

## Legal Updates & News

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

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For more than 13 years, biotechnology companies have been able to count on one thing: a claim to a novel gene was nonobvious 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 nonobvious.

The *Deuel* inventors claimed isolated and purified DNA and cDNA sequences that encoded heparin-binding growth factors ("HBGFs"). *Id.* at 1556 n.5. The prior art contained references disclosing a group of similar heparin-binding proteins, including a partial amino acid sequence, and general techniques of isolating a gene using a gene probe. *Id.* at 1556. The Federal Circuit held that knowledge of general cloning techniques and partial knowledge of the protein's amino acid sequence would not necessarily lead a person of ordinary skill in the art to prepare the specific sequence claimed: "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. Although it may have been "obvious to try" to prepare the claimed sequences, the actual sequences themselves were not obvious. *Id.* Thus, *Deuel* followed in the footsteps of *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993). There, the Federal Circuit rejected an argument by the Patent and Trademark Office that "a gene is rendered obvious once the amino acid sequence of its translated protein is known." *Id.* at 785.

However, the *Deuel* rule no longer applies. On April 3, 2009, the Federal Circuit issued *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009),<sup>[1]</sup> where it 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). Under *Kubin*, 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 clone the gene that provide a reasonable expectation of success. *Kubin*, 561 F.3d at 1360. *Kubin* therefore marks a substantial shift in the law of obviousness as applied to biotechnology inventions.

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

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The inventors in *Kubin* claimed “DNA molecules (‘polynucleotides’) encoding a protein (‘polypeptide’) known as the Natural Killer Cell Activation Inducing Ligand (‘NAIL’).” *Kubin*, 561 F.3d at 1353. 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. *Id.* The key piece of prior art was the Valiante patent, which disclosed “a receptor protein called ‘p38’ that is found on the surface of human” natural killer cells. *Id.* at 1354. It was undisputed that “p38” is the same protein as NAIL. *Id.* Thus, the prior art established that the protein encoded by the inventor’s claimed DNA was previously known to exist.

Valiante also disclosed 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,” describing several such methods that could be tried. *Id.* The Court recognized, however, that Valiante disclosed “neither the amino acid sequence of p38... nor the polynucleotide sequence that encodes p38.” *Id.*

Nevertheless, the Board found the claims at issue obvious in light of Valiante and Sambrook, a laboratory manual providing general methods for cloning genetic material incorporated by reference into Valiante.

### The Federal Circuit Opinion

The Federal Circuit affirmed the Board, finding all of the claims in *Kubin* obvious. The Court held 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.*

The Federal Circuit noted that Valiante disclosed “the very protein of appellants’ interest – ‘p38’” as well as the “a five-step protocol for cloning nucleic acid molecules encoding ‘38/ NAIL.’” *Id.* at 1360. This record reinforced “the Board’s factual finding that one of ordinary skill would have been motivated to isolate NAIL cDNA.” *Id.* Thus, the claimed invention was “the product not of innovation but of ordinary skill and common sense.” *Id.* (quoting *KSR*, 550 U.S. at 421).

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 expressed the limits of the “obvious to try” analysis. *O’Farrell* court described two situations in which “obvious to try” should not be “erroneously equated with obviousness under § 103”: (1) “where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities;” and (2) where “what was ‘obvious to try’ was to explore a new technology or general approach that seemed to be a promising field of experimentation,” but “the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.” *Id.* at 1359. Thus, the *Kubin* decision provides some potential protection against future attempts to characterize an invention as invalid due to “obvious to try.”

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 inventors “trumpet[ed] their alleged discovery of a binding relationship between NAIL and a protein known as CD48.” *Id.* at 1352. 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 1357. 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 biotechnology inventions. Biotechnology inventions frequently involve previously unknown genetic material. In many cases, however, the existence of a biological molecule itself was known, allowing for a credible argument that one of skill in the art could have discovered the sequence coding for the molecule. In the future, we

can expect the Patent Office to be much more likely to reject such patents on obviousness grounds. Indeed, reexamination, already on the rise in the wake of *KSR*, is likely to be increasingly invoked in an attempt to invalidate biotechnology patents.

As a result of *Kubin*, we can expect increasing reliance on claims to methods of use of genetic material. Such claims may be immune from a *Kubin*-style attack, as the prior art is less likely to include explicit or implicit guidance to use a novel protein in a particular way. Moreover, method of use claims may be better positioned to permit an inventor to introduce evidence of unexpected success to rebut a *prima facie* case of obviousness.

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## Footnotes

[1] Morrison & Foerster LLP filed an amicus brief in the *Kubin* case.