

CRISPR Patent Ruling May Push Warring Sides To A Deal

By Ryan Davis

Law360 (September 11, 2018, 10:09 PM EDT) -- The Federal Circuit's decision Monday rejecting the University of California's efforts to secure control over patents on the breakthrough gene-editing system CRISPR in a fight with the Broad Institute leaves an unsettled patent landscape for the technology that could spur the parties to strike a deal, attorneys say.

The appeals court upheld a Patent Trial and Appeal Board ruling that found no overlap between patents sought by UC covering the use of CRISPR in any environment and those issued to Broad that cover its use in plant and animal cells. While UC maintained it invented the technology first and was entitled to the patents issued to Broad, the court disagreed.

The decision leaves companies that wish to use CRISPR in the position of potentially having to license separate patents from both UC and Broad, a research institute associated with Harvard and the Massachusetts Institute of Technology. Since some potential licensees may not want to pay for both sets of patents, it may be in the interest of the warring sides to bury the hatchet and reach a cross-licensing deal.

"It seems to me the landscape will move forward with UC and Broad both having some patent rights," said Brian Nolan of Mayer Brown LLP. "That may mean they need to come up with a way to coexist."

The Federal Circuit's decision did not foreclose future challenges to the validity of either group's patents, so ending the dispute, dividing up the royalties and sharing the technology in a way that allows it to develop may be the best outcome for both of them, said Kevin Noonan of McDonnell Boehnen Hulbert & Berghoff LLP.

"There are lots of potential pitfalls, and it's easier for them to get together, now that they have this decision that gives some finality, and just move on," he said. "I don't think that's necessarily, or at all, a bad thing."

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

The technology has been described as potentially being worth billions of dollars, turning control of the key patents on it into a hotly contested fight in a PTAB proceeding known as an interference, which aims

to determine which of two sets of inventors was the first to come up with something.

A team led by UC's Jennifer Doudna and the University of Vienna's Emmanuelle Charpentier first applied for a patent on using CRISPR in any cellular environment in 2012, based on their experiments with bacteria. A Broad team led by Feng Zhang of MIT applied months later for patents on using CRISPR to edit DNA in plant and animal cells, known as eukaryotic cells. The Broad patents were issued on an expedited basis, while UC's applications remain pending. Attorneys noted it is common for one entity to hold a patent on the broad strokes of a technology and another on a narrower application.

The PTAB determined, and the Federal Circuit agreed, that both claimed inventions were separately patentable and did not interfere with each other. It found that using CRISPR in eukaryotic cells would not be obvious from UC's claims, since a skilled artisan would not reasonably expect that system to work in plant and animal cells.

UC argued that using CRISPR in plant and animal cells was the "natural next step" based on its work and that Broad's patents did not involve any "genuine innovation" beyond what UC had done. The PTAB and the Federal Circuit disagreed, in part based on a statement from Doudna herself that it was not clear the CRISPR system would work in more advanced cells.

If UC had prevailed in the case, it could potentially have possessed the foundational patents for the use of CRISPR. But after the ruling, both UC and Broad will potentially have some patents on the technology, depending on whether UC's patents are ultimately issued. Those who want to use CRISPR technology, particularly in plant and animal cells, will now have to carefully determine which patents to license.

"If potential licensees want to be conservative, they'll license both," Nolan said. "If an organization is a little more risk-tolerant, they may only license the Broad patents."

That leaves "a complex and somewhat uncertain landscape for licensees," said Michael Stramiello of Paul Hastings LLP, who noted that "it seems like the decision brings some closure, but in a lot of ways, it really might not."

Attorneys said they will now be watching to see what happens with UC's pending applications, and whether any patents that ultimately issue are as comprehensive as what the university claims in its application.

"If UC does end up with claims for the use of the CRISPR system in all environments, including eukaryotic environments, you may very well need to approach both entities to cover your bases when using this technology," Stramiello said.

However, the Federal Circuit stressed in the last line of its opinion that its holding "is not a ruling on the validity of either set of claims." That could mean that both the Broad patents, and any patents that might potentially issue to UC, could be subject to re-examinations, post-grant reviews or validity challenges in litigation if the patents are asserted in an infringement case.

UC's applications face a potential risk due to the Federal Circuit's holding that its claims are distinct from Broad's, Noonan said. The patent examiner may conclude that UC didn't possess the ability to use CRISPR in plant and animal cells when it applied for the patent, and reject the applications based on a finding that the claimed invention lacks a proper written description.

In addition, UC argued to the PTAB that Broad's patents are unenforceable due to inequitable conduct because the inventors allegedly withheld information about an essential element of the claimed system with intent to deceive the patent office.

Since the board determined that the two sets of patents do not interfere with each other, it never addressed that issue, but the argument could be raised again in litigation over Broad's patents, and could be a potential "Achilles' heel" for the institute, Noonan said.

"There are land mines for both sides if they get into serious litigation, and at the end of the day, they might not have any patents that are worth anything," he said, which could motivate UC and Broad to reach an agreement.

The ideal end result for potential licensees would be the creation of a patent pool where all the patents needed to work with CRISPR could be licensed in one place. Broad has advocated for that route and said after Monday's decision that institutions should "move beyond litigation" and "work together to ensure wide, open access to this transformative technology."

"The easiest way to deal with it would be some mechanism to bundle the patents all together and license them to companies that need them," but that will require UC and Broad to strike a deal, Nolan said.

A resolution might still be some way off, as UC suggested Monday that it is not ready to give up the fight. The university said it is evaluating its legal options and will continue to seek to prove that it was the actual inventor of the use of CRISPR in plant and animal cells.

Attorneys said further review of the Federal Circuit's decision, either by the en banc court or the U.S. Supreme Court, may be a long shot given the fact-specific nature of the holding, which appears not to involve broad legal principles that might attract the attention of the courts.

At some point, UC and Broad will likely have to arrive at some kind of settlement to allow CRISPR technology to develop, Noonan said.

"Because so much money has been invested on both sides, they're going to have to figure out a way to come to an economic commercial agreement," he said.

The case is Regents of the University of California et al. v. The Broad Institute Inc. et al., case number 2017-1907, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Jill Coffey and Pamela Wilkinson.