Patents on Genome Editing in Canada

This factsheet provides an overview of the intellectual property issues surrounding the new genetic engineering (genetic modification or GM) techniques of genome editing (commonly called gene editing), with a focus on CRISPR-Cas9.

Summary

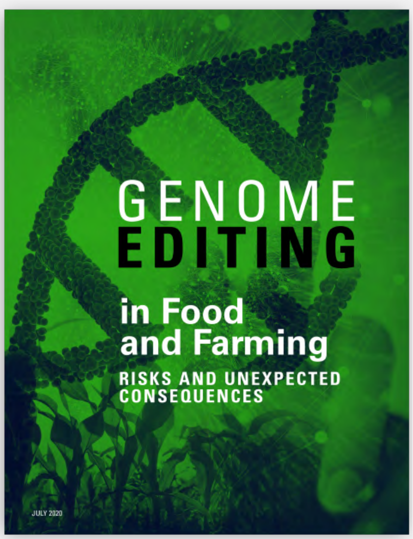
- **Genome editing (gene editing) techniques are powerful new research tools that are accelerating the development of genetically engineered (genetically modified or GM) plants and animals.**
- **Genome editing methods and products are patentable and patented.**
- **CRISPR-Cas9 is the most frequently used genome editing technique in laboratory research and dominates the current patent landscape for genome editing.**
- **The patent landscape for CRISPR-Cas9 is already highly complex.**
- **Ownership of CRISPR-Cas9 technology has not yet been established in Canada, with most patent applications still awaiting examination by the Canadian Patent Office.**
- **The use of genome editing will significantly increase plant-related patents. It will also lead to more crop kinds with patented GM traits on the market.**
- **The few biotechnology companies that dominate the global commercial seed and pesticide markets also dominate the patents on genome editing. Corteva (formerly DowDupont) is the top CRISPR patent holder.**
- **The patenting of genome editing will facilitate more corporate control over seeds than occurred with the patenting of first generation genetically modified organisms (GMOs).**

Introduction

With genome editing, just as with earlier genetic engineering (genetic modification or GM) techniques, patents apply to both the techniques used to transform an organism and to the resulting genetic traits. The new genetic engineering techniques of genome editing allow scientists to use DNA-based tools to alter genetic sequences to create new traits in an organism, without having to incorporate transgenic sequences in the resulting genetically modified organism (GMO). While many new GMOs created by genome editing will not have foreign DNA incorporated in them, they will be produced using patented techniques, and the new traits and sequences can be patented.

Higher life forms such as plants cannot be patented in Canada, as ruled in 2002 by the Supreme Court of Canada in the Oncomouse case (*Harvard College v. Canada (Commissioner of Patents)*). However, patents on GM traits have functioned as a mechanism of corporate control over seed (as interpreted by the Supreme Court of Canada in 2004 in the case against Saskatchewan farmer Percy Schmeiser (*Monsanto Canada Inc. v. Schmeiser)*). First generation GM seeds have been largely limited to just a few commercial crop kinds (soybean, canola, corn and cotton account for around 99% of GM crops grown globally) and two traits (over 99% of GM crops are engineered with herbicide-tolerance and/or insect resistance).[1] In contrast, genome editing could extend new patented GM traits to many more crop kinds.

Patents are granted by national laws, to allow inventors to benefit from the sale of their work by excluding others from making, using, importing and selling the patented invention for a specific time period (usually twenty years). Inventors must provide detailed technical information to successfully argue that their product or process is new, involves an inventive step, and is capable of industrial application. Typically, an inventor will first file an application in one of the main patent jurisdictions – either the US Patent Office or the European Patent Office. Second, the inventor will file an "international patent application" under the Patent Cooperation Treaty (PCT) administered by the World Intellectual Property Organization (WIPO). Third, the inventor will file patent applications in the various countries where they seek protection, for example Canada. The PCT does not grant patents per se, but it facilitates the process of obtaining patents in multiple countries.



For a description of genome editing techniques, see CBAN's report.

cban.ca/GenomeEditingReport

How CRISPR is Transforming the Patent Landscape

The development of CRISPR-based genetic engineering in 2012 unleashed a new patent race. A decade later, the CRISPR patent landscape is highly complex, and key foundational patents are tied up in court cases whose outcomes are uncertain.

