

# Considering the legal and IP implications of gene editing

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**G**lobal food security is increasingly challenging in light of population growth, the impact of climate change on crop production, and limited land available for agricultural expansion.

One solution has been presented in the form of gene editing, a technology – based on a natural process – that allows researchers to cut out certain bits of DNA in order to control traits. In practice, this can make a significant contribution to global food security, in part by improving so-called ‘orphan’ crops, which are regionally important to health, food security and rural incomes. But what are the intellectual property (IP) implications of gene editing?

## Introducing genome editing

Traditional gene modification in plants involves modifying the genome of cultured plant cells by introducing new genetic material and then regenerating whole plants. These methods have been vilified by the anti-GMO (genetically modified organisms) movement for introducing foreign DNA from other organisms, with anti-GMO groups arguing that we do not know what the effect of introducing foreign genes into plants, nor the potential effect of consuming them down the line, will be.

But gene editing is different: It mimics the natural process of mutagenesis (changing or mutating DNA). It targets a single nucleotide in plant DNA to make it change advantageously, instead of waiting for nature to do so and hoping for advantageous mutations.

In my opinion, there is a significant difference between introducing foreign DNA into a crop that will eventually be eaten and changing a single nucleotide in the plant's

DNA in much the same way that naturally arising mutations would. This could also be why opinions are more polarised when it comes to GMOs than gene editing.

## Regulating gene-edited crops

Regulatory developments indicate that some governments are adopting unnecessarily rigid regulations, considering that gene editing techniques are not that different from what occurs naturally through mutagenesis, barring the fact that the former are targeted.

One example of what is emerging as a seemingly rigid regulatory landscape is that of Europe. Recently, the highest court in the European Union ruled that gene-edited crops are GMOs and must comply with the tough regulations applied to plants made with genes from other species.

In South Africa, our law is very similar to European law in many respects. South Africa's regulatory law for GMOs, the *Genetically Modified Organisms Act, 1997 (Act 15 of 1997)*, says that a GMO is an organism of which “the genes or genetic material has been modified in a way that does not occur naturally through mating, natural recombination or both”.

This is broad enough to encompass gene editing and to hamper the regulatory approval of plants that have been modified using gene editing techniques.

## Intellectual property issues

But what of the IP implications of gene editing? South African patent law, according to Section 25(4) of the *South African Patent Act, 1978 (Act 57 of 1978)*, provides that a patent shall not be granted for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process.



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However, there is no case law in South Africa to interpret the meaning of this section. In Europe, it is possible to obtain patent protection for transgenic plants, plants obtained by mutagenesis (including gene editing) and/or biotechnological methods of producing them, so it is likely that our courts will follow the European approach.

In addition, it is also possible to obtain plant breeders' rights protection, provided that the plant meets the requirements of protection, i.e. that it is new, distinct, uniform and stable.

## Democratising gene editing

CRISPR, also called CRISPR/Cas9, stands for Clustered Regularly Interspaced Short Palindromic Repeats/CRISPR associated protein 9, which is the full name for the gene editing technique often applied to selective breeding.

“CRISPR has been democratised,” says Rodolphe Barrangou, editor of *The CRISPR Journal* and head of a multi-disciplinary CRISPR lab. “With 100 000

labs and ten people per lab, we now may have over a million geneticists working with this technology.”

This bodes well for food security.

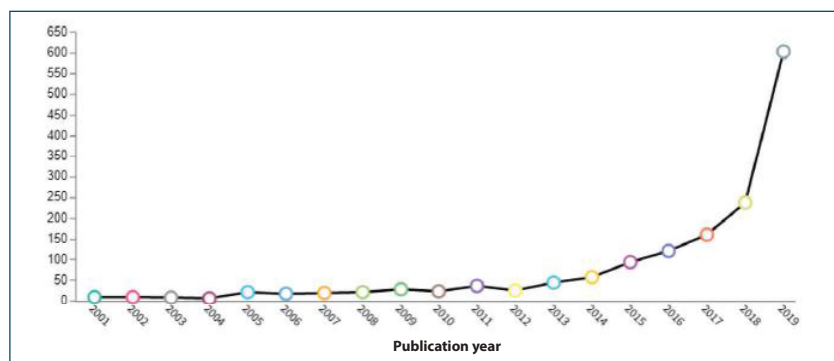
Figure 1, which is based on a patent search formulated to identify patent filings related to gene editing in plants or crops, shows that this appears to be an exponentially and rapidly increasing field, especially over the last decade.

What's more, the fact that the CRISPR/Cas9 system is patented, does not prevent others from obtaining patents for specific embodiments of this technology and, in particular, from using it to produce new, stronger crops.

### Considering a patent commons

In other areas, a standard mechanism for creating openness in research and development has involved putting material in the public domain, outside the world of property. So, researchers in the field of gene editing may decide to use IP rights to create a ‘food security commons’ – much like developers of free and open source software use software copyrights to impose requirements

**Figure 1: Gene editing patented inventions for plants or crops by publication year.**  
(Source: Derwent™ World Patents Index)



of openness on future programmers; requirements greater than those attaching to a public domain work.

There is nothing that precludes a patent commons for gene editing technologies, and this could be a great way to develop technologies for solving problems linked to food security. For example, a similar COVID-19 commons was recently proposed for sharing solutions to combat the pandemic. Although a patent commons operates much in the same way as open source software or creative commons, the

difference is that copyright is automatic, while patents need to be applied for.

My view is that, if we can combine the scientific strides being made with the appropriate IP protection and alignment of the regulations with the actual risks posed, gene editing could very well turn out to be an important technology for future food security. 🌱

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