

## Broad, UC Each Tell PTAB It Invented CRISPR First

By Britain Eakin

*Law360 (May 19, 2020, 10:21 PM EDT)* -- A Patent Trial and Appeal Board panel has given few hints about which way it is leaning in a hotly contested fight over whether the University of California or the Broad Institute invented the breakthrough gene-editing technology CRISPR first.

At a hearing Monday, the PTAB reviewed patents issued to Broad and applications filed by UC on technology for using a version of the tool called CRISPR-Cas9 in plant and animal cells known as eukaryotes, and the board could determine who should get the key patents for the potentially billion-dollar technology if the interference proceeding continues.

Whether it carries on is a matter for the PTAB to decide. An attorney for Broad, a research institute associated with Harvard and the Massachusetts Institute of Technology, argued during the 50-minute remote hearing that it shouldn't go forward because UC is trying to relitigate issues he said were settled in an earlier interference proceeding between the parties in 2017, which was also related to CRISPR.

"The law does not allow a redo," said Broad's counsel Raymond N. Nimrod of Quinn Emanuel Urquhart & Sullivan LLP.

But the panel didn't bite at that argument. Administrative Patent Judge Deborah Katz — the only judge to ask any questions — waited until Nimrod's 20 minutes of argument time had nearly expired to chime in, asking him to identify where in the briefing Broad elaborated on which claims are limited to a single-molecule system.

That question got to the heart of the current fight between the parties, which is primarily about who has priority of invention for CRISPR in eukaryotes using a single-molecule guide RNA.

In this stage of the proceedings, each side is trying to prove it is entitled to its earliest filing date. For UC, that's May 25, 2012, and for Broad that's Dec. 12, 2012, according to PTAB filings. To meet that bar, each side need only show that its claims have one embodiment — a detailed description of how the invention is made or used — in claims the PTAB selected.

UC attorney Eldora L. Ellison of Sterne Kessler Goldstein & Fox PLLC argued during Monday's hearing that all that is required for UC to get the earlier priority date is to show a constructive reduction to practice — that UC was in possession of single-molecule guide RNA and that a skilled artisan could make and use it without undue experimentation — a bar she said was easily met.

To support that contention, Ellison argued that experiments done by others after the filing date were able to practice the invention as described in the priority application.

Judge Katz interjected to ask Ellison why UC's briefs focused primarily on microinjection in fish cells and whether they differ from other eukaryotic cells in such a way that it might overcome issues the PTAB identified in the earlier interference proceeding. In that case, the board determined microinjection was well known and that a skilled artisan would not reasonably expect UC's patent claims on CRISPR technology to work in eukaryotic cells.

Ellison responded by telling the panel that fish cells are commonly used in gene therapy experiments and said the PTAB's earlier findings of no reasonable expectation of success shouldn't control the issue of whether the priority application describes the invention and teaches a skilled artisan how to make and use the invention without undue experimentation, which she said it does.

Counsel for the parties declined to comment, but Broad said in a statement Monday that it was time for the parties to settle their dispute.

"Although we welcome this second action before the PTAB and are confident these patents have been properly issued, we continue to believe it is time for all institutions to move beyond litigation and instead work together to ensure wide, open access to this transformative technology," the statement said.

A spokesperson for UC said in a statement that the university remains confident the USPTO will ultimately recognize that its team of inventors was first to invent the CRISPR-Cas9 gene-editing technology in eukaryotic cells, as well as other settings covered by the team's previous patents.

Unless the PTAB buys into Broad's argument that the proceeding can't go forward because it covers the same subject matter as the first interference proceeding, or it decides there's no interference because the claims are patentably distinct, then a testimonial phase of the proceedings will get underway after the PTAB decides which side should get the earliest priority date.

That phase will include testimony from the inventors and the admission of evidence that includes their lab notebooks to get at who conceived of the invention first and was working diligently to reduce it to practice. If the interference proceeding gets that far, that's when the PTAB will actually decide who first invented CRISPR and who is entitled to the patents.

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.

Monday's hearing marked the latest development in a broader dispute between UC and Broad, which have been duking it out for several years in a highly public dispute that has riveted the biotech world.

In September 2018, the Federal Circuit affirmed the PTAB's decision in the 2017 interference proceeding, which found that the CRISPR technologies were patentably distinct. 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.

The technology was first disclosed by a team that included UC's Jennifer Doudna and the University of Vienna's Emmanuelle Charpentier in May 2012.

Broad applied for patents later that year, along with MIT and Harvard University, on using CRISPR in eukaryotic cells. The Broad team led by MIT's Feng 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 instant interference proceeding after UC filed 10 additional applications for using CRISPR in plant and animal cells.

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

Broad is represented by Raymond N. Nimrod of Quinn Emanuel Urquhart & Sullivan LLP.

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 Jill Coffey.