Protection of New Plants and New Plant Technologies in Canada and the United States

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In Canada, the protection and commercialization of intellectual property associated with new plant varieties and cultivars are governed federally under one or both of the Canadian Seeds Act[1] and the Canadian Plant Breeders' Rights Act,[2] while protection of new plant-related inventions is generally governed under the Canadian Patent Act.[3] In addition, the Canadian Seeds Act specifies rules and regulations for the importation, labeling, and distribution of seeds and propagules of novel plants.

In the United States, new asexually propagated plant varieties can be protected under the U.S. Plant Patent Act,[4] while novel sexually propagated plant varieties can be protected under the U.S. Plant Variety Protection Act.[5] Novel plant-related technologies, as well as new plant varieties produced with novel technologies, can be protected under the U.S. Patent Act.[6] The U.S. Federal Seed Act[7] provides federal governance for the importation of novel agricultural and vegetable seeds and their interstate commerce.

This chapter will compare relevant acts and regulations and discuss the similarities and differences between the options for protecting new plants and new plant technologies in Canada and the United States.

Plant Breeders' Rights

Canada

Canada is a member of the International Union for the Protection of New Varieties of Plants (UPOV). UPOV is an intergovernmental organization with headquarters in Geneva, Switzerland, established by a diplomatic convention in 1961 with the objectives of provid-

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ing an internationally recognized and adhered-to system for plant variety protection and encouraging the development of new varieties of plants for the benefit of society.

The International Convention for the Protection of New Varieties of Plants came into force on August 10, 1968, after ratification by the United Kingdom, the Netherlands, and Germany. The UPOV convention[8] was subsequently revised three times[9] to reflect technological developments in plant breeding and experience acquired with the application of the UPOV convention. As of June 2007, there are sixty-four member countries of UPOV. Canada formally joined UPOV in 1990 and promulgated the UPOV Convention of 1978 as the Canadian Plant Breeders' Rights Act (PBRA) in August 1990. The Canadian Food Inspection Agency operates the Plant Breeders' Rights Office (PBRO) on the behalf of the Canadian federal government. The PBRO receives and assesses plant breeders' rights (PBR) applications and grants rights for individual plant varieties that meet the specified criteria in the form of PBR certificates.

PBR Certification Criteria and Stipulations

All categories of the plant kingdom qualify for a PBR certificate except for algae, bacteria, and fungi. The new variety must be clearly distinguishable from all other known varieties by one or more identifiable characteristics. The new variety must be stable in its essential characteristics so that, after repeated reproduction or propagation, the progeny remain true to type. The new variety must be sufficiently homogenous so that during the course of its sexual reproduction or vegetative propagation in large, i.e., commercial quantities, any variations in the commercial crops are predictable and commercially acceptable.

The primary method for determining if an application for a PBR certificate will be granted is the assessment of the novel plant variety's distinctness, uniformity, and stability (DUS) in comparative tests and trials with suitable reference varieties. The selection of the reference varieties and the organization of the trial designs must be done in accordance with test guidelines published by UPOV, and the PBR application must contain photographs of the new and reference varieties as specified in the Canadian PBRA and guidelines.

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While many UPOV countries have state-run testing systems for assessing PBR candidates, Canada has a breeder-run testing system in which the trials are conducted by the breeder and/or applicant, its agent, or by someone contracted by the applicant. The PBRO conducts a review of the applicant's data as well as one or more independent onsite trial examination(s) to verify the DUS results. It is important to note that the Canadian PBRA requires the submission of one year of testing data for asexually propagated plant varieties, and two years of testing data and independent site examination for sexually propagated (i.e., seed-sown) plant varieties. Another important component of the Canadian system is the publication, in the PBRO's *Plant Varieties Journal,* of trial designs, data, and photographs of the novel variety in comparison to the reference varieties, for public and/or peer information and opportunity for input regarding the new variety's DUS prior to the granting of a PBR certificate.

It should also be noted that a registration under the Canadian Seeds Act is a requirement for the newly certified PBR plant variety before it can be commercially sold and distributed within Canada and before it can be exported from Canada.

