



24 Jul
2019

CRISPR patent pool will do little to quash licensing uncertainties

Two major rights holders in the CRISPR space have joined forces to establish a shared framework for the non-exclusive licensing of their intellectual property. MilliporeSigma – Merck KGaA's North American life sciences business – and the Broad Institute, along with its partners MIT and Harvard University, argue that the new patent pool will simplify and widen access to key CRISPR technology.

But, although it is a welcome collaboration effort and may prove attractive to some research organisations, the framework solves few of the big problems facing potential CRISPR patent licensees at present. Excluding licences for human therapeutic applications and agricultural uses, the patent pool also shows little sign of bringing the University of California, Berkeley – a major CRISPR-Cas9 rights holder, which is embroiled in a long-term dispute with the Broad – to the table.

[Announced at the end of last week](#), the agreement lays the ground for organisations to gain a non-exclusive licence to both companies' CRISPR intellectual property – as well as to patents co-owned by the Broad and its partners – for uses in commercial research and in research tools and kits. The rights will be available royalty-free to non-profit academic institutions and governmental agencies, while profit-seeking organisations will be charged a fee. Both sets of patents will be licensed through the Broad; and all parties will retain the right to issue licences independently.

The initiative is launched against a background of uncertainty and complexity regarding patent rights to CRISPR, the revolutionary gene-editing technology which looks set to have a range of healthcare, scientific, industrial and agricultural applications. The grant of large numbers of (sometimes overlapping) CRISPR-related rights has created an IP landscape that is difficult to navigate for would-be licensees; and a [hard-fought patent dispute](#) between UC Berkeley and the Broad has caused serious fractures in that terrain.

As such, the new framework is a welcome effort to streamline access to CRISPR technology. “CRISPR is complex to say the least,” MilliporeSigma’s head of IP strategies for gene-editing and novel modalities, Jon Kratochvil, told *IAM*. “We are trying to make it possible for people to use CRISPR technologies without the fear of people coming after them. We do not want them to have to shop around all the various potential licensors that hold CRISPR rights. We are trying to create a one-stop shop, at least for Broad and MilliporeSigma patents.”

And there are strong synergies between the two organisations’ patent portfolios. MilliporeSigma owns important rights to the use of CRISPR-Cas9, including several covering the use of Cas9 to insert a donor sequence in a chromosomal sequence of a eukaryotic cell. (The rest of its 20 patents claim a new gene-editing technique known as proxy-CRISPR, as well as the cleavage of chromosomal sequences using Dual Nickases.) The Broad owns the fundamental rights to the application of CRISPR-Cas9 in eukaryotic cells (human, animal and plant cells) in several jurisdictions. As such, those seeking to license MilliporeSigma’s rights are likely to also need a patent agreement with the Broad.

The two portfolios are also complementary in geographical terms. The Broad has a strong position in the US, where its plethora of rights have survived an interference proceeding initiated by rival innovator UC Berkeley. But it has suffered major setbacks in Europe, where a key patent was [cancelled by the EPO last year](#). MilliporeSigma, on the other hand, has been granted a slew of important patents in Europe, as well as Israel, South Korea, China and Japan. It has struggled in the US, however, where patent applications for Cas9 integration have been rejected as obvious in the light of UC Berkeley’s fundamental patent to Cas9 use across all cell types.

But the attractiveness of a joint licence from the two organisations will depend somewhat on whether the royalty rate being sought represents a discount on the price of taking out separate licences from each entity. And the initiative’s

value to the market is limited by the fact that it makes no new rights available for non-exclusive licensing.

Other (very important) commercial CRISPR uses, such as in human therapeutics and diagnostics, are excluded from the pool. “Those are not on the table, partly because the Broad already has an exclusive arrangement with another company, so they are less able to license these rights than we are,” says Kratochvil. Those seeking to make use of the Broad’s Cas9 rights must seek an exclusive licence from its surrogate, Editas Medicine.

And the framework can have only limited value as a one-stop shop, as long as other major rights holders – most notably UC Berkeley – do not pool their patents. As things stand, those seeking to use MilliporeSigma and the Broad’s patents also need a licence from the Californian entity. But it too has granted exclusive licences for human therapeutics – through its surrogates Caribou Biosciences and Intellia Therapeutics – meaning that both organisations’ licensees face uncertainty over their right to operate.

The Merck subsidiary and its partner hope that more organisations will join them in pooling CRISPR patents, at least for non-human therapeutic uses. Both organisations have been among those in discussions about [the potential creation of CRISPR patent pool](#) to be administered by licensing organisation MPEG LA. “Thus far, UC Berkeley has rejected overtures to pool their patents with us and the Broad, and to enter into these or similar talks,” said MilliporeSigma’s senior patent counsel Benjamin Sodey.

With another battle in the patent war between the Broad and its Californian rival in the offing as the result of a [new interference](#) – in which MilliporeSigma is also [trying to become involved](#) – it seems unlikely that all the key rights holders will reach a joint licensing agreement any time soon.

But if such an agreement is reached in the long term, the involvement of a non-aligned licensing organisation – whether that be MPEG LA or some other entity – is likely to be important in reconciling the conflicting parties. Fortunately, in the view of Benjamin Sodey, “nothing about the Broad/Sigma patent pool forecloses a future opportunity with MPEG LA”.

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