

APRIL 6, 2009

Biotechnology patents just became harder to obtain and enforce. In *In re Kubin*, decided April 3, 2009, the U.S. Court of Appeals for the Federal Circuit affirmed a Board of Patent Appeals and Interferences decision finding obvious claims that recite a gene sequence encoding a protein where prior art disclosed the existence of the protein and known methods for obtaining the sequence of genes.

Historically, determinations of obviousness for a chemical compound focused on the structural differences between a known compound and the claimed compound and reasons to modify the known compound. In deciding *KSR v. Teleflex* (2007), the Supreme Court made clear that the Federal Circuit should apply the obviousness standard more flexibly than in the past. Indeed, the Supreme Court set forth a number of bases for finding obviousness, such as by showing that the claimed invention was "obvious to try" if: (1) a design need or market pressure existed to solve a problem; (2) a finite number of identified, predictable solutions existed; and (3) pursuit of the known solutions led to the anticipated success.

In *In re Kubin*, the Applicants claimed genes encoding proteins that bind to a receptor on specialized cells of the immune system and are "at least 80% identical" to a protein now known as NAIL. The Examiner rejected the claims as obvious over the combined teachings of three references and as insufficiently described. The primary reference disclosed NAIL and an antibody specific to this protein, and it also provided a prophetic example explaining how to isolate and sequence the gene encoding NAIL. The secondary references taught conventional methodologies for determining DNA and protein sequences. The Board upheld the Examiner's rejections, concluding that based on the teachings of the prior art, isolating and sequencing the claimed genes were "the product not of innovation but of ordinary skill and common sense." The Federal Circuit agreed, finding the claims obvious and declining to decide whether the invention was insufficiently described.

According to the Federal Circuit, the prior art teaches the protein of interest, provides a motivation to isolate the gene coding for that protein, and provides instructions on how to use a monoclonal antibody specific to the protein in cloning this gene. Reiterating that obviousness does not require absolute predictability, but only a reasonable expectation of success, the Federal Circuit found the claimed results "profoundly predictable." It concluded that based on these specific teachings, Applicants' "minor advance in the art" was reasonably expected in light of the prior art and, therefore, obvious to try. Acknowledging that the Supreme Court discredited the Federal Circuit's holding in *In re Deuel* (1995) that "obvious to try" does not constitute obviousness, the Federal Circuit similarly rejected that holding in this case.

Representatives from the pharmaceutical and biotechnology industries made their views known during briefing to the court as *amici*. The Biotechnology Industry Organization (BIO) contended that the Board's decision opens the door to a new and potentially dangerous basis for rejecting claims to new chemical and biochemical compounds, threatening the development of new drugs, diagnostic tests, and other biotechnology-derived products. Novartis Vaccines and Diagnostics, Inc. argued that the Board's opinion suggests that a claim to a compound is *prima facie* obvious where there are a "limited number of methodologies" available for discovering the compound, regardless of the relationship between the new compound and the prior art. GSK, Johnson & Johnson, and Amylin, pharmaceutical companies, expressed concern that the Board violated the statutory proscription that "the patentability of the invention shall not be negated by the manner in which the invention was made," by relying, at least in part, on the route actually taken by the Applicants of making the claimed invention.

Whether the fears expressed by the *amici* will come to fruition remains to be determined. Nevertheless, *In re Kubin* has ostensibly raised the threshold for patenting biotechnology inventions.