 Patent is invalid. Eli Lilly's counterclaim of infringement of its '826 Patent is hereby DISMISSED.

SO ORDERED.

Dated: August 17, 2009

s/George Caram Steeh
GEORGE CARAM STEEH
UNITED STATES DISTRICT JUDGE

CERTIFICATE OF SERVICE

Copies of this Order were served upon attorneys of record on August 17, 2009, by electronic and/or ordinary mail.

s/Josephine Chaffee
Deputy Clerk