

Federal Circuit Patent Bulletin: *AbbVie, Inc. v. Mathilda & Terrance Kennedy Inst. of Rheumatology Trust*

August 21, 2014

"There is no meaningful distinction between examining the disclosed utility of an earlier patent to determine the overall question of obviousness and looking at the disclosed utility of an earlier patent to determine whether the utility of the later patent was unexpected at the time of the earlier patent. Neither involves improper use of the reference patent's specification as prior art."

On August 21, 2014, in *AbbVie, Inc. v. Mathilda & Terrance Kennedy Inst. of Rheumatology Trust*, the U.S. Court of Appeals for the Federal Circuit (Dyk,* Wallach, Chen) affirmed the district court's judgment that U.S. Patent No. 7,846,442 was invalid for obviousness-type double patenting over U.S. Patent No. 6,270,766. The patented technology related to methods of treating rheumatoid arthritis by co-administering a disease-modifying antirheumatic drug such as methotrexate and an antibody such as antiTumor Necrosis Factor (TNF)-alpha. The Federal Circuit stated:

The obviousness-type double patenting analysis involves 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." . . .

Through claim construction, Kennedy attempts to enlarge the scope of the '766 patent while narrowing that of the '442 patent. First, Kennedy urges that the district court erred in limiting the term "co-administering" in the '766 patent to three modes of administration. The district court construed "co-administering" to mean that treatment with the antibody can be: (1) started at approximately the same time as treatment with methotrexate (concomitant administration); (2) added after treatment with the methotrexate has already begun (adjunctive administration); or (3) begun first, with the methotrexate treatment later added (adjunctive

administration). Kennedy argues that this definition erroneously excludes a fourth form of co-administration: administration of the antibody alone after discontinuing the administration of methotrexate. . . . The plain text of the '766 patent's specification and claims supports the district court's claim construction of "coadministering."

Kennedy also contests the district court's construction of the term "active disease," as used in the '442 patent. . . . We assume, without deciding, that Kennedy's proposed construction of "active disease" was correct. The consequence is the genus claimed in the '766 patent (treating all patients in need thereof) is broader than the species claimed in the '442 patent (treating patients with "active disease," i.e., particularly sick patients). Thus, assuming Kennedy's construction of the term "active disease" is correct, we must decide whether a patent that claims to treat a subset of patients with more severe rheumatoid arthritis (the '442 patent) is an obvious variant of a patent that claims treatment of rheumatoid arthritis patients generally (the '766 patent).

[T]he law of obviousness-type double patenting looks to the law of obviousness generally. . . . Thus, if the later expiring patent is "merely an obvious variation of an invention disclosed and claimed in the [reference] patent," the later expiring patent is invalid for obviousness-type double patenting. But "the nonclaim portion of the earlier patent ordinarily does not qualify as prior art against the patentee." To be sure, obviousness is not demonstrated merely by showing that an earlier expiring patent dominates a later expiring patent. Nor do we think that the district court here relied on any such principle. It is well-settled that a narrow species can be non-obvious and patent eligible despite a patent on its genus. But not every species of a patented genus is separately patentable. . . . Thus, species are unpatentable when prior art disclosures describe the genus containing those species such that a person of ordinary skill in the art would be able to envision every member of the class. Here, we think it is clear that a reader of the '766 patent could have easily envisioned a species limited to sicker patients. The district court was correct in concluding that the species of the '442 patent was not patentably distinct from the genus of the '766 patent.

Moreover, even if Kennedy were to show that not every species could be envisioned from the '766 patent's genus, Kennedy's claim of non-obviousness rests on its contention that the species has unexpected results. A species contained in a previously patented genus may be patentable if the species manifests unexpected properties or produces unexpected results. . . . To determine whether the '442 patent is directed to a species that yielded unexpected results, we must necessarily look to the '766 patent's disclosures to assess what results were expected at the time the '766 patent application was filed. The demonstration of utility of the '766 patent relies on the T-14 study, the very study that Kennedy now relies on to show that the '442 patent led to unexpected results and merits a separate patent. . . . Thus, the '442 patent merely claims the known utility of

the '766 patent and does not claim a species with unexpected results. . . .

It is true that a reference patent's specification cannot be used as prior art in an obviousness-type double patenting analysis. But, it is also well settled that we may look to a reference patent's disclosures of utility to determine the question of obviousness. . . . There is no meaningful distinction between examining the disclosed utility of an earlier patent to determine the overall question of obviousness and looking at the disclosed utility of an earlier patent to determine whether the utility of the later patent was unexpected at the time of the earlier patent. Neither involves improper use of the reference patent's specification as prior art. The '442 patent does not claim a species manifesting unexpected results. The '442 patent would have been obvious over the '766 patent. In sum, we conclude that the '442 patent is invalid for obviousness-type double patenting in light of the '766 patent.