CRISPR-Cas9 is the most popular genome editing technique used in laboratory research, and it dominates the patent landscape for genome editing.[2] However, other genome editing techniques have been developed and patented, such as TALENs and zinc finger nucleases. More techniques are in development, including other CRISPR systems.

In 2021, across all fields, the US Patent and Trademark Office had around 6000 CRISPR patents or patent applications, with 200 being added every month, mostly from China and the United States.[3] Agriculture is one of the main fields of applications along with healthcare. According to a 2020 survey, 17% of CRISPR patent families were for plant modification, and 13% were for animal modification.[4] A patent family includes all worldwide patent applications and granted patents that cover a single invention.

CRISPR opens up new crops and traits to genetic engineering because of its speed and because the technology gives access to previously inaccessible areas of the genome for manipulation.[5,6] **Patenting of genome editing tools and products is therefore expected to significantly expand plant-related patents.**[7] Furthermore, if genome editing is faster and cheaper to use, it could result in a shorter product development cycle where several overlapping patents will be stacked together in products.[8]

Who Owns CRISPR?

A small number of university-based researchers who first developed CRISPR-Cas9 hold the foundational patents on the invention. These patent claims relate to broad uses of the CRISPR-Cas9 technology.

Two teams of researchers from University of California and the Broad Institute developed CRISPR around the same period:

- Dr. Jennifer Doudna at the University of California Berkeley (UC Berkeley) and Dr. Emmanuelle Charpentier at the University of Vienna led one team. (In 2020, they were jointly awarded The Nobel Prize in Chemistry "for the development of a method for genome editing.") This group's patent filing claimed rights over the use of CRISPR-Cas9 in any living cell, outlining how CRISPR-Cas9 could be used to cut isolated DNA.
- Dr. Feng Zhang led the group from the Broad Institute, which is affiliated with MIT and Harvard in Massachusetts. This group's filing claimed rights over the use of CRISPR in human, animal and plant cells, showing how the CRISPR-Cas9 system could be adapted to edit DNA in all cells that have a nucleus.[9]

The two groups filed patent applications months apart and have since been embroiled in a dispute before patent authorities and courts. In Europe, the Broad Institute's CRISPR patents were invalidated by the European Patent Office due to a technical issue.[10] As a result, **UC Berkeley holds the foundational patents on CRISPR-Cas9 in Europe**. In contrast, **in the US, the Broad Institute has been favoured in the decisions issued so far.**[11]

The CRISPR-Cas9 Licensing Strategy

The inventors of CRISPR-Cas9 have made the technology available free of charge to anyone who conducts research for non-commercial purposes, or in other words, for basic laboratory research conducted in public universities.

However, **to commercialize products developed using CRISPR-Cas9, the inventors, who are also the foundational patent holders, have set up surrogate companies that license CRISPR-Cas9 patents to other companies around the world that can then use CRISPR-Cas9 to develop and commercialize products.**

Table 1 summarizes some of the main licensing agreements concluded in the field of food and agriculture as of January 2022.

TABLE 1 | AN OVERVIEW OF CRISPR-CAS9 LICENSING AGREEMENTS IN FOOD AND AGRICULTURE

<table>
<tr><th>Institution/
Patent holder</th><th>Surrogate company</th><th>Licensee</th><th>Field of application</th><th>Type of license*</th></tr>
<tr><td rowspan="6">Broad Institute,
Harvard University
& MIT
(F. Zhang)</td><td rowspan="4">—</td><td>Bayer-Monsanto[12]</td><td>Agricultural applications (seed development)</td><td rowspan="5">Non-exclusive</td></tr>
<tr><td>BASF[13]</td><td>Agricultural applications</td></tr>
<tr><td>Corteva Agriscience (DuPont Pioneer)[14]</td><td>Agricultural applications</td></tr>
<tr><td>Syngenta[15]</td><td>Agricultural applications</td></tr>
<tr><td rowspan="2">Pairwise[16]</td><td>—</td><td>Plant-based applications (fruits and vegetables)</td></tr>
<tr><td>Bayer-Monsanto[17]</td><td>Agricultural applications (in corn, soybean, cotton, wheat and canola)</td><td>Exclusive</td></tr>
<tr><td rowspan="4">University of California,
Berkeley
(J. Doudna)</td><td rowspan="4">Caribou Biosciences</td><td>Corteva Agriscience (DuPont Pioneer)[18]</td><td>Agricultural applications (major row crops)

