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PTAB Judge Grills UC On Evidence It Invented CRISPR First

By **Britain Eakin**

Law360 (February 4, 2022, 8:40 PM EST) -- A Patent Trial and Appeal Board judge called into question Friday whether the University of California has enough evidence showing that the university — rather than the Broad Institute — is entitled to patents on the breakthrough gene-editing technology CRISPR.

The current battle between UC and Broad Institute, a research institute associated with Harvard University and the Massachusetts Institute of Technology, centers on who was first to successfully use a version of the CRISPR-Cas9 tool in plant and animal cells known as eukaryotes.

CRISPR, an acronym for Clustered Regularly Interspaced Short Palindromic Repeats, has been called a major breakthrough in gene editing that is much faster, simpler, cheaper and more efficient than previous technologies. The board will ultimately decide who gets the key patents for the potentially billion-dollar technology after determining who was first to conceive of the invention.

During Friday's remote hearing in the interference — a PTAB proceeding declared when an invention is claimed in more than one patent application or patent — UC attorney Eldora L. Ellison of Sterne Kessler Goldstein & Fox PLLC suggested that the case was closed because Feng Zhang, the Broad Institute's scientist who claimed he was first to make the invention work, succeeded only because he had access to UC's confidential methods, not because of inventive skill.

"Under the law, he cannot be awarded priority," Ellison argued.

UC was first to disclose the technology and says it conceived of the invention in March 2012, while Broad puts its conception date in June of that year. If the board rules strictly on that timeline, it would favor UC. However, Broad argued in case filings that the invention requires "specific biologic results in a eukaryotic cell," and so the inventors have to show they successfully implemented the invention at the time of conception. Broad contends it should prevail because Zhang reduced the invention to practice in July 2012, while UC didn't get the invention to work until that August.

To win, Broad argued that UC must demonstrate the inventors "contemporaneously recognized and appreciated this alleged success, and that corroborating evidence demonstrates both the successful experiments and the inventor's recognition of success."

Administrative Patent Judge Deborah Katz appeared to probe that argument with her questions during Friday's hearing, as she pressed Ellison to address UC's evidence that scientists — including Jennifer Doudna and Emmanuelle Charpentier of the University of Vienna, who received the 2020 Nobel Prize in

chemistry for their work on CRISPR — had a working invention in March 2012.

The judge asked Ellison for any evidence, including emails or conversations, showing that the inventors had gotten it to work.

Judge Katz also called it "a very long time" between when the UC scientists said they knew the technology would work in March until it actually worked more than five months later, on August 9, 2012. The judge cited bumps in the road that sent them back to the drawing board more than once, suggesting that might call into question whether their invention actually worked in March 2012.

"I'm just sort of getting at the multiple failures that happened and [if] that gets to whether they actually had a definite and permanent idea of a system working in a eukaryotic cell," Judge Katz said.

Ellison said it took "at most" five months from that point to reduce the invention to practice, and described the timeline as "lightning fast in the field of biology."

Judge Katz pressed on, asking the attorney to again address the "multiple failures" the scientists did encounter, including conversations the inventors had about "not understanding what was going on."

"If they knew that they had a system that would actually work, why did they have all of these failures?" Judge Katz asked. Rather than taking five months, the administrative patent judge said "it should've worked in the next experiment that they did if they knew exactly how to make it work."

Ellison pushed back on that, saying there's no legal requirement for them to make it work on the first try, and that the timeline reflects "routine experimentation."

Judge Katz did the bulk of the questioning during Friday's hearing and peppered Ellison with questions. But she was relatively quiet when Broad attorney Raymond N. Nimrod of Quinn Emanuel Urquhart & Sullivan LLP argued, and asked him no questions about the research institute's timeline for conception and reduction to practice.

Friday's hearing marks the second phase of the interference proceeding. In May 2020, the board considered, and ultimately rejected, Broad's argument that the case shouldn't go forward because UC was trying to relitigate issues that were settled in an earlier interference proceeding between the parties in 2017, which was also related to CRISPR.

The board terminated the earlier interference after finding that the CRISPR technologies were patentably distinct, and the Federal Circuit affirmed that decision in September 2018. While the UC team sought patents on using CRISPR in any environment, Broad sought patents on using it in plant and animal cells, so the PTAB concluded there was no interference and did not reach the issue of who invented CRISPR first.

Broad applied for the patents in 2012, along with MIT and Harvard, on using CRISPR in eukaryotic cells. The Broad team, led by MIT's Zhang, was issued patents on the technology first because it sought them on an expedited basis, while UC's remain pending.

The PTAB ordered the current interference proceeding in June 2019 after UC filed 10 additional applications for using CRISPR in plant and animal cells.

Administrative Patent Judges Sally Gardner Lane, James T. Moore and Deborah Katz sat on the panel for the Patent Trial and Appeal Board.

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

Broad is represented by Raymond N. Nimrod, Matthew D. Robson and Zach Summers of Quinn Emanuel Urquhart & Sullivan LLP and Steven R. Trybus of Locke Lord.

The case is The Regents of the University of California et al. v. The Broad Institute Inc. et al., interference number 106,115, before the Patent Trial and Appeal Board.

--Additional reporting by Ryan Davis. Editing by Dave Trumbore.

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