

# NGT Plants: Patent Eligibility and Protection in Canada

March 05, 2024

On February 7, 2024, the European Parliament voted in favour of a controversial proposal to ban patents for plants obtained by “New Genome Techniques” (NGT plants), such as gene editing via the CRISPR-Cas9 system. The wording of the proposed ban appears to be broad, extending to “NGT plants, plant material, parts thereof, genetic information and process features they contain.”

Superficially, Canada’s court-created exclusion on the patentability of plants seems to align with the intent of the European Parliament. In practice, however, patent claims can often be obtained in Canada that could cover infringing activities including growing genetically manipulated plants. Process and method claims also tend to be favourably assessed and do not face exclusion merely due the presence of “essentially biological” steps.

This article provides an overview of patentability considerations for NGT plants and related technologies.

## **NGT plants are not patentable per se but could infringe claims to NGT-modified genes and cells**

The Supreme Court of Canada (SCC) considered patentability requirements for claims directed to a new soybean variety developed by artificial (but otherwise traditional) breeding techniques in the 1989 Pioneer Hi-Bred decision.<sup>1</sup> **The SCC disposed of the issue solely on the basis of insufficient disclosure, holding that the skilled person could not arrive at the same result as the inventors due to the unpredictable nature of traditional breeding methods.**

A categorical exclusion of plants as subject matter for patent claims was established in 2002 in a 5-4 split decision of SCC relating to a transgenic oncomouse developed by Harvard College - the so-called Harvard Mouse decision.<sup>2</sup> The majority found that claims to “higher life forms”, including plants and animals, were not patentable stating that:

Only Parliament has the institutional competence to extend patent rights or another form of intellectual property protection to plants and animals and to attach appropriate conditions to the right that is granted.<sup>3</sup>

The practical effect of this categorical exclusion was significantly lessened by the decision of the SCC two years later in *Monsanto v. Schmeiser*.<sup>4</sup> A commercial grower who had never purchased Roundup Ready (i.e. glyphosate-resistant) canola nor obtained a licence from Monsanto was nevertheless found to have produced a crop that was 95-98 Roundup Ready Canola. The SCC distinguished over its earlier precedent in *Harvard Mouse*, holding claims to a chimeric gene and cells comprising it to be patentable subject matter. The SCC acknowledged that:

Huge investments of energy and money have been poured into the quest for better seeds and better plants. One way in which that investment is protected is through the Patent Act giving investors a monopoly when they create a novel and useful invention in the realm of plant science, such as genetically modified genes and cells.<sup>5</sup>

**In a split portion of the decision, the majority disagreed with the minority's view that claims to chimeric genes and constructs were limited to laboratory activities.**<sup>6</sup> The SCC stated that:

Whether or not patent protection for the gene and the cell extends to activities **involving the plant is not relevant to the patent's validity. It relates only to the factual circumstances in which infringement will be found to have taken place.**<sup>7</sup>

The majority endorsed an expansive approach to the concept of infringement, noting that many patented inventions are part of broader unpatented structures or processes.<sup>8</sup> The majority held that the grower had used the patented gene and cell, thereby depriving Monsanto of full enjoyment of its patent monopoly.<sup>9</sup> The SCC upheld a finding of infringement.<sup>10</sup>

The majority stated that Parliament could step in to constrain patent rights in this area if it wished do so:

Where Parliament has not seen fit to distinguish between inventions concerning plants and other inventions, neither should the courts.<sup>11</sup>

During examination, the Canadian Intellectual Property Office (CIPO) distinguishes **between patent-eligible "lower" life forms and non-eligible "higher" life forms, including within the latter category plants and plant parts, such as cuttings, tubers, fruits, and seeds.**<sup>12</sup> Claims directed to this subject matter are routinely objected to during examination for lack of patentable subject matter.

However, CIPO also indicates that a claim to an "animal feed comprising X" may be considered patent-eligible subject matter even if X is higher life form if the claim is construed to be a "use of X" or if X is processed or modified to a significant degree. This provides some leeway to claim products in particular circumstances.

