Legalization of Recreational and Medicinal Marijuana in Canada and the Road for Plant Breeders' Rights for Cannabis

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1. Recreational Marijuana

On October 17, 2018, recreational marijuana became legal across Canada when the *Cannabis Act* (SC 2018, c.16) came into force. The *Cannabis Act* was first introduced by the federal government to the House of Commons on April 13, 2017 and received Royal Assent on June 21, 2018 after undergoing a number of amendments.¹ Individuals who are 18 years or older (depending on the province or territory) are now allowed to possess up to 30 grams of dried cannabis, or an equivalent, in public.² However, it remains illegal to import or export cannabis, unless a licence or permit is obtained which authorizes the import or export of cannabis for medical or scientific purposes, or in respect of industrial hemp.³ An application for a cannabis licence or permit must be filed with Health Canada. Further details on cannabis licensing can be found in the Cannabis Licensing Application Guide.

According to the Canadian magazine Maclean's, citing a report issued by Deloitte in 2016, the estimated retail market value for recreational marijuana could reach figures close to \$8.7 billion, not including the ancillary services such as security.⁴

2. Medicinal Marijuana

Medicinal marijuana has been legal for over 15 years. The legalization of medicinal marijuana in Canada was prompted by the decision in *R v Parker* in 2000,⁵ when the Ontario Court of Appeal held that the prohibition on possession of marijuana was unconstitutional insofar as it prevented those who required it for medical purposes to possess it. The Court delayed the

¹ LEGISinfo, *Bill C-45: An Act respecting cannabis and to amend the Controlled Drugs and Substances Act, the Criminal Code and other Acts; Status of the Bill,* online: Parliament of Canada, https://www.parl.ca/LegisInfo/BillDetails.aspx?billId=8886269.

² Cannabis Act, SC 2018, c.16, s 8(1).

³ Cannabis Act, SC 2018, c.16, s 62(2).

⁴ Joe Castaldo, "How big is Canada's marijuana market, really?", *maclean's* (30 June 2017), online:

https://www.macleans.ca/news/canada/how-big-is-canadas-marijuana-market-really/>.

⁵ R v Parker (2000), 49 OR (3d) 481 (ONCA).

declaration of invalidity for 12 months to give Parliament time to draft appropriate legislation. In 2001, the *Marihuana Medical Access Regulations* (SOR/2001-227) were implemented, enabling individuals with medical needs to access dried marijuana for medical purposes after obtaining the authorization of their health care practitioner.⁶ The regulations have been amended a number of times since then. With the *Cannabis Act* now in force, the regulations that govern cannabis for medical purposes are the *Cannabis Regulations* (SOR/2018-144).⁷ The medical cannabis system continues to exist alongside the recreational cannabis regime.⁸

3. Differences Between Hemp and Marijuana

It is important for breeders and consumers to be clear on the differences between hemp and marijuana. While hemp and marijuana both originate from the *Cannabis* plant, they are distinct entities. Marijuana contains a higher concentration of tetrahydrocannabinol (THC), which is responsible for the psychoactive effects experienced when marijuana is consumed. The THC concentration in dried marijuana can vary anywhere between less than 1% to 30%. Hemp, on the other hand, is primarily grown for industrial use (e.g., manufacturing paper, rope and construction materials) and is regulated so that it contains 0.3% THC or less. Licences to grow hemp for commercial purposes were first issued in 1998, following research that demonstrated that hemp can be grown as a separate entity from marijuana.

4. Protection of Cannabis Varieties

Conditions for Protection

Cannabis breeders can protect cannabis strains under the *Plant Breeders' Rights Act* (SC 1990, c.20). Applications for protection are submitted to the Plant Breeders' Rights Office (PBRO), which is administered by the Canadian Food Inspection Agency (CFIA).

⁶ Health Canada, *Understanding the New Access to Cannabis for Medical Purposes Regulations*, online: Government of Canada (August 2016), https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/understanding-new-access-to-cannabis-for-medical-purposes-regulations.html>.

⁷ Government of Canada, *Cannabis for medical purposes under the Cannabis Act: information and improvements*, online: Government of Canada (modified 17 October 2018), https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/medical-use-cannabis.html.

⁸ Government of Ontario, Cannabis legalization, online: Government of Ontario (updated 29, October 2018),

 $<\!\!\!\text{https://www.ontario.ca/page/cannabis-legalization\#section-8}\!\!>\!\!.$

⁹ Ontario Cannabis Store, Glossary of Terms: THC, online: Ontario Cannabis Store, https://ocs.ca/blogs/glossary-of-terms/thc.

¹⁰ Government of Canada, *Hemp and the hemp industry – Frequently Asked Questions*, online: Government of Canada (modified 7 November 2018), https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/producing-selling-hemp/about-hemp-canada-hemp-industry/frequently-asked-questions.html#a7.

Some conditions must be satisfied before applying for protection. In order to obtain protection, the plant variety must be:

- a) new, meaning that the propagating or harvested material has not been sold in Canada more than 1 year and anywhere else for 4 years before the filing date of the application;
- b) clearly distinguishable from all other known varieties;
- c) stable in all its distinctive essential characteristics; and
- d) sufficiently stable among the generations.¹¹

Applying for Plant Breeders' Rights in Canada

The applicant must be either the breeder, his or her employer, or the legal representative. If the breeder is not the applicant or the employee of the applicant, the application must be supported by an assignment from the breeder to the applicant. When applying for the rights, a list of information must be provided, such as the Applicant's full name and address; the botanical classification of the plant variety; the proposed variety denomination/name; the priority information (if applicable); and information on the sales of the variety.

