

Keywords: obviousness; obvious to try

General: The Federal Circuit upholds the district court's ruling that claimed subject matter is obvious because the methods used to obtain the subject matter were obvious to try and highly predictable, ensuring a likelihood of success.

In re Kubin

90 U.S.P.Q.2d 1417 (Fed. Cir. 2009)

Decided April 3, 2009

I. Facts

Appellants Marek Kubin and Raymond Goodwin filed a patent application (“the ‘859 application”) claiming DNA molecules encoding the Natural Killer Cell Activation Inducing Ligand (“NAIL”) protein. Natural Killer (“NK”) cells play a major role in fighting tumors and viruses. NAIL is a receptor protein on the surface of NK cells that plays a role in activating the NK cells. The appellants’ claimed invention isolates and sequences a DNA molecule that encodes the NAIL protein.

The Board rejected the appellants’ claims under § 103 as obvious in light of the combined teachings of Valiante and Sambrook.

Valiante disclosed a receptor protein called “p38” found on the surface of NK cells. The Board found that Valiante’s p38 protein was the same protein as NAIL. Valiante further disclosed and claimed a p38 specific monoclonal antibody called “mAB C1.7.” Monoclonal antibodies can be used to specifically identify and target a particular kind of cell. While Valiante did not explicitly disclose an amino acid sequence for NAIL or a DNA molecule sequence for the NAIL gene, the reference instructed that conventional methodologies known to one of skill in the art could be utilized to obtain the DNA and protein sequences for receptor p38. Valiante further provided examples of such methodologies, referencing Sambrook. Example 12 of Valiante’s patent provided a five-step cloning protocol to isolate and identify the p38 receptor.

Sambrook, incorporated by reference in Valiante, described methods of molecular cloning. The reference provided detailed instructions on cloning materials and techniques without focusing on particular genes.

The Board found that one of ordinary skill in the art would have recognized the value of isolating the NAIL cDNA because of NAIL’s important role in the human immune response. The Board further found that the appellants used conventional techniques, such as those outlined in Sambrook, to isolate and sequence the gene that codes for NAIL. Additionally, the Board reasoned that there was a reasonable expectation of success in isolating the claimed subject matter in the ‘859 application because Valiante disclosed the p38 protein, detailed a method of isolating its DNA, and provided a specific probe to do so, i.e., mAB C1.7. With these findings, the Board concluded that the appellants’ isolated sequence was obvious, as it was a product of ordinary skill and common sense.

II. Issue

Did the Board correctly determine that the appellants’ claims were unpatentably obvious?

III. Discussion

Yes. The Board correctly determined that appellants’ claims were unpatentably obvious because the prior art provided a reasonable expectation of success in producing the claimed subject matter.

In evaluating the obviousness of claim 73, the Federal Circuit focused on whether the claimed sequence, rather than the process to obtain the sequence, was obvious in light of the prior art. Appellants argued that Valiante and Sambrook were deficient because they did not provide guidance for the preparation of a cell culture that would serve as a useful source of mRNA for the preparation of a cDNA library. However, the Federal Circuit found this argument unpersuasive because the appellants' disclosure represented that the claimed gene sequence could be derived and isolated by "standard biochemical methods (such as those outlined in Sambrook et al.)."

The court then discussed its prior treatment of obviousness in biotechnological inventions. In *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995), the Federal Circuit held that "obvious to try" was not a proper test of obviousness and that "the existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNA...."

The *Kubin* court noted that the Supreme Court's *KSR* decision cast doubts on *Deuel*, to the extent that *Deuel* implied that a court cannot consider whether elements of a claim were "obvious to try" in an obviousness inquiry. Ultimately, the court found that the *KSR* ruling revived the logic found in *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988).

In an effort to differentiate between proper and improper uses of "obvious to try", the *O'Farrell* court focused on two classes of cases where "obvious to try" would not equate to obviousness. In the first class of cases,

what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.

Id. at 903. In the second class,

what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

Id. The court stated that a finding of obviousness was appropriate where the prior art "contained *detailed enabling methodology* for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful." *Id.* at 902 (emphasis added). The court clarified that "obviousness does not require absolute predictability of success... all that is required is a reasonable expectation of success." *Id.* at 903-04 (emphasis added).

The *Kubin* court concluded that claims in the '859 application were obvious based on *KSR* and *O'Farrell*. The court reasoned that Valiante provided the protein of appellants' interest, a monoclonal antibody for the protein, and a five-step protocol for cloning the claimed subject matter through the monoclonal antibody. Further, the court reasoned that the applicants' reference to Sambrook as a source of methods used to isolate the claimed subject matter reinforces obviousness since Valiante discloses the same reference as a source of conventional methods which could be used to isolate the DNA sequence. Because the results were "profoundly" predictable, the court found that the Board did not err in finding the appellants' claims obvious.

IV. Conclusion

The Federal Circuit upheld the district court's finding of obviousness because the prior art provided instruction to obtain the claimed subject matter with a reasonable expectation of success.