A key distinction of "new genome techniques" as compared to techniques for producing conventional genetic modified organisms (GMOs) is the significant reduction or absence

of extraneous genetic elements in the NGT-modified genome of the targeted cell. When claims to NGT-derived edited genes or plant cells containing them are sought, much will **depend on the inventiveness of the technical features of edited gene itself**. Provided that standard criteria for patentability are met, SCC precedent from Schmeiser suggests that claims to NGT-modified genes and plant cells should be eligible subject matter and could be infringed by parties storing and sowing seeds, growing plants, and harvesting material from NGT varieties.

## **Claims to processes for obtaining NGT plants are available in Canada even if essentially biological steps are included**

In Europe, processes are held to be “essentially biological” (and therefore patent-ineligible) if they contain a traditional breeding step within them, regardless of whether or not they recite additional features of a technical nature.<sup>13</sup>

The Pioneer Hi-Bred decision of the SCC confirmed that methods of traditional plant breeding that occur wholly in accordance with the laws of nature are not patentable subject matter in Canada.<sup>14</sup> **However, Canada does not have a comparable outright** exclusion on the patentability of all processes and methods that merely include traditional breeding steps amongst other features. Indeed, the SCC in Schmeiser acknowledged that many patentable inventions make use of natural processes in order to work.<sup>15</sup> Precisely what is enough to meet the threshold for patent eligibility has not been tested.

During examination, CIPO considers a process or method to produce a plant to be **eligible subject matter if it encompasses “significant human intervention”, such as “more than traditional breeding techniques”**.<sup>16</sup> The technical feature must be an essential feature. CIPO provides an example of a patent-eligible claim that includes steps of genetic transformation, traditional crossing, selection, and backcrossing.

Methods and processes involving NGTs are self-evidently technical and are therefore unlikely to be problematic from the perspective of patentable subject matter even when they include steps of traditional breeding or selection.

## **NGT plant varieties may be amenable to protection via Plant Breeders’ Rights**

Plant variety protection is available in Canada in the form of Plant Breeders’ Rights (PBR). Genetically manipulated plants are not excluded from PBR protection, and it is therefore possible that an NGT plant variety could be susceptible to both patent and PBR protection. The PBR system is based primarily on morphological distinctness. Therefore, an NGT plant variety will be most amenable to PBR protection when its genetic differences yield observable distinguishing characteristics.

For conventional GMOs, the Canadian Plant Breeders’ Rights Office indicates that field trials to support a PBR application must include a reference variety that is the most similar and also contains the same construct, if applicable.<sup>17</sup> The guidelines do not

distinguish between GMOs and NGTs and it should be assumed that a similar test requirement will apply for NGTs.

## Conclusion

Canada is a favourable jurisdiction for pursuing patent protection related to NGT plants. Despite a categorical exclusion on plants as patentable subject matter, meaningful patent claims extending to plants and related technologies can often be obtained and have been held enforceable by the SCC.

## Footnotes

<sup>1</sup> Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents) 1 SCR 1623 [Pioneer Hi-Bred].

<sup>2</sup> Harvard College v. Canada (Commissioner of Patents) 2002 SCC 76 [Harvard Mouse].

<sup>3</sup> Ibid at para 199.

<sup>4</sup> Monsanto Canada Inc. v. Schmeiser 2004 SCC 34 [Schmeiser].

<sup>5</sup> Ibid at para 90.

<sup>6</sup> Supra note 4 at paras 19 and 89.

<sup>7</sup> Supra note 4 at para 24.

<sup>8</sup> Supra note 4 at para 43.

<sup>9</sup> Supra note 4 at para 71.

<sup>10</sup> Supra note 4 at para 97.

<sup>11</sup> Supra note 4 at para 94.

<sup>12</sup> [Manual of Patent Office Practice, online](#): The Canadian Intellectual Property Office [s. 23.02.01](#).

<sup>13</sup> [Guidelines for Examination in the European Patent Office, online s5.4.2](#)

<sup>14</sup> Supra note 1 at p1634.

<sup>15</sup> Supra note 4 at para 91.

<sup>16</sup> Supra note 12 [s. 23.02.03](#).

[17 Guidelines for Conducting Plant Breeders' Rights Comparative Tests and Trials, online.](#)

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