Other agricultural and industrial applications</td><td>Exclusive

Non-exclusive</td></tr>
<tr><td>Genus[19]</td><td>Livestock</td><td>Exclusive</td></tr>
<tr><td>Regional Fish Institute[20]</td><td>Non-mammalian marine animals for agricultural purposes</td><td>Non-exclusive

Asia Pacific</td></tr>
<tr><td>TreeCo[21]</td><td>Trees</td><td>Exclusive</td></tr>
<tr><td rowspan="2">University of Vienna
(E. Charpentier)</td><td rowspan="2">ERS Genomics</td><td>Evolva[21]</td><td>Food products (yeast and fungal engineering)</td><td>Non-exclusive</td></tr>
<tr><td>Corteva Agriscience (DuPont Pioneer)[23]</td><td>All agricultural uses and applications in plants</td><td>Exclusive</td></tr>
<tr><td>Vilnius University</td><td>—</td><td>Corteva Agriscience (DuPont Pioneer)[24]</td><td>All applications, including agriculture</td><td>Exclusive</td></tr>
</table>

Some foundational patent holders – the University of California, the University of Vienna and Vilnius University – have taken the approach of granting **exclusive licenses to Corteva (formerly Dow Dupont)** that exclude all other parties (even the licensor) from exploiting the intellectual property in question. In contrast, the Broad Institute has been granting **non-exclusive licenses** that allow the licensor to grant multiple licenses to other parties and to exploit the intellectual property themselves.

"Depending on the specific use of the Cas9 enzyme, four or more licenses may be necessary for a simple edit in a plant."

— Michael A. Kock, analyst, former head of intellectual property at Syngenta, 2021[25]

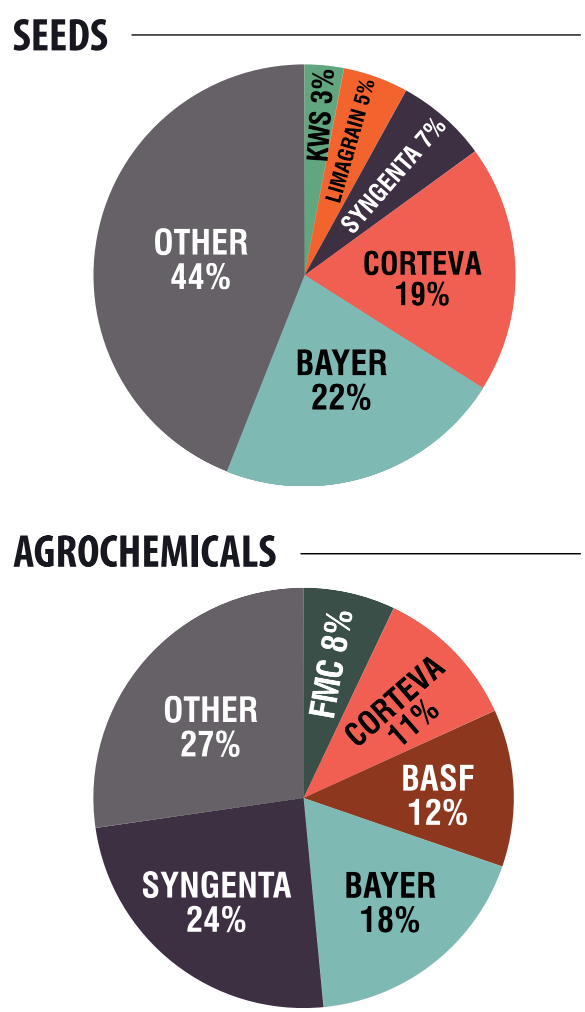
Moreover, the Broad Institute's licensing agreements **include restrictions due to "ethical and safety concerns": on the use of CRISPR for development of sterile (Terminator) seeds,[a] tobacco products for human use, and gene drives.**[26] Gene drives are a CRISPR-based technology designed to spread genetically engineered traits through a whole population of plants or animals within a few generations.[27]

Corporate Control

The enhanced speed and reduced cost of using CRISPR in the laboratory to genetically engineer organisms has led to widespread claims that genome editing will democratize biotechnology, freeing product development from the corporate concentration that has characterized the commercialization of GM crops so far.[28] **However, ownership of the CRISPR-Cas9 patent families show that licenses are dominated by the major companies already invested in genetic engineering and that dominate the global commercial seed and pesticides markets.**

CRISPR-Cas9 is available free of charge to anyone who conducts basic research, helping to facilitate wide experimentation with this powerful, cheaper and faster genetic engineering tool. However, **any commercial application requires a licensing agreement with foundational patent holders or surrogate companies.** These surrogate companies are licensing access to CRISPR-Cas9 to the large seed and agrochemical corporations that already dominate plant breeding and seed production in exchange for a flat fee and royalties on the sales revenue. Surrogate companies are also licensing access to small start-up companies that have been set up to capitalize on CRISPR-Cas9 technology in specific areas such as fish, yeast and fungus.

