

MUST AN EXPERT WITNESS'S OPINION BE  
"SUPPORTED BY CITED LITERATURE"?

By

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I. **Introduction**

Velander v. Garner, 348 F.3d 1359, 68 USPQ2d 1769 (Fed. Cir. 2003) (opinion by Circuit Judge Schall joined by Circuit Judge Prost; dissenting opinion by Circuit Judge Gajarsa<sup>2</sup>), apparently approves a panel of the BPAI's<sup>3</sup> having given no weight to the opinions of the expert witnesses of either of the parties because those opinions were not "supported by cited literature." However, the panel of the BPAI then went on to grant the motion of the party whose expert witness it had denigrated (based on the expert opinions of the APJs), and the panel of the CAFC approved that, too.

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<sup>2</sup> Judge Gajarsa's dissent was not based on the issue discussed here.

<sup>3</sup> The panel was apparently not a panel of the Trial Section. According to Judge Schall's opinion, "On June 30, 1998, the Examiner allowed claims 64-73 of the Velander application, but declared an interference between those claims and the issued Garner patent." 348 F.3d at 1362, 68 USPQ2d at 1770. Of course, examiners cannot declare interferences. Interferences are declared by APJs. 37 CFR 1.610(a) ("Each interference will be declared by an Administrative Patent Judge...."). More importantly, the fact that this interference was declared prior to October 01, 1998, suggests (but does not prove) that it was not conducted by the Trial Section. Regrettably, it is the Federal Circuit's custom not to identify the administrative judges whose decisions they review.

## II. The Proceeding Before the BPAI

Garner filed a 37 CFR 1.633(a) motion for a judgment that Velander's claims were unpatentable over certain prior art and conceded, pursuant to 37 CFR 1.637(a),<sup>4</sup> that, if Velander's claims designated as corresponding to the count were unpatentable, so were Garner's claims designated as corresponding to the count. Garner filed a 37 CFR 1.639(b) declaration from an expert witness in support of that motion, and Velander filed three 37 CFR 1.639(b) declarations from expert witnesses in support of its opposition to that motion. It was common ground that all of the elements recited in both parties' claims designated as corresponding to the count were in the prior art. The key question was whether a person of ordinary skill in the art as of the critical date would have had "a reasonable expectation of success" in combining those elements to obtain the claimed invention. Garner's expert said that such a person would have had such an expectation, and Velander's experts said that such a person would not have had such an expectation.

The panel of the board "cautioned...that the...testimony [of Garner's expert witness] was to be accorded little weight, except where it was supported by cited literature"<sup>5</sup> and "performed a similar analysis with respect to the declarations of

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<sup>4</sup> 37 CFR 1.637(a) reads in relevant part as follows:

If a party files a motion for judgment under § 1.633(a) against an opponent based on the ground of unpatentability over prior art, and the dates of the cited prior art are such that the prior art appears to be applicable to the party, it will be presumed, without regard to the dates alleged in the preliminary statement of the party, that the cited prior art is applicable to the party unless there is included with the motion an explanation, and evidence if appropriate, as to why the prior art does not apply to the party.

<sup>5</sup> 348 F.3d at 1365, 68 USPQ2d at 1773.

Velander's experts...."<sup>6</sup> In particular, "The [panel of the] Board considered, but then discounted, Dr. Rosen's testimony about a lack of reasonable expectation of success because he did not explain how the references that he cited...supported his opinion that a skilled worker would not have expected to succeed."<sup>7</sup>

Notwithstanding its denigration of the testimony of all of the expert witnesses, the panel of the BPAI granted Garner's motion (based on its own analysis of the cited references<sup>8</sup>) and entered judgment that all of the claims of both parties designated as corresponding to the count were unpatentable.

### III. **The Proceedings Before the CAFC**

On appeal, a panel of the Federal Circuit affirmed. The linchpin of its affirmance was, as is so often the case, the court's standard of review:

On appeal, we review the Board's ultimate conclusion of obviousness without deference, while we review the Board's underlying factual determinations for substantial evidence. In re Gartside, 203 F.3d 1305, 1316 (Fed. Cir. 2000). Substantial evidence "means such relevant evidence as a reasonable mind might accept as

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<sup>6</sup> 348 F.3d at 1366, 68 USPQ2d at 1774.

<sup>7</sup> 348 F.3d at 1367, 68 USPQ2d at 1775.

<sup>8</sup> According to 35 USC 6, "The administrative patent judges...[are] persons of competent legal knowledge and scientific ability...." However, there is nothing in the statute, the Code of Federal Regulations, or the Standard Operating Procedures of the BPAI that guarantees that any of the APJs assigned to a panel to decide a given interference are persons of ordinary skill, much less experts, in the field of the invention or inventions involved in that interference.

adequate to support a conclusion.” Consol. Edison Co. v. NLRB, 305 U.S. 197, 229 (1938). Our review of the Board’s factual findings for substantial evidence examines the record as a whole, taking into account evidence that supports as well as detracts from those findings. Gartside, 203 F.3d at 1312. “The possibility of drawing two inconsistent conclusions from the evidence,” however, will not render the Board’s findings unsupported by substantial evidence. Consolo v. Fed. Mar. Comm’n, 383 U.S. 607, 620 (1966). In other words, if the evidence of record will support several reasonable but contradictory conclusions, we will not find the Board’s decision unsupported by substantial evidence because the Board chose one finding over another plausible alternative. In re Jolly, 308 F.3d 1317, 1320 (Fed. Cir. 2002).<sup>9</sup>

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In order to 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. \*\*\* [T]he case boils down to the question of whether, as of the critical date, one of ordinary

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<sup>9</sup> 348 F.3d at 1374, 68 USPQ2d at 1780.

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.<sup>10</sup>

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Understandably, Velander directs our attention to the evidence in the record that discusses the difficulties in transgenic expression of complex proteins like fibrinogen. Such material arguably supports a conclusion contrary to

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<sup>10</sup> 348 F.3d at 1376, 68 USPQ2d at 1782.

the one reached by the Board. At the same time, other evidence in the record supports the conclusion reached by the Board. If 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. Jolly, 308 F.3d at 1320. That is the case here. In other words, in 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. We hold that substantial 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."<sup>11</sup>

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<sup>11</sup> 348 F.3d at 1378-1379, 68 USPQ2d at 1784.

#### IV. Comments

I am concerned by the sweeping statements of the panel of the board that the testimony of the expert witnesses “was to be accorded little weight, except where it was supported by cited literature.” Sometimes there is no citable literature that is directly on point! I have no trouble with saying that mere conclusory statements of expert witnesses are entitled to little weight. However, sometimes all that an expert witness can do is reason from general principles. Sometimes such reasoning is persuasive, and sometimes it isn’t. However, there is nothing wrong with reliance on such evidence!

Moreover, the panel of the board did not really rely on “the evidence” (i.e., the cited literature) so much as on its own assessment of the inferences to be drawn from that literature. That is, having decided to give “little weight” to the inferences drawn from the cited literature by the parties’ expert witnesses (and there was apparently no dispute that those witnesses were experts in the relevant field), the APJs then proceeded to give great weight to their own assessment of the inferences to be drawn from that literature! While the APJs may, in general, be better suited to that task than the average Article III judge, I question whether they were really better suited to that task than the parties’ expert witnesses.

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