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Get ready for the first CRISPR patent pool

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When patent licensing organisation MPEG LA [proposed](#) the establishment of a one-stop patent pool for CRISPR-Cas9 back in 2017, its aim was to increase commercial access to the ground-breaking gene-editing technology and reduce the uncertainty shrouding patent licensing in the field. Two years on, the need for such an initiative is stronger than ever.

Last week, the USPTO [initiated an interference](#) which heralds the latest battle in a hard-fought war over fundamental Cas9 IP between the Broad Institute and the University of California. Meanwhile, the proliferation of CRISPR-related rights for inventions across the fields of human therapeutics, agriculture and industrial biotech adds to the complexity of the Cas9 patent landscape.

Against this background, *IAM* caught up with Kristin Neuman, Executive Director for Biotech Licensing at MPEG LA. We discussed the progress being made with the proposed Cas9 patent pool, how the organisation aims overcome barriers to the initiative's success and its plans for other licensing pools in the life sciences.

[MPEG LA](#) is best-known for administering patent pools outside the life sciences, including its MPEG-2 video compression pool. But it recognised

early on the useful role a patent pool could play in the CRISPR space. “Given the importance and value CRISPR will have around the world and in many industries, there were always going to be a lot of patents filed, many of which would overlap,” Neuman says.

The earliest Cas9 patents are very broad, while subsequent filings – for improvements to the technology and specific applications of it – form layers on top of those patents. “As such, there are many areas where companies seeking to use Cas9 technology would need to license patents from several entities,” Neuman explains. This makes the commercial use of CRISPR-Cas9 difficult and potentially risky from an IP perspective.

In April 2017, MPEG LA made an official call for interested CRISPR-Cas9 innovators to work with it on the establishment of a proposed patent pool and to submit their rights for non-exclusive commercial licensing. Several of the most prominent patent holders in the space signed-up, although most elected to remain anonymous.

A notable coup for MPEG LA is the participation of the Broad Institute, which owns several fundamental patents covering the (potentially highly lucrative) use of CRISPR-Cas9 in eukaryotic cells (human, animal and plant cells). Neuman says that the participants had an initial meeting in 2018 and are currently working to draft a licence for the pool.

Ending the CRISPR patent war

The most obvious potential stumbling block for the initiative is the long-standing dispute between the Broad and the University of California – which did not sign up to the scheme – over fundamental Cas9 IP rights. The latter was the first to invent CRISPR-Cas9, though it initially developed and tested the technology in prokaryotic cells (bacterial cells).

UCal has come into conflict with the Broad in a number of jurisdictions – most notably the US, where in a high-profile interference it argued that the East Coast entity’s patents for eukaryotic Cas9 uses was obvious in the light of its application for Cas9 uses across all cell types.

UCal’s absence is a significant limitation for any Cas9 patent pool, substantially diminishing its commercial value for licence seekers. There was a glimmer of hope that the two parties and their affiliates might reach a settlement when the Court of Appeal for the Federal Circuit [upheld](#) an earlier Patent Trial and Appeal Board finding that the Broad Institute’s rights cover separately patentable inventions that do not interfere with UCal’s wider claims. But last week’s decision by the USPTO to initiate a second interference to find

out which of the two first invented eukaryotic uses of CRISPR-Cas9 suggests that UC and the Broad will continue to fight it out over their respective rights for several years.

Neuman, though, does not regard this as an insurmountable barrier for the proposed pool. “Of course, we would like to have as many – or indeed all – of the important Cas9 patent holders in the pool at the time it goes to market,” she says. “But we are prepared to go ahead even if we do not have all of the important patents in the pool.”

The pool would still offer significant value to industry players without the UC’s patents, Neuman argues: “It should be remembered that the Broad and the UC are not the only important patent owners. Without the UC, the pool would offer a bundle of rights that I would expect to be very popular with potential licensees.” Especially when patent enforcement increases, many companies currently sitting on the side-lines will need to take out licences.

And initial successes could make the patent pool more attractive to potential new licensors. “The door does not close when the pool goes to market,” she states. “Patent pools typically start small and, when they become popular with industry, other patent holders find it in their interests to join the pool...I think getting started is more important than waiting for all of the pieces to be put together.”

The new interference – which potentially jeopardises the Broad’s key Cas9 US patents – could have an impact on ongoing discussions, Neuman concedes. But she argues that a pool can go forward on a parallel track with any legal proceedings about who was first to invent: “If a patent is found to be invalid, it comes out of the pool at that point and remuneration to the rights holder is adjusted accordingly.” A winner-takes-all outcome is unlikely, she adds; and any settlement in which both parties retained fundamental rights would make involvement in the pool attractive.

Moving to a non-exclusive model

MPEG LA must also overcome the challenges of creating a patent pool in a space where they are almost unknown and exclusive patent licensing is the norm. “Patent pools have been underutilised in biotechnology, especially where you have platform technologies which may one day move towards standardisation,” Neuman claims. “Now we are living in the golden age of biotech thanks to the output of the human genome project. I would hate to see the technology development being held in check because of traditional forms of patent monetisation. This traditionally means licensing exclusively to one or a handful of players.”

She continues: “If the patent holders in these spaces can get on the same page in terms of offering non-exclusive licences, we will see swifter development of these technologies and there will be plenty to go around for all the patent holders.”

Non-exclusive CRISPR-Cas9 patent licensing is a highly appealing model for uses in sectors like industrial biotech and agriculture, where the technology is being widely used, Neuman argues: “Human therapeutics poses more of a challenge, because of the high cost of developing and gaining regulatory approval for new treatments.”

But even in the field of human therapeutics, a patent pool should be achievable: “It would provide an opportunity for owners of broad enabling patents – which are not target focused – to pool their rights. This would allow more companies to become involved in the development of CRISPR therapeutics, while holding on to their own patents for target specific inventions. This is a new idea, but I believe it could work.”

However, a patent pool focussing on CRISPR uses outside human therapeutics may get off the ground first. “The other uses are the low-hanging fruit, so it is quite possible that a pool may go forward addressing some of these other areas first, before we get to human therapeutics,” Neuman says.

Looking beyond Cas9

While CRISPR-Cas9 is the best-known CRISPR gene-editing system – and the one whose patent landscape has been most discussed – other systems have been developed and are the subject of an increasing number of patent applications. For example, Cas12a (Cpf1), Cas13 and Cas12 are being widely used in industry.

And Neuman is keen to stress that MPEG LA is currently considering establishing a patent pool for other CRISPR systems. “I think it will be very important for the pool to expand beyond CRISPR-Cas9,” she comments. “Some of the other Class 2 CRISPR-Cas systems that use a single sector protein, such as Cpf1, are being used widely in the field. Some of them have advantages over Cas9.”

Many companies that would like to have a pool license to Cas9, Neuman says, would also like to have access to other systems too. “That way they can use the whole toolbox,” she states. But it is not clear yet whether other CRISPR systems would need to have their own patent pool(s) or whether these systems could be incorporated into the currently proposed patent pool.

MPEG LA also sees opportunities for patent pooling for a number of biotech technologies. “CRISPR is our main patent pool development project, but we have our eye on other areas where the technology is highly important to the market,” Neuman notes. “Areas that look like they are moving one day towards standardisation are of great interest: regenerative medicine, for example, as well as stem cell technologies/cell therapies and delivery technologies for new drug modalities.”

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