

dystrophy, joined by its international counterpart, United Parent Projects Muscular Dystrophy, filed an *amicus curiae* brief with the appellate court in support of PTC's position on the appeal. In addition, an *amicus curiae* brief supporting PTC was filed by the family of a boy with muscular dystrophy. This support from the patient community results from PTC's long-standing efforts to engage clinicians, regulators and patient advocates in the development of PTC124, in the belief that an open and direct approach to patient communications is in the best interests of all stakeholders. It is this openness that is threatened by the lower court's decision.

Note added in proof: On December 16, 2008, in a 3–0 decision, the Third Circuit Court of Appeals vacated the lower court's order, finding that there was no clear promise made to the Gunvalsons and thus no basis for their reliance. This is an important ruling for all companies conducting clinical trials in the area of rare or orphan diseases.

COMPETING INTERESTS STATEMENT

The author declares competing financial interest: details accompany the full-text HTML version of the paper at <http://www.nature.com/naturebiotechnology/>.

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1. Allison, M. *Nat. Biotechnol.* **26**, 1201–1202 (2009).

in the art, despite some degeneracy of the genetic code. (Yamanaka acknowledges the possibility of this narrow reading when he states “the *Kubin* decision will make it harder to obtain claims to a polynucleotide encoding a protein *when that encoded protein is already known*” [emphasis added].) But claims to DNA sequence derived from amino acid sequence are mainly confined to some ‘first generation’ gene patents based on cloning genes for known proteins. Most DNA sequence patents that we study in our work, for example, are not based on prior characterization of a protein, but start from a genetic discovery or DNA sequence variation.

Even if *Kubin* is read more broadly, to render invalid all composition of matter claims to DNA sequence patents where the procedure for finding the sequence is obvious to the ordinary genomic scientist, the case should not affect claims to inventions identified by procedures that are not obvious at the time of patent application. *Kubin* does not call into question patents on DNA sequences that arise from genuine invention; rather it corrects the anomalously low threshold for nonobviousness established by *Deuel*. *Kubin* is not a “nail in the coffin of DNA sequence patents,” but rather a mechanism for culling marginal patents based on an accurate reading of the state of the science.

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1. Yamanaka, M. *Nat. Biotechnol.* **26**, 1085–1086 (2008).
2. *Ex parte Kubin*, 83 USPQ2d 1410 (Bd. Pat. App. & Int. 2007).
3. *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995).

DNA sequence patents are not in the grave yet

To the Editor:

Some DNA sequence patent holders may be feeling like Mark Twain when he read his premature obituary. We believe the patent article by Miles Yamanaka¹ in the October issue entitled “A nail in the coffin of DNA sequence patents?” is unduly alarmist. The headline and final sentence both imply that the decision by the Board of Patent Appeals and Interferences (BPAI) on the patent application of Kubin and Goodwin (application no. 09/667,859) threatens all DNA sequence patents. This is misleading because it is overly broad. In *Kubin*, the BPAI does suggest a higher standard for nonobviousness², a criterion that the US

Court of Appeals for the Federal Circuit unwisely rendered largely inoperable for DNA sequence patents in its 1995 *Deuel* decision³. In the eyes of most analysts, *Kubin* is a sensible corrective. But, even assuming that the Federal Circuit goes along with the BPAI's reasoning, precisely how *Kubin* will affect DNA patents as a whole is hardly clear.

Read narrowly, the BPAI decision precludes only claims on DNA sequence based on prior characterization of a protein's amino acid sequence. On that reading, *Kubin* merely captures a judgment that deriving a nucleic acid sequence from a corresponding amino acid sequence is straightforward to those with ordinary skill