After a PBR certificate has been issued, the PBRO may grant compulsory licenses to third parties upon their application to ensure that the PBR-certified variety is made available to the public at reasonable prices, is widely distributed, and maintained in quality. In such circumstances, the holder of the PBR certificate is required to make propagating material available to the third-party holders of the compulsory licenses for which they will receive remuneration. In addition, the holder of the PBR certificate is required to maintain propagating material of the PBR-certified variety for the eighteen-year term of the certificate.

PBR Applicant Criteria and Application Stipulations

A breeder, its employer, or an entitled person (e.g., a licensee) may apply for a PBR certificate. The applicant must be a Canadian citizen or a resident or alternatively have a registered office in Canada. Citizens or residents of UPOV member countries may also apply for Canadian PBR certificates but must use a Canadian agent to file the application and correspond with the PBRO regarding prosecution of the PBR application, its granting, and maintenance.

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Sales of the new variety in Canada are not permitted before filing a PBR application. In the case of an international filing for PBR protection in Canada, such applications must be filed within twelve months of the first filing in a UPOV member country. In such cases, the Canadian application will be given the foreign priority date with the effect being that sales in Canada are permissible as of the foreign filing date.

PBR-Related Costs

The PBRO fee to (a) file and examine a PBR application is Can$1,000, (b) issue a PBR certificate is Can$500, and (c) maintain a PBR certificate is Can$300 annually for the eighteen-year term of the PBR certificate from the date of its issue. Accordingly, the cost to file, issue, and maintain a PBR certificate in Canada for a novel variety will be at least Can$6,600 for the PBRO fees plus the agent's costs to file and prosecute the application through to issuance of the certificate and pay annual maintenance fees.

PBR-Infringing Acts

The following acts by a third party will infringe a Canadian PBR certificate:

1. unauthorized selling or offering to sell, exchanging, or transferring possession of propagating material of a PBR-certified variety;
2. unauthorized production of a PBR-certified variety for sale as planting seed or propagation material; or
3. unauthorized importation of a PBR-certified variety into Canada. [10]

The holder of a PBR certificate is entitled to undertake legal actions against the infringing parties and receive compensation and relief against the infringing acts.

Exemptions and Limitations for PBR Monopolies in Canada

Canada's PBRA is based on the 1978 UPOV convention that contained the following exemptions to PBR certificate holders' monopoly over their novel plant varieties. A first exemption is referred to as the *farmer's rights*[11] to retain and carry-over portions of the crop seed produced from a PBR-certified variety for planting the following year with the proviso that the farmer purchased the PBR-certified variety from the PBR certificate holder.

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A second exemption is referred to as *brown bagging*,[12] which occurs when a farmer who is legally entitled to carryover a portion of his production of a PBR-certified variety for his or her own use provides excess leftover seed to his neighbors. While such brown bagging is considered to be an unauthorized practice, the terminology regarding farmer's rights in the 1978 UPOV convention and as promulgated in the Canadian PBRA is unclear.

A third exemption is referred to as an *innocent bystander*[13] exemption, which occurs when the pollen from a PBR-certified variety growing in an authorized grower's field is carried by wind into adjacent third-party fields where it crosspollinates with another variety, thereby transferring one or more of PBR-protected novel traits to a third party's crop. The answers to questions regarding compensation, if any, due to the PBR certificate holder in such situations are not readily apparent under the 1978 UPOV convention or in the Canadian PBRA.

The fourth exemption is referred to as the *breeder's exemption*[14] and allows a plant breeder to use a PBR-certified variety once, and once only, in a new breeding program. The use of a PBR-certified variety a second time in a breeding program (e.g., in second generation, third generation, or further generation crosses) is considered a repeated use and not allowable under the current Canadian PBRA.

UPOV recognized the deficiencies in the 1978 convention regarding the above exemptions and significantly clarified the language and eliminated or limited the scope of the above-noted exemptions in the 1991 convention. The Canadian government conducted an extensive plant breeders' rights consultation[15] with Canadian stakeholders in mid-2004 through early-2005 to determine if the UPOV 1991 convention should be adopted and promulgated in Canada.

