

Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.

No. 10-1105, Fed. Cir. (Bryson, Gajarsa, Prost*)

[The holding] 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.

On July 28, 2010, the Federal Circuit affirmed the district court’s judgment that U.S. Patent No. 5,464,826 was invalid for obviousness-type double patenting over U.S. Patent No. 4,808,614. The patented technology related to gemcitabine, which Lilly markets as Gemzar® for cancer treatment. The Federal Circuit stated:

“The doctrine of double patenting is intended to prevent a patentee from obtaining a timewise extension of [a] patent for the same invention or an obvious modification thereof.” The proscription against double patenting takes two forms: (1) statutory double patenting, which stems from 35 U.S.C. § 101 and prohibits a later patent from covering the same invention, i.e., identical subject matter, as an earlier patent, and (2) obviousness-type double patenting, which is a judicially created doctrine that prevents a later patent from covering a slight variation of an earlier patented invention. The second type of double patenting, obviousness-type double patenting, prohibits “claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent.” An obviousness-type double patenting analysis, which “compares claims in an earlier patent to claims in a later patent or application” consists of two steps. First, the court “construes the claim[s] in the earlier patent and the claim[s] in the later patent and determines the differences.” Second, the court “determines whether those differences render the claims patentably distinct.” “A later claim that is not patentably distinct from,” i.e., “is obvious over[] or anticipated by,” an earlier claim is invalid for obviousness-type double patenting.

Our prior obviousness-type double patenting decisions in Geneva and Pfizer, which addressed factual situations closely resembling that presently before the court, control this case. In both cases, we found claims of a later patent invalid for obviousness-type double patenting where an earlier patent claimed a compound, disclosing its utility in the specification, and a later patent claimed a method of using the compound for a use described in the specification of the earlier patent. We held 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.”

In Geneva, the earlier patent claimed a compound, potassium clavulanate, and the specification disclosed its effectiveness in inhibiting β -lactamase in humans. The later patent then claimed a method of using the compound to effect β -lactamase inhibition in humans or animals. In our obviousness-type double patenting analysis, we determined that to ascertain the scope of the earlier patent’s claim to the compound itself, we had to examine the specification of the earlier patent, including the compound’s disclosed utility. Upon reviewing this disclosure, we concluded that the claims of the two patents were not “patentably distinct” and thus the later patent was invalid for obviousness-type double patenting, because the later patent “claim[ed] nothing more than [the earlier patent’s] disclosed utility as a method of using the . . . compound.” Similarly, in Pfizer, the earlier patent claimed several compounds and the specification disclosed their use in treating inflammation and inflammation-associated disorders. The later patent then claimed a method of using these compounds for treating inflammation, inflammation-associated disorders, and specific inflammation-associated disorders, including arthritis, pain, and fever. After rejecting the patentee’s objection to our consideration of the specification of the earlier patent, we determined that the later patent “merely claims a particular use described in the [earlier] patent of the claimed compositions of the [earlier] patent.” As such, we concluded that the asserted claims of the later patent were not “patentably distinct” from the claims of the earlier patent, and thus the later patent was invalid for obviousness-type double patenting. . . .

We disagree with Lilly’s attempt to characterize Pfizer as involving a single disclosed utility, as well as with its argument that the decision’s rationale turned on this alleged single utility. . . . Moreover, the analysis in the Pfizer decision shows that obviousness-type double patenting encompasses any use for a compound that is disclosed in the specification of an earlier patent claiming the compound and is later claimed as a method of using that compound. Pfizer never implies that its reasoning depends in any way on the number of uses disclosed in the specification of the earlier patent. Instead, its broad analysis reflects that the court considered the multiple uses for the compound that were discussed in the specification of the earlier patent. Indeed, the Pfizer decision ultimately invalidated claims in the later patent that were separately directed to these multiple uses, including inflammation, inflammation-associated disorders, and the specific inflammation-associated disorders of arthritis, pain, and fever.

Thus, 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. . . . Furthermore, we reject Lilly’s argument that the district court erred in consulting the specification of the issued ’614 patent, as opposed to the specification of an earlier application, to ascertain the relevant disclosed uses of the compound gemcitabine for its obviousness-type double patenting analysis. [W]here a patent features a claim directed to a compound, a court must consider the specification because the disclosed uses of the compound affect the scope of the claim for obviousness-type double patenting purposes. In Geneva, we acknowledged the general rule that an earlier patent’s specification is not available to show obviousness-type double patenting. We have held, however, that there are “certain instances” where the specification of an earlier patent may be used in the obviousness-type double patenting analysis. Specifically, the specification’s disclosure may be used to determine whether a claim “merely define[s] an obvious variation of what is earlier disclosed and claimed,” “to learn the meaning of [claim] terms,” and to “interpret[] the coverage of [a] claim.” [A] court considering a claim to a compound must examine the patent’s specification to ascertain the coverage of the claim, because a claim to a compound “[s]tanding alone . . . does not adequately disclose the patentable bounds of the invention.” In examining the specification of the earlier patent, the court must consider “the compound’s disclosed utility.” [W]e have expressly held that, where a patent claims a compound, a court performing an obviousness-type double patenting analysis should examine the specification to ascertain the coverage of the claim.

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