

24 May 2004



# TECHNOLOGY LAW UPDATE

A report of the latest Federal Circuit updates brought to you by Preston Gates.

## Velander v. Garner

No. 02-1366 (Fed. Cir. Nov. 5, 2003)

***“[I]f the evidence [supports] several reasonable but contradictory conclusions, [ the] Board’s decision is not unsupported by substantial evidence simply because the Board chose one conclusion over another plausible alternative.”***

On November 5, 2003, the Federal Circuit affirmed the decision of the Board of Patent Appeals and Interferences that granted Garner’s preliminary motion to have all of the allowed claims of U.S. patent application Serial No. 08/443,184 (Velander) held unpatentable as obvious. The interference involved the ‘184 application and U.S. Patent No. 5,639,940 (Garner), both of which related to transgenic animals expressing heterologous fibrinogen. The Federal Circuit stated:

[T]he Board determined that the preponderance of the evidence supported the conclusion that claims 64-73 of the ‘184 application were obvious as of the critical date based on the following findings: (1) all the elements of Velander’s claim 65, and by extension all of Velander’s involved claims and all of Garner’s claims, were in the prior art; (2) there was a motivation in the prior art to combine those elements; and (3) one of ordinary skill in the art would have had a reasonable expectation of success in generating a recoverable amount of biologically active fibrinogen. [T]o affirm the Board’s decision, we must be convinced that substantial evidence supports the Board’s conclusion that Garner established by a preponderance of the evidence that the claims of the Velander application were unpatentable. As noted, Velander does not dispute that all of the elements of claim 65 of the ‘184 application were in the prior art. Neither does it dispute that there was a motivation to combine those elements. Thus, [t]he case boils down to the question of whether, as of the critical date, one of ordinary skill in the art would have had a reasonable expectation of success in producing a recoverable amount of biologically active fibrinogen from a “transgenic non-human female mammal that produces recoverable amounts of biologically active human fibrinogen . . . in its milk,” as required by claim 65. What that means for us is that we must decide whether there is (i) relevant evidence that a reasonable mind might accept as adequate to support a conclusion (substantial evidence) that (ii) supports the Board’s conclusion that Garner established that it was more probable than not (a preponderance of the evidence) that, as of the critical date, one of ordinary skill in the art would have had a reasonable expectation of success in generating a recoverable amount of biologically active human fibrinogen. This is a close case. However, at the end of the day, we cannot say that Velander has established that the Board’s decision is not supported by substantial evidence.

[I]t is Velander’s position that the complexity of fibrinogen and the difficulties and uncertainties that would necessarily be associated with the production of human fibrinogen in a transgenic system bar the conclusion that, as of the critical date, there was the required reasonable expectation of success. . . . Understandably, Velander directs our attention to the evidence in the record that discusses the difficulties in transgenic expression of complex proteins like fibrinogen. [Where] the evidence will support several reasonable but contradictory conclusions, we will not find the Board’s decision unsupported by substantial evidence simply because the Board chose one conclusion over another plausible alternative. [I]n this complex case, it is not for us to second-guess the Board’s assessment of the evidence. Our task is to determine whether substantial evidence supports the conclusion chosen by the Board. [S]ubstantial evidence supports the Board’s conclusion that Garner established by a preponderance of the evidence that, as of February 18, 1993, one of ordinary skill in the art would have believed that there was a reasonable expectation of producing a recoverable amount of biologically active fibrinogen by successfully generating a “transgenic non-human female mammal that produces recoverable amounts of biologically active human fibrinogen . . . in its milk.”