However, no action has yet been taken by the Canadian government toward this end as of July 2008 and, at this time, there are no clear indications if and when the 1991 UPOV convention will be promulgated in Canada.

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The United States

In comparison to Canada, intellectual property (IP) protection for novel plants produced by plant breeders can be secured via (a) a plant patent for an asexually reproducible variety under the U.S. Plant Patent Act[16] or (b) a plant variety protection certificate (PVP certificate) under the U.S. Plant Variety Protection Act (PVPA).

The U.S. Plant Patent Act (1930)

The statutes governing the content and format of plant patent applications, their submission, prosecution, allowance, and issue are outlined in (a) the U.S. Consolidated Patent Laws[17] and (b) the U.S. Consolidated Patent Rules[18] and are under the purview of the United States Patent and Trademark Office (USPTO). A U.S. plant patent is issued with one claim only that describes the distinguishing characteristics of the novel plant being claimed.

In general terms, U.S. plant patents provide breeders with protection for the exclusive reproduction, use, and sale of the novel whole plant, produced through breeding or naturally occurring, for a period of twenty years from the filing date of the U.S. patent application. U.S. plant patents, however, do not provide protection for plant parts (e.g., propagules or cuttings, genes, or traits) and, furthermore, do not provide protection against sexual reproduction by third parties (i.e., via seed production) of the novel plants. Consequently, the scope of legal protection provided by U.S. plant patents is rather narrow and cannot be extended to germplasm or the products of biotechnology.

The USPTO fee to (a) file a U.S. Patent is US$80 for a small-entity applicant (i.e., a non-profit organization or a small business with less than 500 employees) and US$160 for a large-entity applicant, (b) issue a U.S. plant patent is US$550 for a small-entity applicant and US$1,100 for a large-entity applicant, and (c) maintain the plant patent through the end of its term is US$3,500 for a small-entity applicant and US$7,000 for a large-entity applicant, payable at three, four-year intervals. Accordingly, the USPTO fees to file, issue, and maintain a plant patent in the U.S. will be at least US$4,130 for a small-entity applicant and US$8,260 for a large-entity applicant, plus the agent's costs to file and prosecute the application through to issuance of the patent and for attending to the three maintenance fee payments.

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The U.S. Plant Variety Protection Act (1970)

The PVPA was drafted and enacted in the U.S. in 1970 to provide plant breeders with similar scope and quality of IP protection for novel plants that reproduced sexually as provided by the UPOV conventions. The United States became a member of UPOV in 1981 and became party to the 1991 UPOV convention in 1999. Consequently the granting and protection of plant breeders' rights according to the UPOV convention are governed under the PVPA by the Plant Variety Protection Office (PVPO), which is an agency of the United States Department of Agriculture (USDA).

PVPA Features and Stipulations

Although the PVPA is generally modeled after the other U.S. patent laws, it is consistent with the UPOV conventions and includes the UPOV criteria for registration of new varieties such as that new varieties have a distinctive appearance from all other varieties of the species, uniformity among all individuals of the new variety, and generational stability. As under the Canadian PBRA, all categories of the plant kingdom qualify for a plant variety protection (PVP) certificate except for algae, bacteria, and fungi.

PVP certificates are granted on a first-to-file basis as compared to the first-to-invent basis currently in use at the U.S. patent office. The granting of a PVP certificate is based on the PVPO's examination and evaluation of merits of the application contents as filed. Onsite examination of trials comparing the new variety with reference varieties is not a PVPA requirement, but will be done if so requested by the applicant.

Another key difference from the Canadian PBRA is that PVPA applicants must deposit at least 3,000 seeds of the new variety with a USDA-approved depositary within three month of the PVPA application filing date.

PVP applications must be filed within twelve months of the first commercial sales of the new variety in the United States and/or within four years of commercial sales in any foreign jurisdiction. A PVP certificate provides the holder the legal right to exclude others from selling or offering for sale; from reproducing, importing, or exporting the novel variety for a period of twenty years from the date of the certificate's issue; and for a twenty-five-year period in the case of a novel tree or vine variety.

