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Clearing a way through the CRISPR patent jungle

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There may be a path through the CRISPR patent jungle, but there are many obstacles still in the way, say European academics Timo Minssen, Esther van Zimmeren and Jakob Wested.

The revocation of the Broad Institute's patent [EP2771468](#), reported and discussed [here](#), marks the latest major development in a series of patent battles over the revolutionary and highly lucrative CRISPR/Cas 9 technology (and other gene-editing technologies) in the [US](#) and [Europe](#).

While this is the first European Patent Office (EPO) decision in an opposition procedure concerning the Broad patent portfolio, the outcome may have implications for other related patents as the rationale for the revocation reflects a larger, systemic challenge based on the different rules regarding priority claims in different jurisdictions.

This is a rather complex legal issue, but with potentially important implications in practice that require patent applicants to be very careful about when they assign their patent application. The Broad Institute has already made clear that it intends to [file an appeal](#) at the EPO, which again highlights the commercial relevance of the CRISPR patent concerned.

At present, there exist [more than 1,700 applications](#) for CRISPR patent families, ie, sets of patent applications covering the same or similar technical content that have been filed in different jurisdictions. Every month around [100 new families are published](#). Hence, researchers and companies looking to commercialise CRISPR/Cas9 gene-editing and comparable techniques will probably continue to face a very complex, highly fragmented patent landscape for the next decades.

Typically, patent claims will become narrower and may be harder to enforce. This may prompt some inventors to rely on trade secret protection or on specific business models that could safeguard their competitive advantage rather than on patent protection.

The EPO decision stresses the importance of harmonising material and procedural patent rules in order to simplify the international protection of valuable patent portfolios and to create legal certainty for patents practitioners, industry, scientists and society at large.

Whereas the EPO CRISPR decision focuses on priority claims, co-inventorship and assignments, the need for harmonisation obviously goes beyond this essential, but very specific topic. It also entails the need to clarify the scope of research and experimental use exemptions, and the legal concept of co-inventorship, as well as the demand for some more extensive guidance on [patent pledges](#), [ethical and joined licensing initiatives](#) and the creation of [user-generated solutions](#).

In a series of short contributions we will discuss some of these notions, starting with user-generated licensing models:

Potential of user-generated mechanisms

[Various](#) scholars and policymakers, and major companies, as well as national and international advisory organs have recognised the role patent pools and clearinghouses could play in dealing with fragmented patent landscapes in the health and life science sector.

Typically, pools and clearinghouses are initiated by the “user community” (hence the term “[user-generated mechanisms](#)”) and offer a one-stop shop licensing mechanism that enable access to and use of the patented technology in exchange for a reasonable royalty. However, while consumer electronics and telecommunications pools are common, life science pools, such as the [Golden Rice](#) and the [Medicines Patent Pool](#), are rather uncommon and often not profit-driven.

One reason for this may be the prevalence of exclusive patent licensing in the health and life science sector as well as the nature of most biomedical inventions, that do not involve the interoperability and compatibility required by consumer electronic and telecommunication products.

A particularly noteworthy development in the CRISPR context is [MPEG LA's announcement in December 2016](#) that it was examining the CRISPR landscape to identify essential patents that could be bundled together in licensing pools. MPEG LA is one of the main operators of patent pools, providing one-stop licences for sets of standard-related patents in the consumer electronics and telecommunications sectors.

It has been exploring opportunities for pools and similar management models, such as clearinghouses, in the biotechnology field for several years but with limited success, although in [July 2017](#), the Broad Institute, Harvard University, the Massachusetts Institute of Technology and Rockefeller University announced that they had submitted

22 CRISPR/Cas9 patents (including key patents involved in the aforementioned patent disputes) for consideration in a patent pool.

As CRISPR is a platform technology that can be applied to many different sectors (eg, industrial biotechnology, therapeutics, diagnostics and agriculture), a patent pool holds great potential and could enable a broader dissemination of the technology. Without a one-stop shop mechanism, freedom to operate (FTO) in the CRISPR context will not be possible without multiple licences that may result in royalty stacking and burdensome reporting and diligence obligations.

A voluntary pool or clearinghouse model may give rise to [a robust commercial ecosystem for CRISPR](#) and could include special provisions for royalty-free research use by academics (taking away the uncertainty of the current national research exemptions) and provisions taking into account ethical concerns regarding particular CRISPR applications. To the authors' knowledge, discussions are ongoing.

These initiatives align well with the [criticism of the CRISPR licensing strategies](#) adopted by the main stakeholders Broad Institute and UC Berkeley. According to some authors, the complex licensing structure consisting of surrogate companies with exclusive licences for broad fields of use for therapeutic applications would probably create a bottleneck for the use of CRISPR technology in developing useful therapeutics.

A one-stop shop could create the transparency which is desirable for foundational patents. It would facilitate non-exclusive licensing and wide dissemination of the technology, which ultimately should be the main aim for publicly-funded research.

However, to properly assess the potential and chances of success, these initiatives need to be put into a broader perspective, taking into account the inherent unpredictability of biological sciences and evaluating how this initiative fits within the unique culture, applications and stakeholders within the life sciences, and within the context of gene-editing technologies in particular.

Lessons and challenges

A lot of [legal and economic research](#) has been carried out analysing patent pools and clearinghouse mechanisms. [Four key lessons](#) that can be derived from this stream of literature and from an analysis of past pools and clearinghouses relate to the governance of such mechanisms.