The global markets for genetically engineered crops are dominated by just a few seed and pesticide companies, companies that together control over half of the global commercial seed and pesticide markets. Source: ETC Group, 2019[29]



a There is a global moratorium on genetically engineered sterile seed technology at the United Nations Convention on Biological Diversity (2000).

"Democratization of the scientific process … may not translate into democratization of gene-edited products..."

— Maywa Montenegro de Wit,
University of California, 2020[30]

As shown in Table 1, **the major agribiotech corporations are consolidating their CRISPR-Cas9 patent portfolio.**[31]

Corteva (formerly DowDuPont) holds more patents on CRISPR technology for agriculture than any other company or institution in the world,[32] in what it calls the "broadest CRISPR patent estate in the agriculture industry."[33] The company holds non-exclusive global rights to the Broad Institute's CRISPR-Cas9 patents for agricultural use. The company holds exclusive global rights to UC Berkeley's CRISPR-Cas9 technology for major row crops, as well as non-exclusive global rights to all agricultural uses and applications. Corteva also holds a license from ERS Genomics for all agricultural uses and applications in plants. In addition, Corteva has patents of its own. For example, there are several patents and licensing agreements that cover Corteva's "CRISPR-Cas waxy corn" (Corteva's CRISPR test product that is legal to use but not commercialized in Canada).[34] These include patents held by Corteva and licensing agreements with the Broad Institute of MIT and Harvard, UC Berkeley, and Vilnius University, for different aspects of CRISPR-Cas9 technology.[35]

Bayer (which acquired Monsanto in 2018), BASF and Syngenta all hold non-exclusive rights to the Broad Institute's CRISPR-Cas9 technology for use in agricultural applications. Bayer also holds non-exclusive rights to ERS Genomics's CRISPR-Cas9 technology. In addition, Bayer entered into a collaboration and licensing agreement with the start-up Pairwise for the use of CRISPR in corn, soybeans, wheat, cotton and canola.[36]

The vast majority of patents come from China and the US. A recent survey found that 69% (259 out of 374) CRISPR patent families for agricultural applications (plants, farm animals and aquaculture) originate in China.[37] Another survey found that the main owners of CRISPR patent families across all types of applications (agricultural and pharmaceutical) are Chinese Academy of Agricultural Sciences (415), Chinese Academy of Sciences (414), MIT (353), University of California (333), Broad Institute (316), Harvard (262), and **Corteva Agriscience** (130).[38]

New CRISPR systems – such as Cas12 and Cpf1 – could soon displace CRISPR-Cas9 and lessen the importance of the foundational CRISPR-Cas9 patents. However, these new CRISPR technologies follow the same intellectual property (IP) model. For instance, **BASF** has signed a global non-exclusive licensing agreement with the Broad Institute for the use of CRISPR-Cpf1 technology in agricultural applications.[39] According to a firm specialized in CRISPR IP analytics, there are "more than 100 variants of CRISPR enzymes beyond the best known Cas9 discovery of 2012, with some commercial players trying to exhaustively claim them to secure as broad an IP exclusivity as possible."[40]

The CRISPR-Cas9 Patent Landscape in Canada

Ownership of CRISPR-Cas9 technology has not yet been established in Canada.[41]

The inventors of CRISPR-Cas9, including UC Berkeley and the Broad Institute, have filed patent applications with the Canadian Patent Office.[42] A search for "CRISPR" and "plant" in the Canadian Patent Office database shows 2446 pending applications.[43] In most cases, the applicants have not yet requested that the Patent Office begin examining their applications. Canada allows patent applicants to wait up to five years after filing an application before initiating the examination process.