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Most significant with respect to the Canadian PBRA is that the current form of the PVPA corresponds to the 1991 UPOV convention, which clarified and restricted the scope of the farmer's exemption and the breeder's exemption. Under the current PVPA, U.S. farmers are entitled to carryover PVPA-certified seed for their planting use only during the next growing season but are prevented from brown bagging excess seed. As in Canada, the PVPA allows a plant breeder to use a PBR-certified variety once, and once only, in a new breeding program. The use of a PBR-certified variety a second time in a breeding program (e.g., in second generation, third generation, or further generation crosses) is considered a repeated use and not allowable under the current PVPA. However, the PVPA explicitly prevents the use of a protected variety in the production of a hybrid (as opposed to developing a hybrid in a breeding program).

The PVPA fee (a) to file an application is US$5[18], (b) for searching and examining the application is US$3,864, and (c) for allowance and issue of the PVP certificate is US$786, for a total of US$5,168 plus the agent's costs to file and prosecute the application to grant the certificate. The PVPA does not require the payment of post-issue annual maintenance fees.

The key differences and similarities between the Canadian Plant Breeders' Rights Act, the U.S. Plant Patent Act, and the U.S. Plant Variety Protection Act are summarized in Table 1.

Utility Patents

Although similar language is used to define the word *invention* in the Canadian and United States patent acts, legal interpretations of the definitions by the supreme courts in the two countries are very different and significantly impact the scope of IP protection available for novel plant technologies and novel plants that may be produced.

The Canadian Patent Act states that an invention, "means any new and useful art, process, machine, manufacture or compositions of matter, or any new and useful improvement in any art, process, machine manufacture or composition of matter."[19]

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Table 1: Comparison of the Canadian Plant Breeders' Rights Act, the U.S. Plant Patent Act, and the U.S. Plant Variety Protection Act.

	Canada	USA	
	PBRA	**PVPA**	**PPA**
Protects			
All plant species except algae, bacteria, and fungi	Yes	Yes	Yes
Asexually propagated varieties	Yes	Yes	No
Sexually propagated varieties	Yes	No	Yes
Whole plants	Yes	Yes	Yes
Seeds	Yes	No	Yes
Propagules (e.g., cuttings, tissue culture, somatic embryos)	Yes	Yes	No
Application Bars			
Domestic applications	No sales prior to filing	Sales more than 12 mos. prior to filing	Sales more than 12 mos. prior to filing
Foreign applications	Sales more than 12 mos. prior to filing	Sales more than 12 mos. prior to filing	Sales more than 48 mos. prior to filing
Key Features			
On-site trial examination	Yes	No	No
Deposit of the novel variety with an approved depository	No (holder must maintain the variety)	No	Yes, at least 3,000 seeds
Term of protection	18 yrs from certificate issue	20 yrs from application filing date	(1) 25 yrs from certificate issue for trees and vines (2) 20 yrs from certificate issue for all other species
Minimum office fees (agents' and prosecution fees are additional)	Can$6,600	(1) US$3,500 for a small entity (2) US$7,000 for a large entity	US$5,168
Exemptions			
Farmer's exemption	Yes	No	Yes
Breeder's exemption	Yes	No	Yes
Research exemption	Yes	Yes	No
Brown bagging	Yes	No	Yes
Innocent bystander	Yes	No	No

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The U.S. Patent Act reads, "whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirement of this title."[20]

The question of whether or not utility patents are available in the U.S. for living biological materials was addressed by the U.S. Supreme Court in *Diamond v. Chakrabarty*.[21] Chakrabarty filed a patent application, assigned to his employer General Electric Co. (GE), for his invention of a genetically engineered bacterium capable of breaking down crude oil, the process of making the genetically engineered bacterium, and inoculum compositions comprising a carrier and the genetically engineered bacterium. Chakrabarty's patent application was rejected by the USPTO. GE appealed the rejection to the USPTO Board of Appeals. The appeal was denied and the Board of Appeals upheld rejection of the patent application on the ground that living things are not patentable subject matter under definition of *invention* as written in 35 C.F.R. 101. GE appealed the Board of Appeals decision to the Court of Customs and Patent Appeals, which reversed the rejections while concluding that the fact that microorganisms are alive is without legal significance for purposes of the patent law.

