Federal Circuit Refines Its Position on "Obvious To Try" in view of KSR

On April 3, 2009, the Federal Circuit decided In re Kubin, a case involving a claim to the isolation of a human gene involved in the immune response, and the court effectively overturned its precedent that "obvious to try" is an improper standard for evaluating obviousness of inventions in the "unpredictable arts" such as biotechnology. **The practical effect of the Kubin decision is that pending and issued claims to amino acid sequences of a protein or nucleic acid sequences encoding a protein - where the protein is disclosed in the prior art - may now be more vulnerable to obviousness challenges. In addition, the decision signals a willingness by the Federal Circuit to embrace the Supreme Court's KSR decision in the context of biotechnological inventions and will likely make overcoming obviousness rejections more difficult.**

The claims at issue in *Kubin* were to DNA molecules encoding the Natural Killer Cell Activation Inducing Ligand ("NAIL") protein, which was known in the art. On appeal, the court was required to reconsider its long standing (since 1995) positions that "knowledge of a protein does not give one a conception of a particular DNA encoding it" and "that 'obvious to try' is an inappropriate test for obviousness." The court concluded that the Supreme Court's landmark decision in *KSR* "unambiguously discredited" the Federal Circuit's earlier position that "the obviousness inquiry cannot consider that the combination of the claim's constituent elements was 'obvious to try.'" Nevertheless, the Federal Circuit was careful to explain that it was not holding that "obvious to try" always means an invention is obvious. Instead, "it's now apparent[, in light of *KSR*, that] 'obvious to try' may be an appropriate test in more situations than we previously contemplated."

The Federal Circuit then set forth the relevant question: "when is an invention that was obvious to try nevertheless nonobvious?" According to the Federal Circuit, there are "two classes of situations where 'obvious to try' is erroneously equated with obviousness under § 103." The first class of cases are those for which an investigator would have "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 indications of which parameters were critical or no direction as to which of many possible choices is likely to be successful." "In such circumstances, where [an investigator] merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness." Conversely, as stated in *KSR*, obviousness arises "where a skilled artisan merely pursues 'known options' from a 'finite number of identified, predictable solutions.'"

The second class of cases where "obvious to try" does not render an invention obvious is the exploration of "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." But, as affirmed by KSR, "§ 103 bars

patentability unless 'the improvement is more than the predictable use of prior art elements according to their established functions.'" As such, where the prior art contains "*detailed enabling methodology*" for practicing the claimed invention and "*a reasonable expectation of success*," the claimed invention is obvious.

In addition to changing course on "obvious to try," the *Kubin* decision appears to signal a shift in the Federal Circuit's treatment of inventions in the "unpredictable arts," in particular when evaluating obviousness. Specifically, the Federal Circuit stated that it "declines to cabin *KSR* to the 'predictable arts' (as opposed to the 'unpredictable art' of biotechnology)." "This court cannot, in the face of *KSR*, cling to formalistic rules for obviousness, customize its legal tests for specific scientific fields in ways that deem entire classes of prior art teachings irrelevant, or discount the significant abilities of artisans of ordinary skill in an advanced area or art." Therefore, biotech practitioners will likely be required to provide more evidence that arriving at the invention in question was unpredictable. This will be even more difficult as the Federal Circuit seems to have signaled that at least certain aspects of biotechnology have become more predictable.

This Client Alert is intended to make you aware of the recent U.S. Court of Appeals for the Federal Circuit's decision regarding obviousness of biotechnology inventions, but not to provide legal advice. Recipients should seek legal advice with respect to any specific application of the information set forth in this Client Alert.

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