

U of California Vows CRISPR Patent Spat Not Over as Experts Weigh in on Legal Options

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NEW YORK (GenomeWeb) – Despite suffering a setback in the CRISPR patent fight, the University of California and its licensees are vowing to press on in their bid to control the entire CRISPR patent estate.

UC Berkeley and two publicly-traded sublicensees to UC's CRISPR/Cas9 patent rights, Intellia Therapeutics and Crispr Therapeutics, have publicly commented on the available options in the US. The responses include various combinations of appealing the patent interference outcome in Federal court, pursuing a broadly applicable patent on CRISPR/Cas9 not limited to use in eukaryotic cells, and directly challenging the Broad Institute's patents on using CRISPR/Cas9.

"The university continues to believe that the use of the CRISPR/Cas9 system in eukaryotic cells is not separately patentable from the general application of the CRISPR/Cas9 system in any cell type," UC-Berkeley Vice Chancellor for Research Paul Alivisatos said in a statement. "As such, we will be carefully considering all possible legal options at this juncture."

The comments from UC officials came after a three-judge panel from the Patent Trial and Appeal Board (PTAB) hearing the interference case between the university and the Broad Institute issued a judgement of no interference-in-fact. The decision was viewed as a significant blow to UC Berkeley in asserting its patent rights covering the gene editing technology.

Officials from UC, Intellia, and Crispr Therapeutics all stressed that the patent interference decision did not rule on the validity of any of UC's patent claims. "This ruling does not take anything away from the UC or its licensees," Sam Kulkarni, Crispr Therapeutics chief business officer, said on a conference call following the decision. In fact, UC can still pursue intellectual property based on the original patent application, which did not specify a limitation on a eukaryotic cell environment.

Depending on how UC proceeds — and how the USPTO and the courts respond to it — the full range of outcomes is still in play. A victory on appeal could be total, but other scenarios could leave UC on shaky footing. But it doesn't have much time to decide how to proceed: if it's going to appeal, it has just two months to decide to do so.

The decision by the PTAB to end the patent interference preserved the Broad Institute's patents on genome editing in eukaryotic cells, a major victory for the institute. To be sure, the most lucrative applications of CRISPR/Cas9 are in human gene therapy, ag-bio, and industrial synthetic biology, all of which use eukaryotic cells.

By declaring use of CRISPR/Cas9 in eukaryotes to be a separately patentable invention, the USPTO's Patent Trial and Appeals Board ended UC's best chance to wrest control of that IP. In a 50-page decision, the three-judge panel detailed the reasons it seemed

unobvious that CRISPR would work in human or animal cells, often referencing comments made by UC-Berkeley professor Jennifer Doudna, a main inventor on the patent application.

To some observers, that sets up a scenario where UC will soon obtain a "genus"-level patent on CRISPR/Cas9, compared to the Broad Institute's "species"-level patent for use in eukaryotes.

Following the PTAB decision, Doudna put it this way to Science: "[Broad has] a patent on green tennis balls. We [likely] will have a patent on all tennis balls."

According to Kristin Neuman of patent pooling firm MPEG LA, this is a fairly common scenario, where one entity has a broader patent and another, a more specific one. "It's a simple analogy, but it really explains the potential situation we have now," she said.

Neuman, a former patent attorney, is leading an effort at MPEG LA to put together a pool of licenses that would allow companies a one-stop shop for CRISPR IP rights, including the foundational patents and related ones, such as delivery methods into cells. "If UC is able to maintain breadth of their pending claims, it lends support to this notion of patent pooling," she said, although neither a patent pool nor a settlement are options that UC or its licensees have publicly discussed.

However, there's no guarantee that UC will get that genus-type patent upon further review by the USPTO's examiners. Even if it does, that patent could be easily challengeable, according to legal experts.

"That [genus] patent would be pretty weak," said Jacob Sherkow, a professor at the New York Law School who has been closely following the case. "Anyone who wanted to challenge it would be able to go to courts, and the first piece of evidence they would use would be the PTAB decision from last Wednesday. The PTAB judges spent 40-plus pages going out of their way to talk about how Doudna did not sufficiently disclose or enable how to get [CRISPR/Cas9] to work in eukaryotic cells."

That's partially why he thinks UC will appeal the PTAB decision at the US Court of Appeals for the Federal Circuit, even if the chance of success is low. "The risk of shooting themselves in the foot is kind of low," he said. "The upside is potentially huge."

If an appeal fails, UC will be back before the USPTO's examiners trying to salvage what it can from its patent application.

Another option UC, Intellia, and Crispr Therapeutics have floated is using a separate patent application to try to force another confrontation with the Broad, this time directly over the use of CRISPR in eukaryotic cells.

"A new interference can be sought with respect to eukaryotic claims currently pending in a separate UC patent application, once deemed allowable [by the USPTO]," Intellia officials said on a conference call. However, Sherkow noted that the US law on patent interferences says, "No second interference should occur between the same parties on patentably indistinct subject matter. ... If a party that lost the earlier interference is again claiming the same invention as the count, the interfering claims should be rejected."

"There's no second bite at the apple there," he said. "I do not understand where a second interference would potentially come from."

For the time being, the Broad Institute may not be UC's biggest concern, it could be the USPTO. UC must convince the patent examiners that it deserves a broadly applicable

patent on the use of CRISPR/Cas9 in any environment. An examiner might only allow claims with a non-eukaryotic limitation, Sherkow said. "If the UPSTO says that, that is really, really bad news for Berkeley," he said.