

## 'Jury's Still Out' On CRISPR Patent Licensing Pool

By **Matthew Bultman**

*Law360, New York (July 13, 2017, 9:56 PM EDT)* -- The owners of key CRISPR patents have joined discussions to create a worldwide patent licensing pool, an important step in efforts to make the powerful gene-editing technology more widely available, although experts say "the jury's still out" about whether such a pool will be viable.

The Broad Institute of MIT and Harvard, along with joint owners Harvard University, the Massachusetts Institute of Technology and Rockefeller University, announced this week that it had submitted 22 CRISPR-Cas9 patents for consideration in a nonexclusive joint licensing pool.

There are concerns the current licensing landscape could impede development of human therapeutics because it can be complex and difficult to navigate, and the goal with the pool is to create a one-stop shop for companies and researchers to license CRISPR patents.

But there are lingering questions, including to what extent there is an interest from other holders of important CRISPR patents to join the pool. Some also wonder whether companies would be willing to invest in drug development without more exclusivity.

"It's a good idea, but the jury's still out," Gerard Norton of Fox Rothschild LLP said.

CRISPR, an acronym for clustered regularly interspaced short palindromic repeats, represents a major advance in the field of gene editing, allowing scientists to edit DNA in a way that is cheaper and easier to use than previous methods. Norton said the "sky is the limit" in terms of the potential benefits of the technology. Among its applications, the technology could be used to eliminate genetic diseases and combat hunger by producing stronger plants.

In the U.S. alone, there are about 60 patents with claims to CRISPR-Cas9 technology that have been issued to inventors from almost two dozen organizations. That means drug companies and other commercial users in many cases have to apply for licenses with multiple parties.

Advocates of a licensing pool say that grouping foundational CRISPR rights under a single license could help reduce some of the uncertainty in the current landscape and expand the deployment of the groundbreaking technology.

"We look forward to working with others to ensure the widest possible access to all key CRISPR

intellectual property,” Issi Rozen, chief business officer of the Broad Institute, said in a statement.

Among the patents the Broad Institute submitted for consideration to the proposed pool are 12 that were at the center of a closely watched dispute with University of California, Berkeley at the Patent Trial and Appeal Board over who was the first to invent the gene-editing technology.

In February, the PTAB held the Broad Institute’s patents contained distinct subject matter from technology invented by a team of scientists at UC Berkeley and the University of Vienna. The decision allowed the Broad Institute to keep its IP rights despite a pending application from Berkeley. Berkeley has appealed the decision to the Federal Circuit.

Not long after, the European patent office said it intended to grant Berkeley’s application for patents covering the use of CRISPR across prokaryotic and eukaryotic cells and organisms, which includes uses that the PTAB left to the Broad Institute team.

Brian Nolan of Mayer Brown LLP said these are going to be fundamental patents that people will want to use. It’s unclear whether Berkeley or any other group that holds rights in CRISPR have expressed a desire to join the patent pool. While the Broad Institute made its application public, disclosure is not required.

A spokesman for Berkeley declined to comment.

“In order for this to work, I guess ideally you’d want to have the folks in California in on this,” Norton said.

The proposed pool is being coordinated by MPEG LA LLC, an organization based in Denver that operates licensing pools for technologies used in electronics and other areas. The terms of the patent pool and a potential license have not yet been decided.

Attorneys said that will be an interesting aspect to watch. Innovative drug companies, for example, typically want some exclusivity when licensing patent rights, given the high costs associated with development of new drugs and treatments.

“I think that’s a big question right now,” said Tara Nealey of Polsinelli PC. “How can they balance this in a way that provides something of real value to the licensees, but it’s going to be, by definition, nonexclusive?”

While there are examples of patent pools in the biopharmaceutical sector — Roche makes access to its patent portfolio for PCR, a molecular biological research tool, available through licensing programs — they are far less common than in other markets, such as electronics.

Experts attribute this, in large part, to the substantial amount of money that drug companies invest in research and development of new drugs and treatments. Nolan also noted the uncertainty involved with the development of things like human therapeutics.

It remains to be seen how “innovative drug companies will consider a patent pool concept when they can’t obtain the exclusivity they might normally want to get,” he said.

Still, there is a good deal of excitement about the potential for CRISPR, which Nolan said many believe to be “game-changer technology.” He said that could overcome any concern about a lack of exclusivity and help make the patent pool a reality.

“I think at the end of the day, if MPEG can pull in all the necessary patents and get a framework that all the owners of the IP are comfortable with, there’s likely going to be a pool that can be put together that’s beneficial because it will be easy one-stop shopping,” he said.

--Editing by Christine Chun and Aaron Pelc.

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