The U.S. Supreme Court upheld the Court of Customs and Patent Appeals decision and provided the following statements in the written decision, which set the foundation for a broad and wide scope of patent protection available in the United States for living organisms and the products of biotechnology:

> HELD: A live, human-made micro-organism is patentable subject matter under 35 C.F.R. 101. Respondent's microorganism constitutes a "manufacture" or "composition of matter" within that statute.[22]
>
> (a) In choosing such expansive terms as "manufacture" and "composition of matter," modified by the comprehensive "any," Congress contemplated that the patent laws should be given wide scope, and the relevant legislative history also supports a broad construction. While laws of nature, physical phenomena, and abstract ideas

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> are not patentable, respondent's claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter a product of human ingenuity "having a distinctive name, character [and] use."
>
> (b) The passage of the 1930 Plant Patent Act, which afforded patent protection to certain asexually reproduced plants, and the 1970 Plant Variety Protection Act, which authorized protection for certain sexually reproduced plants but excluded bacteria from its protection, does not evidence congressional understanding that the terms "manufacture" or "composition of matter" in 35 C.F.R. 101. do not include living things.[23]

In summary, the consequence of the *Diamond v. Chakrabarty* (1980) U.S. Supreme Court decision is that it made it possible to successfully obtain in the United States patent claims protecting novel gene constructs for insertion into plant genomes for the purpose of creating novel plants; processes for creation of novel plants; processes for production of novel plants, novel plants, plant parts, and propagules; novel traits expressed by plants produced by such processes; novel metabolites and compounds produced by novel plants; novel compositions containing novel metabolites and/or compounds produced by novel plants, and novel uses and methods of use of novel plants, plant parts, propagules, their compounds, and/or metabolites; and compositions containing their compounds and/or metabolites. The criteria that will be used by the USPTO during its assessments of the patentability of such claims will be strictly based on the novelty, nonobviousness, and utility of the subject matter being claimed.

The situation in Canada is not as clear and straightforward. There have been three significant Canadian Supreme Court decisions during the past twenty years that served to confuse and then slightly clarify the options available for patenting life forms and the products of biotechnology in Canada. These decisions are:

1. *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*[24]
2. *Harvard College v. Canada (Commissioner of Patents)*[25]
3. *Monsanto Canada Inc. v. Schmeiser*[26]

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The *Pioneer Hi-Bred v. Canada* case was the first legal test in Canada regarding the patenting of life forms and products of biotechnology under the Canadian Patent Act. Pioneer Hi-Bred filed a Canadian patent application for a novel genetically engineered soybean variety (variety 0877) in 1983. The application was rejected by the Canadian patent office on the grounds that a new variety developed from an artificial crossbreeding program did not constitute an invention as defined by the patent act, and its decision was subsequently affirmed on appeal by the Canadian Commissioner of Patents.

Pioneer Hi-Bred appealed the rejections to the Federal Court of Appeal, which affirmed the examiner's and commissioner's rejections. Pioneer Hi-Bred then appealed the rejections to the Supreme Court of Canada. The Supreme Court recognized that the real issue in this case was the patentability of life forms.[27]

However, the Supreme Court chose to avoid dealing with this issue at that time by finding that, while the patent disclosure described the basic materials used for the crossbreeding component of the invention, there was no indication of the genetic engineering steps undertaken to develop soybean variety 0877 and, therefore, the application did not meet the disclosure requirement of the patent act.

Furthermore, the Supreme Court stated that a deposit of soybean variety 0877 did not constitute an adequate disclosure, and for those reasons, denied Pioneer Hi-Bred's appeal. As such, a clear answer was not provided in that decision to the question of whether human intervention in the reproduction of a life form constituted a patentable invention.

The *Harvard v. Canada* case was a landmark case in which the Canadian Supreme Court considered whether life forms were patentable in Canada. The Canadian patent office decided that, while process claims for producing and manufacturing a genetically engineered mouse were patentable, product claims for the genetically engineered mouse were not.

