

## Legal Updates & News

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#### Federal Circuit Changes Course, Finds Claims to Novel Gene Obvious

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For more than thirteen years, biotechnology companies have been able to count on one thing: a claim to a novel gene was non-obvious where the gene's sequence was unknown in the prior art. Under *In Re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995), even where one of skill in the art might have a reasonable expectation of success at cloning an unknown gene, the gene itself was still held to be non-obvious: "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 . . . . A general incentive does not make obvious a particular result." *Deuel*, 51 F.3d at 1559.

The *Deuel* rule no longer applies. On April 3, 2009, the Federal Circuit issued *In re Kubin* [\[1\]](#), No. 2008-1184. The court reconsidered *Deuel*, and concluded that it had been overruled by the Supreme Court's recent decision in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

Now, a claim to a novel gene may be obvious if the prior art teaches "a protein of interest, a motivation to isolate the gene coding for that protein, and illustrative instructions" for methods to isolate the gene that provide a reasonable expectation of success. (*Kubin*, slip op. at 16.) The *Kubin* case marks a substantial shift in the law of obviousness as applied to biotechnology inventions.

#### The Invention in the *Kubin* Case

The Kubin inventors claimed "DNA molecules ('polynucleotides') encoding a protein ('polypeptide') known as the Natural Killer Cell Activation Inducing Ligand ('NAIL')." (*Kubin*, slip op. at 2.) NAIL is a "specific receptor protein on the cell surface that plays a role in activating" natural killer cells, immune cells that play a role in fighting tumors and viruses. The key piece of prior art was the Valiante patent, which "discloses a receptor protein called 'p38' that is found on the surface of human" natural killer cells. (*Id.* at 4.) It was undisputed that "p38" is the same protein as NAIL. (*Id.*) Thus, the protein encoded by the inventor's claimed DNA was known in the prior art.

Valiante also discloses that "[t]he DNA and protein sequences for the receptor p38 may be obtained by resort to conventional methodologies known to one of skill in the art," and goes on to describe several such methods that could be tried. (*Id.* at 5.) The court recognized, however, that "Valiante discloses neither the amino acid sequence of p38 . . . nor the polynucleotide sequence that encodes p38." (*Id.*)

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The Board of Patent Appeals and Interferences found the *Kubin* claims obvious in light of Valiante and Sambrook, a laboratory manual providing general methods for cloning genetic material.

### The Federal Circuit Opinion

The Federal Circuit affirmed the Board, finding all of the *Kubin* claims obvious. The court found that the case “requires the court to consider the Board’s application of this court’s early assessment of obviousness in the context of classical biotechnological inventions, specifically *In re Deuel*.” (*Id.* at 12.) The court concluded that “[i]nsofar as *Deuel* implies the obviousness inquiry cannot consider that the combination of the claim’s constituent elements was ‘obvious to try,’ the Supreme Court in *KSR* unambiguously discredited that holding.” (*Id.* at 13.) The court went on to discuss an older decision, *In re O’Farrell*, 853 F.2d 894 (Fed. Cir. 1988), which the court believed more accurately addressed the “obvious to try” analysis. In particular, the court explained there were two situations in which “obvious to try” could be “erroneously equated with obviousness under § 103.” (*Id.* at 14.) First, “where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness.” (*Id.*) Second, where “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.* at 14-15.)

As for *Kubin*’s invention, Valiante “discloses the very protein of appellants’ interest – ‘p38’ as per Valiante.” Valiante also discloses “a five-step protocol for cloning nucleic acid molecules encoding ‘38/NAIL.’” (*Id.* at 15.) “Moreover, the record strongly reinforces . . . the Board’s factual finding that one of ordinary skill would have been motivated to isolate NAIL cDNA.” (*Id.* at 16.) “Therefore, the claimed invention is ‘the product not of innovation but of ordinary skill and common sense.’” (*Id.* (citing *KSR*).)

Another potentially significant portion of the opinion addressed the fact that certain of *Kubin*’s claims recited as a limitation “wherein the polypeptide binds CD48.” The *Kubin* inventors “trumpet[ed] their alleged discovery of a binding relationship between NAIL and a protein known as CD48.” (*Id.* at 2.) Prior to the *Kubin* inventors’ discovery, it was apparently not known that the NAIL polypeptide binds CD48. The court ruled, without extended discussion, that “[e]ven if no prior art of record explicitly discusses the ‘wherein the polypeptide binds CD48’ aspect of claim 73,” the claims were still obvious, as “Valiante’s teaching to obtain cDNA encoding p38 also necessarily teaches one to obtain cDNA of NAIL that exhibits the CD48 binding property.” (*Id.* at 11.) Thus, the court appears to have endorsed a finding of obviousness based on inherent properties that were not known to one of skill in the art at the time the application was filed. This portion of the opinion is only a paragraph long, however, and cites to a 1945 case from the Court of Customs and Patent Appeals. If the court adopts this approach in future cases, it could have profound implications, not just in biotechnology cases.

### Implications for Biotechnology Inventions

The *Kubin* case represents a major change in the law governing patentability of biotechnological inventions. Biotechnology inventions frequently involve previously unknown genetic material. In many cases, the existence of a biological molecule itself was known, and a credible case could be made that one of skill in the art might have discovered the sequence coding for the molecule. In the future, we can expect the Patent Office to be much less willing to issue patents to such inventions. In addition, those accused of infringing biotechnology patents can be expected to mount newly invigorated obviousness challenges. Finally, reexamination, already on the rise in the wake of *KSR*, is likely to be increasingly invoked in an attempt to invalidate biotechnology patents.

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### Footnotes

[1] Morrison & Foerster LLP has filed an amicus brief in this case. For more information, please contact Brian Matsui at [bmatsui@mofo.com](mailto:bmatsui@mofo.com) in the D.C. office, or Matt Kreeger at [mkreeger@mofo.com](mailto:mkreeger@mofo.com) in the San Francisco office.