Variety Denomination

A variety denomination (name) must be provided when filing the application. It may be a temporary designation or an experimental number. However, a final denomination should be submitted prior to publication of the variety description in the *Plant Varieties Journal*.

Canadian breeders must be very careful when selecting a name for their varieties. CFIA guidelines on variety denominations state that names cannot be misleading or offensive. Furthermore, comparatives or superlatives such as "purest" or "stronger" should be avoided. If a variety has been protected or if an application has been filed in another country, the denomination used in that country must also be used in Canada. Additional directions for naming varieties can be found in the <u>Variety Naming Guidelines</u>.

It is also important for breeders to know that the variety denomination cannot be registered as a trademark.

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¹¹ Plant Breeders' Rights Act, SC 1990, c.20, s 4(2).

Claiming Priority

Breeders are entitled to claim priority in Canada for a variety which has been previously filed for protection in a country member of the International Union for the Protection of New Varieties of Plants (UPOV). The date the foreign application was originally filed would be considered as the date of filing in Canada. However, as it remains illegal to import or export cannabis unless there is an authorization for medical or scientific purposes, it might be difficult to claim priority for recreational marijuana.

Additional Information Required from the Breeder

An application for protection requires further details from the breeder regarding the plant variety. Such details include the origin and breeding history of the variety; a statement of distinctness; a statement of uniformity and stability; and the methods for maintaining the variety.

Canadian breeders must also be very careful with the requirement for a sample of the propagating material. In the Plant Breeders' Rights protection system, there is a requirement to supply a seed sample to the PBRO at the time of filing an application if the crops are propagated by seeds. Vegetatively propagated crops, on the other hand, are exempt from this requirement. Most cannabis breeders are choosing to use asexual reproduction due to the prohibition on circulating cannabis sample plants and seeds.

Plant Breeders' Rights Examination

As there are currently no specific examination guidelines for cannabis, the PBRO is considering using the Hemp Test Guidelines to conduct its examinations (these guidelines can be obtained by submitting a request to the PBRO). Generally, asexually reproduced species require one growing cycle of trials to determine whether the candidate variety is distinct, uniform and stable (DUS), while seed reproduced and woody species require two growing cycles of trials. As discussed above, most cannabis breeders are choosing to use asexual reproduction due to the prohibition on circulating cannabis sample plants and seeds.

In Canada, the duration of DUS testing for cannabis will be one year if asexually propagated and two years if propagated from seed, although the PBRO is considering requiring two growing cycles of trials for asexually reproduced cannabis as well. While this information is not reflected in the present Hemp Testing Guidelines, the PBRO plans on updating the document.

Duration of Plant Breeders' Rights

Once granted, Plant Breeders' Rights protection can last up to 20 years, although breeders can surrender their rights any time before the end of the 20-year period. To maintain their rights, breeders must pay an annual fee. Following the expiry of the protection term, the plant variety may be used by individuals other than the plant breeder in Canada.

<u>Facilities</u>

There are no guidelines specifying the type of facilities or security required for growing cannabis for examination. This will likely have to be determined by law enforcement entities in agreement with the CFIA. Generally, however, facilities are required to conduct the comparative tests and trials and to maintain the plant variety, which may or may not be the same facilities. During examination, an examiner from the PBRO will visit the trial site to verify the results of the trial. After rights have been granted, the Commissioner may request to inspect the facilities where the variety is being maintained.

<u>Branding</u>

In addition to applying for Plant Breeders' Rights, breeders should consider registering a trademark for the commercialization of the plant variety as part of a branding and recognition strategy. This course of action will allow breeders to build equity and prevent others from propagating or selling the variety without a proper licence.

A trademark registration involves a separate application process, wherein an application is submitted to the Canadian Intellectual Property Office (CIPO). To obtain a trademark registration, the trademark must be sufficiently distinctive from the corresponding variety name or from any known variety name. Trademarks that resemble a plant variety denomination will not be accepted, as it may lead to confusion.

Below is a link to the Trademarks page on CIPO's website:

http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h wr00002.html

5. Restrictions on Plant Breeders' Rights

The *Plant Breeders' Rights Act* includes a Research Exemption, permitting the use of a protected variety for breeding and developing new plant varieties. A Farmers' Privilege also exists, which permits farmers to save and plant their own seed of protected varieties on their land.

6. Assignment of Rights

Holders of plant breeders' rights may assign their rights to another person or company. The PBRO will not become involved in these agreements. However, an assignment of a plant breeders' right is not considered valid by the PBRO unless it is registered by the assignee with the PBRO within 30 days of the assignment. See the form "Assignment of Plant Breeders' Rights".

7. Enforcement and Infringement

It is the responsibility of the holder of the plant breeder's right to bring legal action against any person infringing on his or her rights. Court proceedings may be taken to the appropriate court in the province in which the infringement occurred.

8. The Road Ahead for Cannabis Breeders

The Plant Breeders' Rights practice for cannabis in Canada, including examination and other details, is still in the process of development. Further clarifications, guidance and definitions are expected to be announced by the CFIA. The CFIA's role in cannabis regulation is described on their website as follows:

"The CFIA administers a number of acts and regulations that relate broadly to the import, production and use of plants. These requirements also apply to cannabis, industrial hemp, cannabis products and by-products, such as regulations for livestock feed and the disposal of unused plant parts. The legalization of cannabis and the passing of the Cannabis Act does not affect these acts and regulations; they remain in effect.

The CFIA continues to assess the effect the new legislation will have on its operations and program delivery, involving, for example, cannabis seeds, plants with novel traits, plant breeders' rights, fertilizers, livestock feed, and food safety".