In re Kubin: Gene Patents in the Post-KSR Era

A recent decision by the Court of Appeals for the Federal Circuit threatens to raise the hurdle for those seeking to patent biotechnology inventions. *In re Kubin* will shift the standard used to evaluate obviousness of claims to nucleic acids in certain circumstances.

Kubin and Goodwin claimed a genus of nucleic acid molecules encoding a portion of a protein expressed on Natural Killer cells, called NAIL (for Natural Killer Cell Activation Inducing Ligand). Kubin appealed a rejection by the US Patent and Trademark Office Board of Patent Appeals and Interferences on the grounds of lack of written description and obviousness. The obviousness rejection was based on a combination of two references: a gene cloning manual, Sambrook et al; and a reference that disclosed a protein that was later identified as NAIL, a monoclonal antibody specific for the protein, and prophetic methods for obtaining NAIL DNA and amino acid sequences.

The question of patentability of claims to nucleic acids had been examined by the Federal Circuit 14 years earlier in *In re Deuel*. The *Deuel* applicant's claims to DNA had been rejected as obvious over a reference disclosing a partial amino acid sequence of the protein encoded by the DNA in combination with a reference that taught gene cloning methods. In *Deuel*, the Federal Circuit held that a finding of unpatentability of claims to new chemical entities in structural terms "requires that the teachings of the prior art suggest the claimed compounds"(emphasis in original). That it might have been obvious to try and isolate the claimed DNA from the prior art was not sufficient. That the art had suggested a process for isolating nucleic acid molecules was not found to "fill the gap" required for a finding of obviousness.

In Kubin, however, the Federal Circuit declined to follow *Deuel's* direction to evaluate obviousness of the structure of the claimed compositions rather than the method with which they were isolated. It agreed with the Board's finding that *Deuel's* caution against using an "obvious to try" test was somehow discredited in *KSR International Co. v. Teleflex Inc.*, and looked back to *In re O'Farrell*, a decision predating *Deuel* by seven years, for guidance in evaluating obviousness. *O'Farrell* outlined two situations in which it is impermissible to find that an invention was "obvious to try":

- when trying all parameters or each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful; or
- when exploring 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.

According to the Federal Circuit, Kubin's claims did not fall into either category. Kubin's claims failed under *O'Farrell*, which dictates that an obviousness finding is appropriate where the prior art contained a detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the invention and evidence suggesting that it would be successful. Because the prior art disclosed the NAIL protein, an antibody specific for the NAIL protein and a protocol for isolation of sequences encoding the NAIL protein, the Federal Circuit found that Kubin's claims were "the product not of innovation but of ordinary skill and common sense." That Kubin supplied for the first time the amino acid and nucleotide sequences of NAIL was considered only a "minor advance in the art." Because it affirmed the Board's finding of unpatentability for obviousness, the Federal Circuit did not address the Board's finding that Kubin's claims were also invalid for lack of written description.

Going forward, applicants for nucleic acid claims should be aware that recitation of structure (*e.g.,* identity to a newly discovered DNA sequence) may not be enough to overcome an obviousness rejection in cases where the protein encoded by the nucleic acids have been isolated or characterized. Nonetheless, *Kubin* should not raise the bar for patenting nucleic acids in cases where less is known about the encoded protein or where determination of a claimed nucleotide sequence was not accomplished using routine methods.

If you wish to discuss any of these matters further, Brenda Jarrell can be reached by telephone at (617) 248-5175 or by email at bjarrell@choate.com.

©Copyright 2011 CHOATE HALL & STEWART LLP

Information contained herein should not be construed as legal advice or legal opinions on specific facts. The enclosed material is provided for education and information purposes by Choate, Hall & Stewart LLP to clients and others who may be interested in the subject matter.