

Federal Circuit Reverses \$4.7M Verdict in Labcorp v. QIAGEN: Claim Scope and Doctrine of Equivalents in the Crosshairs

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The Federal Circuit <u>recently reversed</u> a \$4.7M verdict in a patent lawsuit involving two patents concerning next-generation sequencing methods—U.S. Patent Nos. 10,017,810 and 10,450,597. Both patents concern DNA preparation using different types of primers: "target-specific primers" that bind to regions of interest in the genome and other primers or adaptors that enable sequencing.

The dispute boiled down to whether QIAGEN's primers—specifically, its "second indexing primer" (SIP) and "forward primer" (FP)—could qualify as the claimed "second target-specific primer" and "target-specific primer." Labcorp persuaded the jury they did. But on appeal, the Federal Circuit held that there was no legally sufficient evidence of infringement—either literal or under the doctrine of equivalents (DOE).

Key Holdings from the Federal Circuit

1. Claim construction is the court's job—"identical" means identical.

The '810 Patent required a primer with a portion "identical to a second sequencing primer." Labcorp argued that QIAGEN's SIP satisfied this because its 19 nucleotides matched part of a longer 34-nucleotide sequencing primer. The district court let the jury decide whether "identical" could mean "identical to a portion." But the Federal Circuit flatly rejected this construction, in part because the claims used the term "portion" elsewhere, but not here. Moreover, the Federal Circuit noted that it was "error for the district court to turn a matter of claim construction over to the jury to decide as a factual dispute."

Doctrine of Equivalents: Conclusory Testimony Won't Cut It

Labcorp also argued that even if the SIP wasn't literally "identical," it was still equivalent under the DOE. But DOE requires a particularized, element-by-element analysis of function, way, and result. And the Federal Circuit found that the evidence provided by Labcorp did "not rise to the level of 'particularized testimony and linking argument' showing substantial similarity between the accused products and asserted claims in function way or result." Accordingly, the Federal Circuit found that no reasonable jury could have found that the SIP was substantially similar in either function, way, or result.

Negative Limitations Have Teeth

The '597 patent defined (and the court construed) a "target-specific primer" as one that anneals only to the target nucleic acid and "will not anneal" to non-target sequences. Labcorp's evidence that QIAGEN's FP mostly bound to target sequences wasn't enough. Because the FP could still bind adaptor-complement molecules without the target sequence, no reasonably jury could find that it avoided non-target binding as required. This strict reading of the negative limitation doomed Labcorp's case.

Lessons for Litigators and Patent Owners

Don't leave claim scope to the jury. The Federal Circuit continues to police against "outsourcing" claim meaning. Disputes over simple words—here, "identical"—must be resolved at claim construction, not left to the jury to decide. Expect *Labcorp* to be cited alongside *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, for the principle that courts, not juries, decide claim scope.

Mind the "portion" trap. Drafting and litigating alike, courts take seriously when the patentee uses the term "portion" in one place but omits it in another. If "identical to a portion of X" is intended, the claims must say so. Opponents should push the superfluity canon to block attempts at broadening mid-trial.

DOE remains demanding. Since *Warner-Jenkinson*, the DOE has been narrowing, and with *VLSI Technology LLC v. Intel Corporation* and now *Labcorp* the Federal Circuit reinforces that bare expert say-so will not save a weak equivalence case. Particularized testimony—preferably supported by experimental data—is mandatory.

Negative Limitations can be fatal. Claims or claim constructions that include "will not" or "does not" language require proof that the accused product actually avoids the excluded feature. Showing that a component mostly performs as required is insufficient if the claim demands exclusivity.

Takeaway

The Federal Circuit's decision in *Labcorp v. QIAGEN* underscores two recurring themes: (1) claim scope belongs to the court, not the jury, and (2) patentees must present rigorous, particularized evidence—especially under the doctrine of equivalents and for negative limitations. For litigators, this opinion provides fresh precedent to attack broad infringement theories that rest on "close enough" reasoning. For patent prosecutors, this is a drafting lesson in choosing words carefully and considering whether "portion," "identical" or "does not" language could box in future enforcement.

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