

## UCal granted wide-ranging CRISPR rights, but future patent landscape remains uncertain

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The US patent application at the heart of the University of California's much-watched interference proceeding against the Broad Institute has finally been granted, giving the university extensive rights to exclude others from using CRISPR-Cas9 gene-editing technology without its say-so. The breadth of the patent's claims has come as a surprise to some experts who believed the application would face difficulties following the west-coast institution's recent defeat at the Federal Circuit and the grant of other core CRISPR patents.

The grant means that organisations seeking to commercialise CRISPR-Cas9 in potentially lucrative fields such as human therapeutics and agriculture will need to seek a licence from the University of California, as well as the Broad Institute. But with doubts remaining about the patent's validity, there is a high chance it will be challenged, meaning that the future of the US CRISPR-Cas9 patent landscape remains uncertain.

Last week's granting of patent (10,266,850) follows a bitterly-fought, high-profile dispute between its owners – the University of California, Emmanuel Charpentier and the University of Vienna – and fellow CRISPR innovators the Broad Institute, Harvard University and the Massachusetts Institute of Technology.

Having developed foundational CRISPR-Cas9 gene-editing methods (though it only tested them in bacterial cells), the University of California group filed for the patent in 2012, claiming uses of CRISPR-Cas9 in all cell types. The Broad Institute and its associates subsequently applied for a patent claiming the use of CRISPR-Cas9 in eukaryotic cells (human, animal and plant cells). After the Broad's patent was granted by expedited process, the University of California sought to invalidate the right, arguing that the claimed invention was obvious in the light of its discovery and therefore interfered with its own pending application.

The University of California was unsuccessful: the Patent Trial and Appeal Board dismissed the interference process in February 2017, holding that Massachusetts-based organisation's patent claims a distinct and separately patentable innovation. It was a decision upheld in a much-anticipated Federal Circuit ruling in September 2018.

Reaffirming the Broad Institute's position in the US CRISPR-Cas9 patent landscape, the CAFC decision was argued by some expert commentators to be even more of a blow to the University of California than it appeared. New York Law School Professor Jacob S Sherkow, a prominent thought-leader on CRISPR patent issues, told IAM that the west coast organisation's application was unlikely to be granted with claims to Cas9 use in all cells. Instead, it could be limited to "incredibly narrow" claims for use in bacterial cells – claims that would not cover most of the commercially-important applications of the technology.

This, Sherkow stated, was because the USPTO was likely to reopen prosecution of the patent, and would find two major obstacles in the way of the applicant's fundamental claims:

- The PTAB's ruling, which stated that the application did not sufficiently describe or enable eukaryotic work.
- Virginijus Šikšnys had in the meantime been granted a patent (claiming an earlier prior date) disclosing all guide RNA (single or otherwise) using a ribonucleic protein Cas9 complex, which seemed to overlap with the University of California's claims to all single guide RNA applications of Cas9.

However, the USPTO observed that the guide RNA claimed in the Šikšnys patent is not covalently linked, whereas the guide RNA in the University of California patent is covalently linked, concluding that there was no obviousness problem.

Responding to news of the grant, Sherkow said that he was surprised that the office did not reopen the examination and claimed that its reasons for not doing so were "weak". But, he pointed out, the grant does not resolve the issue with legal finality. "I think it is likely that the patent will be challenged, either at the patent office or in federal court," he said.

Sherkow's view is echoed by [Daniel Lim](#) of Kirkland & Ellis, also a leading commentator on CRISPR patent issues: "In some ways, the grant of the patent signifies not the end of the war, but the beginning of a new battle. Assuming the patent is challenged, depending on the procedure adopted, it could still be years before various appeals run their course and we have certainty in respect of the landscape of foundational CRISPR-Cas9 patents."

It will be particularly interesting to see whether any organisation files for a post-grant review within the nine-month cut off period, Sherkow states: "*Inter partes* review is limited to claims of anticipation and obviousness, whereas any invalidation reason on the books can be asserted in post-grant review. A lot of the PTAB's decision to declare no interference was grounded in argument about enablement and the patent's lack of written description, so post-grant review would be substantially the better vehicle to challenge the patent."

Given the prospect of such challenges, it is not clear how aggressively the University of California and its partners will look for new potential licensees. But given the rapid development of CRISPR-Cas9 technology, there is bound to be a growing desire among companies in this space for greater certainty around the patent licensing environment. "This is the moment when it makes sense for the sides to settle," says Sherkow. "Rather than the Broad Institute or its surrogates ploughing millions more dollars into challenging the University of California's patent, at some point it makes sense to come to an agreement. But there is nothing so far to suggest this is forthcoming."