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Sun Pharm. Indus. v. Eli Lilly & Co.- Care Should Be Taken in the Development of Patent Families Surrounding Particular Technology.

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The doctrine of double patenting is intended to prevent a patentee from, in essence, extending patent rights beyond the term of an initial patent by claiming the same invention or an obvious variation of the patent in a second patent. *See In re Basell Poliolefine Italia S.PA.*, 547 F.3d 1371, 1375 (Fed. Cir. 2008). Obviousness-type double patenting is a judicially created doctrine that prevents a later patent from covering a slight variation of an earlier patent. *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1372 (Fed. Cir. 2005). One situation in which this doctrine arises is where an initial patent is filed that claims a compound and also discusses a use for the patent in the Specification without claiming the disclosed use. The patentee then files a second patent claiming this use of the compound. This is the situation presented in *Sun Pharm. Indus. v. Eli Lilly & Co.* 611 F.3d 1381 (Fed. Cir. 2010) , and the Federal Circuit took the opportunity to clarify its position.

Sun Pharmaceutical Industries ("Sun") is a generic drug manufacturer and it filed an Abbreviated New Drug Application ("ANDA") with the FDA for approval to market a generic version of Eli Lilly's Gemzar®. Gemzar® is a drug that is marketed for the treatment of various types of cancer. As part of Sun's ANDA, Sun stated that the patents surrounding Eli Lilly's drug were invalid or not infringed. Sun then filed a declaratory judgment action against Eli Lilly desiring judgment that the patent at issue is invalid and not infringed. Eli Lilly, in turn, counterclaimed for infringement of its patents.

The patents and patent applications surrounding the dispute include U.S. Patent No. 5,464,826 ("'826 patent"), U.S. Patent No. 4,808,614 ("'614 patent"), and U.S. Patent Application Serial No. 473,883 ("'883 application"). The '614 patent issued from a divisional application as a continuation-in-part of the '883 application, which expired on May 15, 2010. In addition, Eli Lilly filed another application that issued as the '826 patent on November 7, 1995 with an expiration date of November 7, 2012. The '826 patent did not include a terminal disclaimer with respect to the '614 patent and would have expired more than two years after the '614 patent.

The subject matter of the '614 patent and the '826 patent includes the active ingredient of Gemzar®, gemcitabine. The '883 application described gemcitabine's use for antiviral purposes. The '614 patent added the use of gemcitabine in the treatment of cancer. Included in the Specification of the '614 patent is a specific description of the usefulness of gemcitabine as a "preferred compound" for the treatment of cancer. The '614 patent, however, only claims a class of nucleosides that includes

gemcitabine and a dependent claim directly solely to gemcitabine. The ’614 patent does not include a method claim regarding the treatment of cancer. The ’826 patent, in contrast, is directed to a method for the treatment of cancer with a class of nucleosides that includes gemcitabine.

The U.S. District Court for the Eastern District of Michigan ruled, on Sun’s motion for summary judgment, that the claims directed toward a method of gemcitabine’s use for the treatment of cancer were invalid because of obviousness-type double patenting over the earlier ’614 patent. *Sun Pharm. Indus., Ltd., v. Eli Lilly & Co.*, 647 F. Supp. 2d 820 (E.D. Mich. 2009). Eli Lilly appealed the decision to the U.S. Court of Appeals for the Federal Circuit, and the Federal Circuit affirmed the decision.

The Federal Circuit affirmed the decision, citing to two previous decisions of the court. It stated that obviousness-type double patenting prevents an applicant from claiming an invention that is not patentably distinct from claims in a commonly owned earlier patent. *See Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003) and *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008). The Court clarified its position regarding obviousness-type double patenting, stating that “the holding of Geneva and Pfizer, that 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,’ extends to any and all such uses disclosed in the specification of the earlier patent.” *Sun Pharm. Indus., Ltd., v. Eli Lilly & Co.*, 611 F.3d 1381, 1387 (Fed. Cir. 2010).

This clarification was made in response to Eli Lilly’s unsuccessful attempt to argue that Geneva and Pfizer limited an obviousness-type double patenting rejection to situations in which the earlier patent discloses a single use for a claimed compound. The Court rejected Eli Lilly’s argument and stated that all uses disclosed in the specification can render a later-claimed method obvious. *Id*.

The Court further considered Eli Lilly’s argument that the district court erred in considering the specification of the issued ’614 patent rather than the more limited disclosure of the original ’833 application specification. The Court did not find the argument persuasive, however, and stated that claim terms must be “construed in light of the entire issued patent.” *Id*. at 1388. After these considerations, the Federal Circuit affirmed the decision of the district court that the asserted claims of the ’826 patent are invalid for obviousness-type double patenting over the ’614 patent. *Id*. at 1389.

Practice Tip:

Care should be taken in formulating IP strategies for the protection of technology, including the development of patent families surrounding particular technology. If further patent protection is sought, the Specifications of patents in patent families should be carefully considered and written to fully disclose and enable the subject matter of a claimed invention without disclosing potential valuable uses for the technology.

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