# EDITORIAL

## CRISPR: SUPERCHARGING GENOME EDITING

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In this special issue we look at genome editing, a form of genetic engineering that covers a range of new precision laboratory techniques, in particular CRISPR/Cas9 (CRISPR). Like older genetic engineering methods, CRISPR – a gene editing technology derived from bacteria – can change the genetic material (usually DNA) of a living organism without breeding. What differentiates these new techniques is that they can change the genetic material of an organism at a particular targeted location.

These techniques have the potential to provide new therapeutic, agricultural, environmental and industrial life sciences products. Dr Joanna Baxter in her article reviews the history and the science behind the discovery of CRISPR and considers why CRISPR is a game-changer.

Complex ethical concerns and limitations placed on what is deemed appropriate may, however, restrict how these new techniques are used. Organisations and governments around the world are grappling with the ethical issues. In the United Kingdom, the Nuffield Council of Bioethics published an initial report in September 2016.[1] This report, reviewed in this issue by Tim Roberts, considers a range of ethical questions these techniques raise. Additional reports addressing the ethical issues in two areas – the avoidance of genetic disease and livestock farming – are expected in 2017. Recently a government committee also considered the issues in a short initial report *Genomics and genome-editing: future lines of inquiry*,[2] following an inquiry launched in November 2016. At the European level, a committee of the European Parliament recently adopted recommendations on the use of new genetic technologies in human beings.[3]

It could be argued that the legal, regulatory and ethical concerns around these new advances in genome editing are just a continuation of those raised by all methods that modify the genome. Nevertheless, they accentuate previous concerns because they enable modifications to the genome to be generated more easily, more quickly and at lower cost.

The legal framework regulating the use of genome editing is also uncertain. An opinion from the EU Commission on the regulatory status of organisms produced using seven new genetic breeding techniques (including genome editing) is long overdue. Trevor Cook's article focuses on the issue the EU Commission is considering: whether the products (plants, in this case) of these techniques are covered by the existing EU legislation regulating genetically modified organisms. Other countries around the world are also wrestling with how to regulate genome editing and James Ellsmore and Tim Craven provide an overview of the legal and regulatory framework in Australia.

A recent reference to the Court of Justice of the European Union (CJEU) by the French Conseil d'État provides the prospect of some, albeit limited, guidance for the future. Although the CJEU has only been asked to address one gene editing technique, it is possible that its reasoning may provide some guidance that can be applied elsewhere. A decision, however, is unlikely before 2018.

1) Nuffield Council of Bioethics, *Genome editing: an ethical review*, 30 September 2016.

2) House of Commons Science and Technology Committee, *Genomics and genome-editing: future lines of inquiry*, Sixteenth Report of Session 2016–17.

3) Committee on Social Affairs, Health and Sustainable Development report, 'The use of new genetic technologies in human beings'. Rapporteur: Ms Petra DE SUTTER (Belgium, SOC) (http://website-pace.net/documents/19855/3313570/20170426-recours-nouvelles-technologies-g%C3%A9n%C3%A9tiques-EN.pdf/75b25d58-a122-4896-91ae-295d49d42549 – accessed 11 May 2017).

Navigating the patent landscape around CRISPR is complex. Attention is currently focused on the Berkeley–Broad patent battle discussed in Asawari Churi's article. The Broad and Berkeley patents are seen as being crucial to many commercial applications of CRISPR. However, according to a report by consultancy firm IP Studies, the patent landscape surrounding CRISPR continues to expand and is populated by a multitude of patent owners holding rights on more than 1,000 patent families worldwide.[4] Therefore, it has been suggested that CRISPR may benefit from a non-exclusive licensing mechanism managed and maintained by an independent entity.[5] World licensing company MPEG LA is inviting holders of CRISPR patents to pool their rights and participate in the creation of a global CRISPR Joint Licensing Platform. Although CRISPR is not standardised in the traditional sense, it is thought that one or more reference models could be used to determine essential patents that could then be pooled for commercial licensing on FRAND (fair, reasonable, and non-discriminatory) terms.

This is not the first time universities and companies have fought over a lucrative invention that could further scientific research. Harvard fought for years for rights to the cancer-prone, genetically engineered oncomouse. Churi, in her article, likens the current CRISPR situation to the early days of PCR (the polymerase chain reaction). Laboratories initially used just one enzyme, Taq1 polymerase, to carry out the protocol; now there is a multitude of suitable enzymes. Researchers in academia and industry are already pushing CRISPR gene editing beyond the scope of the Broad and Berkeley patents. There are already alternatives to Cas9 that offer a possible way to sidestep these patents, such as Cpf1, C2c2, and NgAgo.

As ever the legal and regulatory landscape is complex. Many people remain unconvinced that genome modification should be pursued, and therefore it is essential that early engagement with the public is properly framed, possibly in the context of a real world problem to be addressed such as disease prevention.

4) CRISPR patent landscape IP Studies (https://www.ipstudies.ch/crispr-cas-patent-landscape/ – accessed 11 May 2017).

5) AIPLA Biotech Buzz presentation, 'CRISPR Patent Licensing: An Opportunity to Leverage Experience from Patent Pool Models to Help this Technology Reach its Full Potential' (http://www.mpegla.com/main/pid/CRISPR/Documents/Biotech%20Buzz%20article.pdf – accessed 11 May 2017).