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Key issues for senior life sciences executives

Patent pools in the life sciences: a potential facilitator of CRISPR commercialisation

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Patent pools are agreements between two or more patent owners to aggregate a number of patents and then license these to each other or third parties. If well structured, patent pools can benefit patent owners, third parties and the general public by providing efficient and affordable access to the licensed technology, slashing transactional costs, mitigating investment risks and ultimately encouraging further innovation and competition.

Patent pools also offer a solution to impenetrable webs of overlapping patent rights – so-called 'patent thickets'. These result in different patent owners inevitably infringing on each other's patents when using their own technology. Such blocking patents often lead to deadlock situations which stifle innovation, side-track valuable resources to excessive litigation battles and cause production uncertainty. After entering into a patent pool, the patent owners mutually license the technology, thereby avoiding unlawful infringement and associated risks. This is particularly relevant in the research and innovation-intensive life sciences sector. Here, breakthrough inventions are often made in parallel in competing labs, resulting in overlapping intellectual property. Also, it is more common for life sciences patent portfolios to contain many patents on similar technologies, thereby increasing the risk of patent thickets and resulting infringement.

The most renowned patent pool success story is MPEG LA's pool on the MPEG-2 digital video compression technology, which eventually helped that technology to become ubiquitous. However, this could have played out differently were it not for the widespread, non-discriminatory one-stop licensing agreements offered by the patent pool. In the dawning of the MPEG 2 patent pool, countless aspects of the MPEG standards were already protected by an insurmountable number of patents. To comply with the MPEG-2 standard alone, for example, a user would have had to secure licences from a multitude of patent owners. The resulting royalty-stacking effects and immense transactional costs deterred potential users from even considering pre-contractual discussions, let alone investing in the development and application of the technology.

The forward thinkers of the industry realised that without cooperation, market accessibility to the technology would be stifled and extensive litigation costs perpetuated. Instead of maintaining the status quo, they teamed up with a third-party facilitator, MPEG LA, in an initiative to offer one-stop packaged licences on all patents necessary to comply with the standard (ie, standard-essential patents). The MPEG 2 patent pool turned out to make MPEG-2 the most successful technology standard in consumer electronics history.

Implications for life sciences sector

Thinking about the underlying patent thickets that led to the inception of the MPEG 2 patent pool, it is difficult not to draw parallels with the current situation in the life sciences sector, where many complain that existing patent thickets stifle rather than promote innovation. Just as the large number of patent owners in the MPEG-2 technology barricaded market access, the enormous number of patents protecting inventions in the life sciences sector presents similar difficulties. For example, when seeking to develop a personalised medicine, companies must secure licences on various gene segments, mutations, pathways and diagnostic

tools, as well as production and formulation technology – which places a large burden on newcomers.

This has become particularly complicated in the area of genomic engineering. One of the most exciting new technology platforms, with the potential to revolutionise the life sciences industry, is CRISPR gene editing. Here, the discovery of the bacteria-derived RNA-programmable nuclease Cas9 led to the creation of a genome editing tool that allows researchers to accurately target pre-specified (genomic) DNA sequences. CRISPR is highly versatile and much faster, cheaper, more accurate and reliable than other genomic editing tools.

As attractive as this technology is for commercialisation, it is just as well protected by a web of overlapping patents and patent applications owned by different universities that protect the very core of the technology. In addition, an ever-increasing number of follow-up patent applications cover diverse improvements and applications of the technology. This begs the question: could a patent pool be the answer to ensure that this promising technology reaches its full potential?

Before tackling this question, a brief review of other cooperative patent initiatives in the life sciences sector is helpful.

Past and current life sciences patent pools and their success

Patent pools in the life sciences sector are much less common than those in consumer electronics, with many biotech companies following the pharmaceutical model of exclusive patent licensing. Most examples from the life sciences sector are non-profit initiatives.

The Golden Rice pool, for example, concerned genetically engineered rice grains expressing beta-carotene and negotiated a free licence package with public and private entities to be offered to developing countries in order to counteract malnutrition.