Given the patent dispute between UC Berkeley and the Broad Institute in the US and Europe, it is possible that the applicants are waiting to see how related applications will be handled by the US and Europe patent offices and courts before proceeding in Canada. **The EU, and especially the US, decisions will inform their patent strategy in Canada,**[44] and will influence the views of the Canadian Patent Office examiners who review applications.[45,46]

To commercialize genome-edited crops in Canada, companies need licenses to foundational CRISPR patents.[47] It is common for a company to enter into a licensing agreement with a prospective patent owner pending the completion of the patent examination process. In the case of CRISPR-Cas9, because ownership of the foundational CRISPR patents has not yet been established, there is legal uncertainty as to whether companies would enter into a licensing agreement with the Broad Institute or with UC Berkeley.

What Could This Mean for Farmers in Canada?

In Canada, patent protection over new genetic sequences has been used as a mechanism to take control of seeds out of the hands of farmers. While plant varieties and plants themselves cannot be patented in Canada, patent-holders can stipulate the conditions under which the patented genetic material can be used.[48] In practice, this means that it is illegal for farmers to save and replant seed with patented GM traits, and for farmers and other plant breeders to further select or develop the seed without the patent holder's permission. Patents also mean that farmers can be found in violation of intellectual property rights if seeds or plants with patented genetic traits are found on their farms without the patent-holder's permission.[49] **Indications are that the patenting of genome editing will allow the same degree of control over farmers' use of genome edited seeds and plants.**

For developers to enforce patents on genome edited products, they need to be able to detect and identify them. **While detecting genome edited DNA sequences is more challenging than detecting inserted transgenic sequences, it is feasible.**[50] For example, European non-government organizations collaborated to develop a detection test for the Cibus SU Canola, and were able to do so without access to Cibus' proprietary information.[51] If a mutation in an organism is new, it is possible to develop a detection test, and genome-edited GMOs should fulfill newness criteria in order to be patented.

There are several possible scenarios concerning the enforcement of intellectual property rights on genome-edited crop varieties. One is that, in a similar way to earlier GM crops, companies will develop detection tests to analyze seed samples and enforce patent rights and technology use agreements. A second possible scenario is that, for more complex multigene traits, where it is more difficult to obtain meaningful patent protection, companies will rely on a combination of plant breeders' rights and trade secrets for commercial protection.[52]

In most countries, including Canada, farmers do not have the right to save seeds from patented varieties for replanting, like they do for varieties protected by plant breeders' rights (the European Union is an exception in this regard: farmers can save seeds from varieties covered by patents for replanting on their farms). Consequently, an increasing number of crop kinds with patented traits produced through genome editing would substantially constrain farmers' ability to save seed, and the need to purchase seed every year would increase farmers' costs.

Analyst Michael Kock, former head of intellectual property at Syngenta, has projected that if the technology advances and more governments facilitate genome editing through regulation, essentially all new crop varieties on the global market will have five or more genome-edited traits in twenty years, leading to unprecedented patent complexity.[53] As of 2022, five crop kinds with genetically engineered traits are grown in Canada: corn, canola, soy, sugarbeet and alfalfa.[54] **However, a wider proliferation of genetically engineered seeds via the use of genome editing across many crop kinds means that more farmers would be planting patented seed and confronted with having to conform to patent protection measures. An increased use of GM seed across the country would also increase the risks of GM contamination,[55] and raise related patent infringement concerns among farmers who are not using those genome-edited varieties**.

Corporate consolidation in the seed market over the past twenty years has been driven, in large part, by corporate interest in genetic engineering and the potential profits available by exercising patent rights in particular.[56] The patenting of genome editing appears to reinforce this consolidation trend, which has led to higher seed prices and decreased choice in the marketplace.[57]

It is well established that corporate concentration and extensive patent rights can stifle research and development,[58] and further constrain choices for farmers into the future. If public plant breeders pursue the use of genome editing, their work could increasingly be tied up in navigating complex patent licencing issues, and commercializing the resulting varieties could be restricted by disputes over licenses with private companies.[59]

If, as the Canadian Food Inspection Agency and Health Canada propose, many genome edited plants and foods (those with no foreign DNA) are exempted from regulation,[60] then we can expect companies to focus on developing those products for commercial release, resulting in a flood of unregulated, unidentified, patented genetically engineered seeds and foods.

Further Reading

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For more information and updates, see www.cban.ca/patents.

The Canadian Biotechnology Action Network (CBAN) brings together 16 groups to research, monitor and raise awareness about issues relating to genetic engineering in food and farming. CBAN members include farmer associations, environmental and social justice organizations, and regional coalitions of grassroots groups. CBAN is a project of MakeWay's shared platform.

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