1. Pools and clearinghouses are voluntary mechanisms that require the involvement of many relevant stakeholders. As the stakeholders within the CRISPR context are very heterogeneous, it will be rather complex to satisfy this heterogeneous group with a wide variety of interests and values and to propose a licensing scheme that is satisfactory for all key patent owners and potential licensees.

Actually, pools and clearinghouses are "[two-sided](#)" mechanisms and they function as platforms where two sets of "agents"—patent owners and licensees—interact. Getting both sides on board is fundamental for the development and success of such platforms. The engagement of both sides will also affect the design and functioning of the platform. In some cases, stakeholders may be acting on both sides of the platform, as holders of relevant IP assets and as licensees.

The interests of such two-sided actors will naturally differ from the interests of a university or a small or medium-sized enterprise or individual inventor, which is only licensing to the platform and does not need access to its pooled IP.

2. The usual governance of patent pools established since the 1990s is [heavily reliant on the standardisation context](#) for the setting up of a stable pool. Patent owners that are involved in the standardisation context often

recognise the importance of a patent pool for clearing the rights of the standard-essential patents.

Through its [Librassay](#) service, MPEG LA has gathered experience with efforts to establish a one-stop shop mechanism for genetic diagnostics outside of the standardisation context. Yet, apart from the challenges caused by the US Supreme Court's *Myriad*, *Mayo* and *Alice* decisions, Librassay also encountered difficulties in getting the support from key patent owners from the private sector, which was probably partially related to the absence of interoperability standards in that sector to stimulate coordination and drive the creation of the pool.

3. We would like to refine the statement that pools and clearinghouses act as a true one-stop shop. In any case, market players remain responsible for safeguarding that they are not infringing another party's IP. When they engage in a new field of R&D, it remains vital to carry out a FTO analysis to determine the patent landscape. Pools and clearinghouses may facilitate the licensing process, prevent royalty stacking and decrease the transaction costs involved in getting the licences, but generally, they will not provide any FTO guarantee or accept liability charges for IP beyond the scope of their portfolio.
4. Patent pools are subject to competition law. Historically, pools attracted a lot of attention from competition authorities in the US in view of the risk that they would be used as a cover for a cartel. Due to concerns about the anti-competitive effects of pools, competition authorities in many jurisdictions (including the [US](#) and the [EU](#)) have provided guidance and imposed some restrictions on the design of the pools that have been emerging since the 1990s.

[Important considerations](#) relate to the fact that participation in the pool as a licensor or licensee should be open to all (see open [call MPEG LA for the CRISPR pool](#)); only complementary patented technologies can be included in the pool and substitute technologies should be barred; independent experts should be involved in the creation and operation of the patent pool (eg, for the assessment of the complementary nature of the patents that will be covered by the pool); and safeguards against the exchange of sensitive information should be in place.

Pool characteristics

Even though there is [some scope for differentiation](#) of the particular features of pools, in practice many pools follow the model of the MPEG-2 pool, the pioneer pool model that has paved the way for the modern patent pools. The MPEG-2 pool is administered by MPEG LA and, hence, for the CRISPR pool, MPEG LA is very well-positioned to explore potential anti-competitive effects for the business model that will ultimately be chosen.

This leaves MPEG LA with a [tricky task](#) in finding the right balance for establishing the CRISPR pool. The commitment from the Broad Institute is promising. However, UC Berkeley must also join in order for the pool to be commercially successful as it is holding the patents to the underlying technology. These two key players have been involved in patent litigation and might not be so eager to step into a joint licensing scheme.

Moreover, the selection of other complementary patents will require some [difficult choices](#): if the number of participating patent owners is too low, the pool will fail to achieve its aim of reducing transaction costs and potential licensees will therefore be less interested in licensing from the pool (see [two-sided platform dynamics](#)). On the other hand, if a large number of patent owners would be involved they may be concerned about the returns they will achieve by licensing through the pool and this might create an incentive for certain patent owners to stay out of the pool and to free-ride on the investments of the pool in making the CRISPR patent landscape more transparent.

Conclusions

The existence of many businesses buzzing around the CRISPR genome-editing technology reflects the potential of CRISPR but is also a signifier of the maturation of biotechnology from tinkering and exploration in the lab to a versatile

technology platform. The fierce patent fights observed around the CRISPR technology are not just about getting the next blockbuster to the market. It is a fight about control of the biotechnology of the 21st century and getting a bit of that action.

We have touched upon one of the solution models that might contribute to mitigating some of the negative effects of a complex and fragmented patent landscape. However, clearing a path through the CRISPR/Cas9 patent jungle will not be an easy task since many predators, obstacles and persisting problems are lurking in the shadows. More research is needed to align the potential of user-generated licensing mechanisms with the realities of life science innovation.

The task is as formidable as it is important, since it is clear that an environment with much uncertainty about the patent landscape and extensive litigation will distort the innovation dynamics. It favours large players, as more resources have to be allocated to litigation rather than innovation. New products may be delayed in entering the market or altogether abandoned due to legal risks to the disadvantage of public health and the broader socioeconomy.

At the same time, it is important that radical innovators have a strong incentive and are generally encouraged and rewarded for developing groundbreaking technologies to the benefit of society. If all patent criteria are met this should certainly also entail the possibility to obtain patents with an appropriate scope of protection. Yet, it is clear that the development of biotechnology from product to platform technology calls for a recalibration of the mechanisms governing such technologies.

Another issue raised by the CRISPR case discussed above is the uncertainty of the concept of co-inventorship in a research environment where researchers are highly mobile, the market is very fluid and a lot of collaboration and exchange is taking place. This will be the topic of our second article of this series.

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