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## BIOTECH BUZZ

### Technology Transfer & Licensing Subcommittee

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#### **CRISPR Patent Licensing: An Opportunity to Leverage Experience from Patent Pool Models to Help this Technology Reach its Full Potential**

##### INTRODUCTION

CRISPR – a gene editing technology derived from bacteria – holds ground-breaking potential for improving lives around the world through new therapeutic, agricultural, environmental, industrial, and life sciences products. But unfortunately for CRISPR and a society waiting to receive its quality of life-enhancing benefits, the steadily increasing volume of patent grants held by multiple entities creates the foreseeable risk that the desire of large numbers of developers in position to realize its full potential will be thwarted by inaccessibility to the essential patents.

Yet that's exactly what is happening. The parties controlling the fundamental CRISPR patent rights are fighting over priority in the USPTO (Interference No. 106,048) and patentability in post-grant EPO opposition proceedings, while the patent landscape surrounding CRISPR continues to be populated by additional patent owners holding exclusive licensing rights on more than 1,000 patent families worldwide (<http://www.ipstudies.ch/blog-2/>). The result is growing confusion and concern over navigating the patent landscape and negotiating numerous patent licenses, each with its own set of fees, royalties, reporting and diligence obligations, assuming that this were even possible.

Based on experience with the key role that a patent pool played in facilitating the introduction of digital video to a worldwide market, CRISPR, too, may benefit from an efficient, transparent, one-stop non-exclusive licensing mechanism managed and maintained by an independent entity.

##### DISCUSSION

In the 1990s, the consumer electronics industry faced a situation similar to what is now unfolding for CRISPR. Having adopted an international digital video standard of high resolution entertainment quality known as MPEG-2, industry leaders recognized that the

technology would not reach its full potential to achieve ubiquitous deployment and assure a successful transition to the digital age if product development were hindered by inaccessibility to patent licenses and litigation. As the large volume of patents underlying the standard were owned by many different parties both practicing and non-practicing, including a university, they chose to address the market's need for convenience and efficiency with something big and novel: a patent pool providing one-stop nonexclusive licensing access to a package of patents determined to be essential to the MPEG-2 standard.

The pool license was made available to commercial product developers around the world on fair, reasonable, and transparent terms, thereby creating the opportunity for a level new product innovation playing field, while at the same time making it possible for essential patent holders to realize a swift and significant return on their technology investments. By defraying risk and slashing the transactional costs of patent licensing, the MPEG 2 patent pool helped make MPEG-2 the most successful technology standard in consumer electronics history resulting in new global business and supply chain creation generating some 10 billion devices, 65 billion video discs, \$5 trillion in never before available product sales including digital TVs, set-top boxes and media players, unprecedented entertainment choices and information services, and countless jobs to date.

A patent pool could potentially produce the same results for CRISPR. MPEG LA, the independent licensing company created to manage the MPEG-2 patent pool, is leveraging its experience with patent pools in consumer electronics and personalized medicine to form a CRISPR patent pool facility to license essential CRISPR patents worldwide. At its highest level, the basic patent pool model is fairly simple and straightforward. Patent holders agree to license patent rights deemed essential by an independent evaluation to an independent pool administrator under a one-stop license; the pool administrator is charged with licensing the pool on the same terms to industry users (including those who may be patent holders), collecting and auditing royalties, and distributing the royalties to the patent holders in the pool according to agreed terms.

While CRISPR is not standardized in the same way as MPEG-2, it lends itself to the articulation of one or more reference models, according to which essential patents can be determined and bundled for commercial licensing. Provisions can be made, within the structure of the patent pool license, for royalty-free use for research consistent with current licensing practices in the field. With litigation risk and licensing overhead mitigated and managed, there would be more opportunities for the original innovators and new innovators to focus their limited resources on what they do best – translating basic science into life enhancing products for a better world. While the initial focus is on CRISPR/Cas9, MPEG LA also plans to address other genome engineering platform technologies, such as CRISPR/Cpf1, C2c2, and NgAgo.

MPEG LA's CRISPR reference model is nearing completion and the company expects to issue a call for essential patents soon. As such, it provides the parties to the CRISPR patent interference, European oppositions, and other CRISPR patent disputes with a

bold and fresh opportunity to settle these disputes in a way that would immediately accelerate CRISPR product development and returns on investment for patent holders. In addition, it is unlikely that the foundational patents currently in dispute will be the only patents covering therapeutic products once they emerge from R&D and clinical regulatory review. The more likely scenario is that second or third generation patents could be relied upon to provide investment protection for the successful commercial products. Therefore, a patent pool of the foundational patents has the potential to allow CRISPR to reach its full potential to spur new product creation by large numbers of innovators - small startups to larger biotech and pharma companies - thereby accelerating our knowledge base and democratizing the opportunities for innovation and development in a way never before witnessed in biotechnology.

To date, biotechnology has followed the pharma model of exclusive patent licensing. While that has the potential to maximize financial returns to investors if and when product development succeeds, it significantly restrains the number of opportunities for success by limiting the number of licensed developers. By raising the investment risks and rewards, patent exclusivity gives rise to litigation and heightens the likelihood that valuable patent rights will be challenged, reduced in scope or completely invalidated. Given the inherent risk that new technology adoption and exclusive product market share will increase the demand for lower quality alternatives, a patent pool can mitigate future uncertainty and risk for its owners by opening alternative paths for adoption of proprietary technologies, creating alternative product and royalty revenue streams and reducing potential enforcement activity.

One need not look far for parables. Frustration in doctor and patient communities over Myriad's exclusive license to the BRCA gene patents led the ACLU to bring a lawsuit that ultimately resulted in the loss of patent rights for Myriad and a spillover effect that has led to the loss of patent rights by other biotech companies in widely ranging fields. In some areas of biotech, such as synthetic biology, frustration over patents and licensing burdens has resulted in a trend toward open innovation without the property right incentives that patents give their inventors.

But the oft-heard populist argument for eviscerating property rights is short-term and elusive, while the damaging effect on innovation is enduring and immeasurable. Whether innovations will dry up, or trade secrets will fill the void and constrict their public disclosure and availability, the result will be the same. The market is likely to experience a compounding of the problem of access to this growing body of innovation and the private investment necessary to fuel it. In today's world patents still power the private investment needed to commercialize innovation. Other countries, such as China, are deliberate, knowing and unapologetic about the merits of building strong knowledge-based economies with intellectual property as their foundation. Within this landscape, the biotech industry may benefit in adopting a patent pool model for the licensing of patents essential to technological platforms with the potential to succeed on a mass market scale.

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