

## PTAB Upholds IP Involved In \$272M Genetic Testing Verdict

By Britain Eakin

*Law360 (November 2, 2022, 4:12 PM EDT)* -- The Patent Trial and Appeal Board dealt LabCorp a blow by rejecting its arguments that 37 claims in a Ravgen Inc. prenatal genetic testing patent — including the claim at the heart of a \$272 million Texas jury verdict — are invalid.

In a pair of decisions handed down Tuesday, the PTAB found LabCorp. failed to show that any of the 37 claims it challenged were unpatentable. The decision helps solidify a September jury verdict in the Western District of Texas that LabCorp willfully infringed a single claim in the patent. Ravgen, a small Maryland biotech company, has since asked U.S. District Judge Alan Albright to triple the damages and tack on another \$545 million to the \$272 million verdict.

The claim at issue in the Texas suit was among the 37 that LabCorp — one of the largest chains of clinical lab providers in the world — unsuccessfully challenged across its two petitions for inter partes review.

The patent, which the U.S. Patent and Trademark Office issued in 2008, deals with non-invasive methods to detect fetal genetic disorders by isolating cell-free fetal DNA from the sample of a pregnant woman's blood. Prior non-invasive testing methods to detect genetic abnormalities were known to be unreliable because maternal blood samples contain low amounts of cell-free fetal DNA, according to the board's description of the technology. To get around that issue, the patent describes adding an agent like formaldehyde to increase the percentage of fetal DNA in a blood sample.

LabCorp had argued that the claim it was found to infringe, along with some of the other challenged claims, were obvious, in light of several prior art references. LabCorp argued that skilled artisans would have been motivated to modify methods for maternal blood processing and DNA detection as described in two of the references by including paraformaldehyde, a polymer of formaldehyde, as a fixative agent as disclosed in a third reference.

Ravgen countered that theory doesn't withstand scrutiny because paraformaldehyde was known to damage DNA, including cell-free DNA. The board ultimately agreed with that, noting that skilled artisans would have expected paraformaldehyde to create gaps in cell membranes, thus creating a way for cellular DNA to escape.

"On balance, we are persuaded on this record that the [person of ordinary skill in the art] would have had significant, unresolved concerns with introducing formaldehyde, and its potential to adversely affect [cell-free fetal DNA] in the modified method ... undermining Petitioner's challenge," the decision said.

The board credited testimony from Ravgen's expert, along with its evidence in the case, saying it was more persuasive than LabCorp's "comparatively weak showing" that skilled artisans would have been motivated to undertake the proposed prior art combination.

John M. Desmarais, who represents Ravgen in the district court suit, told Law360 his client "is very pleased with the PTAB decision."

Meanwhile, LabCorp representative Rachael Valdez suggested the company will likely appeal.

"We are disappointed with the Patent Trial and Appeal Board's decision and are reviewing our options for further review. We strongly disagree with the jury verdict and will vigorously defend the lawsuit through the appeal process," Valdez said in an email.

Counsel for LabCorp did not immediately return a request for comment on Wednesday.

Ravgen sued LabCorp in October 2020 alleging that its MaterniT21 PLUS, MaterniT Genome, and informaSeq cell-free fetal DNA tests infringe. Ravgen contended that LabCorp, which it had approached about a potential partnership that they discussed for years, stole the invention rather than taking a license for the technology, according to its Oct. 5 motion for enhanced damages.

LabCorp has since urged Judge Albright to deny the request, arguing in a response to the motion that such damages aren't warranted.

"Ravgen fails to show any egregious behavior, litigation misconduct or other conduct warranting enhancement," LabCorp said.

The patent-in-suit is U.S. Patent No. 7,332,277.

Administrative Patent Judges Zhenyu Yang, Timothy G. Majors and David Cotta sat on the panel.

LabCorp is represented by Tina McKeon, Kathryn H. Wade, Allison W. Dobson, John C. Alemanni, Cynthia Rothschild and Leland Black of Kilpatrick Townsend & Stockton LLP.

Ravgen is represented by Gabrielle E. Higgins, Yung-Hoon Ha, Theodoros Konstantakopoulos, Michael A. Stramiello, Brian D. Matty and Joze Welsh of Desmarais LLP.

The case is Laboratory Corporation of America Holdings v. Ravgen Inc., case number IPR2021-00902, at the Patent Trial and Appeal Board.

--Additional reporting by Andrew Karpan and Jasmin Jackson. Editing by Alex Hubbard.