

## **PTAB Told Chemical Co.'s Tech Has 'Full Promise' Of CRISPR**

By **Britain Eakin**

*Law360 (November 21, 2022, 11:04 PM EST)* -- In the latest installment of the battle over who invented gene editing technology CRISPR first, chemical giant Sigma-Aldrich urged the Patent Trial and Appeal Board on Monday to recognize that its contribution to the field sets it apart.

The board is considering multiple requests to further define the inventions at issue in the sprawling fight over who first got gene editing with CRISPR-Cas9 in eukaryotic cells to work. There are multiple interference proceedings on the issue, which the board declares when an invention is claimed in more than one patent application or patent.

Sigma-Aldrich Co. Ltd. attorney Brenton R. Babcock of Loeb & Loeb LLP told a three-judge board panel during the first of two hearings Monday afternoon that the invention at the heart of the interference with the Regents of the University of California, University of Vienna and Emmanuelle Charpentier — collectively referred to as CVC — "represents the full promise of CRISPR."

Whereas the other interference proceedings involving CRISPR technology pertain only to cleaving, or breaking, a target DNA in a eukaryotic cell, Babcock said Sigma-Aldrich has figured out how to fix DNA, not just how to break it.

Sigma-Aldrich wants the board to change the so-called count in the case, which is based on patent claims — usually one from each party — that defines the scope of the invention to include integrating a donor polynucleotide into cleaved target DNA through a process called homology-directed repair.

The integration of a donor polynucleotide is what changes an undesirable DNA sequence to a desirable one, which Babcock told the board panel is really the goal of CRISPR technology. Unless the board changes the count, Sigma-Aldrich argued in case filings that it will be deprived of patent rights "for its distinct and more technically challenging invention."

Babcock tried to distinguish its invention by comparing it to tearing down a skyscraper, which he contended is easier than rebuilding one.

"Think about the complexity of building a skyscraper in a complex regulatory environment of a modern-day city. And then think about how much more complex the regulatory environment is in a eukaryotic cell. Just because you can tear down a skyscraper doesn't mean you can rebuild one that's fundamentally different than the old one," said the attorney.

CVC opposes Sigma's bid to narrow the count, with attorney Eldora L. Ellison of Sterne Kessler Goldstein & Fox PLLC telling the board during the hearing that doing so "would cancel CVC's claim to an invention that [Sigma-Aldrich] chose not to pursue."

Ellison suggested that Sigma-Aldrich doesn't have a leg to stand on because it refused to add a claim for generic cleavage at the request of the patent examiner handling its application for the purpose of the interference. Ellison said Sigma-Aldrich "repeatedly and wrongly" mischaracterized CVC's half of the count as pertaining only to cleavage, ignoring that it can also do editing.

The board panel probed the meaning of editing, which Ellison said means adding or deleting DNA. But Administrative Patent Judge Deborah Katz also asked if homology-directed repair can be done without a donor, and whether "if there's cleavage and no donor sequence, can there be editing?"

Editing was understood by skilled artisans at the time of the invention in 2012 to include homology-directed repair, according to Ellison, which she went on to say means Sigma's proposed count should be rejected because it would have been obvious.

CRISPR, which stands for clustered regularly interspaced short palindromic repeats, has been called a major breakthrough in gene editing technology that is simpler, cheaper and more efficient than previous technologies and could have a wide array of scientific uses, from eliminating genetic diseases to producing stronger plants that could help combat hunger.

In February, the board decided that Broad Institute, the Massachusetts Institute of Technology and Harvard University were first to reduce the use of CRISPR-Cas9 in eukaryotic cells to practice over CVC in another interference. CVC has since appealed that decision to the Federal Circuit and a decision in that case is pending, which means other interference proceedings over CRISPR technology are still at play.

In September, there were more hearings in two more interferences involving Korean biotechnology company ToolGen Inc., which argued it was first to use the technology in plants and animals over CVC, Broad, MIT and Harvard. The board deemed ToolGen to be the senior party in both cases, which means it's given the benefit of the earliest filed patent application.

That shifts the burden of proof to CVC and Broad to show they reduced CRISPR-Cas9 to practice before ToolGen did. And the same holds true for Sigma, which was also deemed to be the senior party.

In addition to CVC, there is yet another interference proceeding between Sigma-Aldrich and Broad, MIT and Harvard, and there was a hearing in that case as well on Monday. In that case, Broad wants to limit the count to "donor template integration" claims, which it argued in case filings is more in line with what each party is trying to patent.

Sigma-Aldrich is pushing back on that, arguing that Broad shouldn't be allowed to change the count because it's based on a claim that wasn't deemed to be allowable by the patent examiner prosecuting Broad's patent application when Broad filed the motion to change the count. Sigma-Aldrich argued in case filings that the board only allowed Broad to file a motion to change the count on the basis that the claim the count was based on had already been deemed allowable by the examiner.

Judge Katz pressed the matter during Monday's hearing.

"Was it stated as being allowable by the examiner when your motion was filed?" Judge Katz asked Broad attorney Raymond Nimrod of Quinn Emanuel Urquhart & Sullivan LLP.

Nimrod argued that the claim was allowable, but Judge Katz pressed the matter further, suggesting the claim had been "amended substantively" before it was deemed allowable, with the attorney eventually conceding that the examiner had not stated that the claim was allowable at the time the motion was filed.

But he still stuck to his guns, telling Judge Katz that "the answer is yes" to whether the claim was allowable.

Administrative Patent Judges Deborah Katz, Sally Gardner Lane and Rachel Townsend sat on the panels.

The University of California is represented by Eldora L. Ellison of Sterne Kessler Goldstein & Fox PLLC.

Broad and MIT are represented by Raymond N. Nimrod of Quinn Emanuel Urquhart & Sullivan LLP.

Sigma-Aldrich is represented by Brenton R. Babcock of Loeb & Loeb LLP.

The cases are The Regents of the University of California et al. v. Sigma-Aldrich Co. Ltd, interference number 106,132, and the Broad Institute Inc. et al. v. Sigma-Aldrich Co. Ltd., interference number 106,133, at the Patent Trial and Appeal Board.

--Additional reporting by Dani Kass. Editing by Jay Jackson Jr.