



Federal Circuit: Expert Testimony Without Express Teaching Away Was Substantial Evidence of No Motivation to Combine

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The Federal Circuit has affirmed the PTAB's determination that a patent challenger did not show the challenged claims were unpatentable for obviousness. The Federal Circuit concluded that substantial evidence, which included expert testimony, showed there was no motivation to combine the references.

The claims at issue relate to non-invasive methods of DNA analysis for prenatal diagnosis. The methods involve the addition of a cell lysis inhibitor (e.g., formaldehyde) to a blood sample from a pregnant mother to increase the proportion of cell-free fetal DNA (cffDNA) for subsequent analysis. At the board, the patent challenger argued that the claims were obvious over the combination of references discussing the effects of blood-processing protocols on the quantification of cffDNA and total DNA in maternal plasma ("Chiu"), with either one of two references disclosing methods of using paraformaldehyde in cell processing—a patent which disclosed plasma membrane permeabilization ("Bianchi"), or a patent application publication which disclosed cancer cell stabilization in blood ("Rao"). The board disagreed, explaining that a POSA would not have been motivated to combine Chiu with Bianchi because Bianchi disclosed the potential for maternal DNA leakage which ran counter to Chiu's teachings. Furthermore, a POSA would not have been motivated to combine Chiu with either Bianchi or Rao because formaldehyde was known to damage nucleic acids.

On appeal, the patent challenger cast the board's decisions as legally erroneous and therefore warranting de novo review. In particular, the patent challenger argued that the board had

applied an improper heightened standard for proving motivation to combine, and had otherwise improperly applied the obviousness test.

First, the patent challenger argued that the board had required the prior art combination of Chiu with Bianchi to be “perfect rather than merely desirable.” According to the patent challenger, the board had been “fixated on the fact that even the potential for only 1% leakage [in Bianchi] would have been contrary to the goals of Chiu” and had not properly considered the cell stabilization benefits disclosed in Bianchi. The Federal Circuit rejected this argument, finding that the board had made factual determinations based on the evidence presented. The Federal Circuit noted that the board had acknowledged Bianchi’s preference to retain 99% or more DNA in the cell, but the board had also evaluated the other teachings of the prior art references and the expert testimony from both parties. Having done so, the board then simply determined that a POSA would find even a 1% DNA leakage unacceptable because such DNA leakage would negatively impact Chiu’s sampling methodology.

Second, the patent challenger argued that the board’s obviousness analysis had improperly relied on generic concerns of DNA damage, and had failed to consider if a highly skilled POSA would have pursued the invention despite those concerns, and had not followed precedent on what constitutes teaching away. The Federal Circuit also rejected these arguments, finding that they were factual disputes rather than legal errors. The Federal Circuit explained that the cited industry concerns were not merely generic, but instead were specific to the combination of references asserted and the claimed invention—formaldehyde’s potential effects on cffDNA. Similarly, the Federal Circuit explained that the board had expressly considered the POSA’s high level of skill, but had rejected the patent challenger’s arguments. Finally, on teaching away, the Federal Circuit explained that the board had not relied on this doctrine; nor did it need to in order to find that a POSA would have been dissuaded from combining the prior art references.

Practice Tip: This case reflects the importance of expert testimony concerning whether a POSA would be dissuaded from combining references even where there is no express “teaching away.” Because obviousness is a question of law founded on factual underpinnings, on appeal, the legal determination will be reviewed *de novo* while the factual findings will be reviewed for “substantial evidence.” Expert testimony on any disadvantages that arise from combining the prior art can be critical evidence in the assessment of obviousness. As such, patent owners and patent challengers should carefully consider the prior art references for

advantages and disadvantages that arise from combining the references, and should adduce expert testimony on those issues.

Laboratory Corporation of America Holdings v. Ravgen, Inc., Appeal Nos. 2023-1342, 2023-1345 (Fed. Cir. Jan. 6, 2025)

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