Although not a formal patent pool, the SNP Consortium was formed in 1999 by a group of 10 major pharmaceutical companies and the United Kingdom's Wellcome Trust, which determined that in order to advance research in the field using the valuable tool of single nucleotide polymorphisms (SNPs), they would have to acquire rights or secure licences on thousands of SNPs. Instead of opting to patent the technology, the consortium was founded with the goal of placing a human genome-wide SNP map in the public domain. Today, thousands of SNPs are publicly available, encouraging collaborative efforts to progress medical and basic genomic research.

The initiative for a severe acute respiratory syndrome (SARS) vaccine patent pool initiative began in 2004 when, following an outbreak of SARS in late 2002, the World Health Organisation SARS Consultation Group introduced a strategy to circumvent potential IP-related issues that might delay the competing institutes from efficiently finding and commercialising a SARS vaccine.

In 2010 UNITAID founded the Medicines Patent Pool (MPP) to improve access to HIV, viral hepatitis C and tuberculosis treatments in developing countries. MPP's success is also based on its notable collaboration with Gilead Sciences – a major pharmaceutical player in the field of anti-retroviral medicine – which placed part of its intellectual property into the pool and thereby at the service of global public health.

One of the more recent and few commercial life sciences patent pools is Librassay®, a private sector solution launched in 2012 by the world's leading packager of patent pools, MPEG LA. By adapting its business strategy to the life sciences market, MPEG LA pooled patent rights from leading research institutions, providing one-stop licence packages for molecular diagnostic testing and personalised medicine.

On December 6 2016 MPEG LA announced an initiative to create a CRISPR patent pool based on a market need to create an efficient one-stop licence for this breakthrough technology. The public call for patents to be included in this CRISPR-Cas9 Joint Licensing Platform followed on April 25 2017. Given MPEG LA's past successes, unprecedented experience and leadership in the conception and

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management of patent pools, the prospects are favourable that this current initiative will resonate with the CRISPR community.

This is also because the owners of the fundamental and follow-up intellectual property in the CRISPR field, as well as potential users of the technology, are likely already weary of the sweeping patent battle that is currently underway on a global scale. The parties controlling the fundamental CRISPR patent rights – the Broad Institute and the University of California – are fiercely fighting over priority in a US Patent and Trademark Office interference proceeding and patentability and inventorship issues in numerous parallel European Patent Office opposition proceedings. The unusually high number of up to nine (anonymous) opponents in the latter proceedings underscores the importance of the technology to the field and the fear of potentially blocking patents.

On February 15 2017 the US Patent Trial and Appeal Board ruled in favour of the Broad Institute in the first-instance proceedings of this high-stakes battle over who will control the valuable intellectual property linked to CRISPR. Kristin Neuman, executive director for biotechnology licensing at MPEG LA, foresees that this decision may open a window of opportunity for settlement talks, also increasing the willingness to enter into a comprehensive CRISPR patent pool.

Even in light of the uncertainties caused by the ongoing patent dispute, it seems that not only is the CRISPR/Cas9 technology already becoming a staple of biotech and genetic laboratories, but its commercialisation is also underway. Both public and private companies have entered the arena, securing large sums from investors and licences from the various IP owners. For example, Editas was founded in 2013, went public in February 2016 and has already secured over $210 million in venture capital financing, making it a promising company in the arena. Founded in 2014, Caribou Biosciences is backed by an $11 million investment from Atlas Venture and raised a further $30 million in a Series B round in May 2016. In November 2014 Caribou and Atlas Ventures founded Intellia Therapeutics to pursue therapeutic applications of CRISPR. Intellia went public in May 2016 and has issued exclusive therapeutic field-of-use licences to Novartis and Regeneron. Additionally, Caribou granted exclusive agriculture and livestock field-of-use licences to Dupont and Genus, respectively. CRISPR Therapeutics – which was founded in 2014 and went public in October 2016 – has secured a $25 million investment from Versant, a $105 million deal with Vertex and recently a whopping $335 million joint venture deal with Bayer Healthcare called Casebia Therapeutics, thus making it another important player in the arena.

It is clear from the densifying patent landscape and surging commercialisation that the CRISPR/Cas9 technology is already on the way to becoming a standard in genomic engineering. In order to ensure that current and future players maintain a competitive market, where this technology can actually be translated into and commercialised in the form of medical and agricultural applications, the need for collaboration seems inevitable. Whether this will be in the form of a patent pool remains unclear, but it seems to be the most sensible option – and maybe the most attractive one yet for a proposed patent pool in the life sciences sector.