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Its decision was upheld by the Commissioner of Patents. Harvard College appealed to the Federal Court Trial Division, the Federal Court of Appeals, and, finally the Supreme Court. The Supreme Court wrote in its decision denying the Harvard appeal, that the main question it considered was whether the words *manufacture* and *composition of matter,* within the context of the patent act, are sufficiently broad to include higher life forms. In answer to that question, they wrote that:

> while the definition of "invention" is broad, Parliament did not define "invention" as "anything new and useful made by man."[28]
>
> The word "manufacture" ("fabrication"), in the context of the Act, is commonly understood to denote a non-living mechanistic product or process, not a higher life form."[29]
>
> The words "composition of matter" ("composition de matières") as they are used in the Act do not include a higher life form such as the oncomouse.[30]
>
> Just as "machine" and "manufacture" do not imply a living creature, the words "composition of matter" are best read as not including higher life forms.[31]
>
> Higher life forms can not be conceptualized as mere "compositions of matter" within the context of the Patent Act.[32]
>
> The current Patent Act does not clearly indicate that higher life forms are patentable. (page 5)

The immediate consequence of the Supreme Court decision in the *Harvard v. Canada* case was that the Canadian Intellectual Property Office began applying this decision to reject all patent claims to all higher life forms including animals, plants, and fungi.

Monsanto v. Schmeiser was making its way through the Canadian courts at about the same time as *Harvard v. Canada*. The issue in *Monsanto v. Schmeiser* was whether a

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farmer, i.e., Schmeiser, infringed Monsanto's Canadian Patent No. 1,313,830 by growing genetically engineered Round-Up resistant canola from seed that he did not purchase from Monsanto. The claims of CA 1,313,830 protected among other things (1) a unique chimeric plant gene and (2) a glyphosate-resistant plant cell comprising the chimeric plant gene.

The lower Canadian courts previously ruled and affirmed that Schmeiser infringed Monsanto's CA 1,31,830 patent. Schmeiser appealed to the Supreme Court on the ground that Monsanto's patent was invalid because the *Harvard v. Canada* decision made it clear that higher life forms such as plants were not patentable. However, the Supreme Court ruled that Monsanto's CA 1,313,730 patent was valid because no claims were issued for "a plant" but instead, for "genes" and "plant cells."

In its decision, the Supreme Court wrote that:

> The patent is valid. The respondents did not claim protection for the genetically modified plant itself, but rather for the genes and modified cells that make up the plant. [33]
>
> A purposive construction of the patent claim recognizes that the invention will be practiced in plants regenerated from the patented cells, whether the plants are located inside or outside a laboratory.[34]
>
> Whether or not patent protection for the gene and cell extends to activities involving the plant is not relevant to the patent's validity.[35]

The consequence of *Monsanto v. Schmeiser* is that the door is open for patent protection of higher life forms and the biotechnology products in Canada and provides at least some assurance that genetically engineered plants can be protected in Canada. However, great care will have to be taken in drafting the specification and claims in Canadian patent applications with awareness of the guidelines put forward by the three Supreme Court decisions referred to.

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First, in reference to the *Pioneer Hi-Bred v. Canada* case, the steps required to produce a novel plant or plant component part must be described in explicit detail. Second, in reference to *Harvard v. Canada*, claims for genetically engineered higher life forms such as whole plants and whole reproductive units such as seeds, bulbs, tubers, and such, will likely be rejected by the patent examiners.

However, it should be possible, in reference to *Monsanto v. Schmeiser*, to secure claim allowance for novel plant genes and plant cells thereby gaining protection for plants wherein they are resident and expressed. However, another strategy worth considering for Canada, is to file:

1. patent applications with (a) process claims to protect methods for developing and producing novel plants, (b) product claims to protect novel genes and gene constructs produce novel plants, and (c) product claims to protect plant cells containing novel genes and/or gene constructs; and

2. PBRA applications to protect reproductive material (e.g., seeds, tubers, bulbs, corms, and somatic embryos) produced from the products of biotechnology.

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United States

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5. 7 U.S.C. §§ 2321-2582 (1970).
6. 35 U.S.C. §41; 66 Stat. 792 (1952).
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