The Federal Circuit, in *In re Kubin*, Dkt. No. 2008-1184 (Fed. Cir. April 3, 2009), addressed the standards for obviousness after *KSR* in the biotechnology sector. The Court held that *KSR* did apply to the unpredictable arts, and found Kubin’s claim to a specific DNA sequence was obvious in light of *KSR* due to the fact that it was “obvious to try” known methods to obtain that sequence.

Kubin attempted to claim the DNA sequence encoding a protein he named the NK Cell Activation Inducing Ligand (NAIL). Kubin’s claims were rejected as obvious over prior art that taught the existence of the protein, and a method by which to obtain the claimed DNA sequence encoding NAIL. The prior art in front of the Patent Office during examination contained no purification or isolation of the human NAIL protein, and no NAIL protein sequence or DNA sequence.

In earlier biotechnology cases, the Federal Circuit held that the mere disclosure of a source of DNA for a protein of interest, in combination with general methods of isolating specific DNAs from that source, cannot render the resulting sequence obvious. See *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995); *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993). At issue in the Kubin appeal was whether this standard remains intact in light of *KSR*. (See BPAI appeal decision at 8 (citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007)).

In the *Kubin* decision, the Federal Circuit affirmed the BPAI interpretation of *KSR* and its impact on *Deuel*. The *Kubin* Court concluded that, “Insofar 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.” Further, the Court rejected the proposition, set forth by Kubin and BioPharma Amici, that the holding in *KSR* should be restricted to the predictable arts. The Court concluded that it cannot “customize its legal tests for specific scientific fields in ways that deem entire classes of prior art teachings irrelevant.”

In declining to apply *Deuel* to the facts at issue in *Kubin*, the Federal Circuit cited its opinion in *In re O'Farrell* to clarify the “obvious to try” standard. According to the *Kubin* holding, *O'Farrell* describes circumstances in which “obvious to try” does not constitute obviousness, while *KSR* firmly establishes the inverse. The Court concluded that the prior art in the *Kubin* appeal taught a “specific enabling methodology” as required by *O'Farrell*, and therefore the fact that it was “obvious to try” such a method was in this case sufficient to render the claims obvious.
The question of whether *KSR* applies to the unpredictable arts has been answered with a “yes” by the holding in *Kubin*. Obviousness is still, however, a fact intensive inquiry and it is yet to be seen how the availability of an “obvious to try” standard in at least some circumstances will impact the patentability of inventions in the biotechnology and pharmacological sciences. In the wake of *Kubin*, the question for patent applicants, examiners and the courts will involve assessing where a claim falls on the “obvious to try” spectrum between the circumstances described in *KSR*, in which “obvious to try” may be synonymous with obviousness, and those set forth in *O’Farrell*, in which the two terms are not synonymous.