In such a fast-moving area, where large financial investments are at stake, it might be more advisable for an independent enterprise to coordinate the licensing agreements in order to provide an objective, balanced and fair proposal to all parties involved and avoid antitrust conflicts.

Potential antitrust issues connected to patent pools

A patent by its nature is seen by some as inherently anti-competitive: after all, it grants the

owner the right to exclude others from producing, selling or using the patented goods. The same is sometimes said of patent pools. However, it is well established that patents foster innovation and private investment needed to commercialise innovation. That said, patent rights are not without limits and are kept in check by antitrust laws and guidelines requiring the maintenance of a competitive market.

While further aggregation of anti-competitive IP rights may at first seem to conflict with antitrust laws, patent pools actually offer an attractive option to promote – rather than stifle – innovation. Many patent pools have been scrutinised and cleared by competition authorities which find no violation of antitrust rules. For example, the aforementioned MPEG 2 pool was reviewed and found pro-competitive by the US Department of Justice based on four criteria:

- The covered patents were essential;
- The patents were complementary (which follows from the first point);
- The structure of the pool was such to prohibit exchange of sensitive information; and
- The licensing agreement did not discourage the development of competing products.

Both the United States and the European Commission have issued guidelines on IP rights and how to avoid anti-competitive behaviour when setting up patent pools, providing general support for the competitive nature that patent pools can embody, albeit under certain conditions.

Recipe for a successful patent pool

To ensure the success of patent pools in the life sciences sector, the following guidelines should be followed to avoid anti-competitive behaviour and continue to promote innovation.

Modern patent pools take precautions to avoid antitrust pitfalls. Arguably, the most critical of these is the choice of patents that the pool comprises. In particular, a patent pool will ideally be composed of essential patents, which are

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patents that read on a certain technical standard or are necessary based on consumer or public demand. Non-essential patents, on the other hand, are alternatives to or substitutes for the essential technology. By selecting only essential patents, a patent pool can ensure that the licensed technology will offer patents that are not in direct competition with one another and thus largely avoid anti-competitive behaviour.

Standards are rarely encountered in the life sciences sector, although they are commonplace in the electronics space. One of the major conceptual challenges for setting up a successful life sciences patent pool will be to create a good reference model that can substitute for the standard in known patent pools.

Another critical factor to take into account is the licensing fee. Licensees can be assured of a fair price without discriminatory restriction of access, while patent owners benefit from the 'essential' label and allotted royalties.

While patent pools can in principle be organised by the patent owners or enterprises themselves, it is more common and advisable today for patent pools to engage an independent licensing entity to organise and manage the licence packages. This entity ensures an unbiased selection of potential pool members and serves as a one-stop shop for flexible licence packages at reduced transaction costs. It also regularly reassesses the essentiality of the patents in the pool, ensuring competitive behaviour even in dynamic markets.

Looking at the recent MPEG LA initiative in the making for CRISPR, it seems that it could become a beacon for package licensing and innovation in the biotech industry.

Outlook

After the start of the Human Genome Project and the onset of personalised medicine, genetic engineering through cutting-edge technologies such as CRISPR/Cas today has a realistic chance of finally curing genetic diseases and cancer. As the field races to find the secrets to health, it seems that commercialisation is struggling to keep up with innovation. This is due in part to seemingly unsurmountable patent thickets in the life sciences sector.

In a recent *Science* article, Jorge Contreras and Jacob Sherkow criticise potential bottlenecks in CRISPR access, innovation and commercialisation due to the current restrictive licensing strategy of the CRISPR foundational IP holders (*Science* vol 355 issue 6326, pp 698-700).

In a case such as this – where the promising and groundbreaking CRISPR technology rests on overlapping patent rights and potentially restrictive licensing strategies – it seems that a patent pool may be just what the doctor ordered. As such, could adapting the patent pooling strategies that helped the digital age to become what it is today finally help to usher in the genetic revolution that has been knocking on our door for the better part of a decade? It seems worth a try. *iam*

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