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The Differences between Plant Variety Protection and Patent Protection on Plants[1]

Summary

This paper summarizes the differences between genetic engineering and traditional plant breeding, plant variety protection and patent protection, and patents on plants and patents on plant-related inventions. First, genetic engineering allows scientists to insert genetic material from one species into another in order to create an organism that expresses particular characteristics. Traditional or conventional breeding, in contrast, allows breeders to develop new plant varieties by the process of selection and seeks to achieve expression of genetic material that is already present within a species. Patent protection provides a more absolute set of rights to breeders than does plant variety protection. Finally, plant patents and patents on plant-related inventions provide breeders with largely the same exclusionary rights over particular plants.

Conventional Plant Breeding versus Genetic Engineering

Today, new plants can be created in two different manners: through genetic engineering or conventional breeding. Genetic engineering and conventional or "traditional" plant breeding differ both in the processes they entail and the products they generate. "As a general rule, conventional breeding develops new plant varieties by the process of *selection*, and seeks to achieve expression of genetic material that is already present within a species."[2] Conventional breeding employs processes that occur in nature, such as sexual and asexual reproduction, with the resulting plant product emphasizing certain characteristics. However, these characteristics are not technically "new" for the species; "the characteristics have been present for millennia within the genetic potential of the species."[3]

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[1] Public Citizen's Global Access to Medicines Program. For more information, please contact Peter Maybarduk at pmaybarduk@citizen.org; Bucru Kilic at bkilic@citizen.org; or Hannah Brennan at hbrennan@citizen.org.

[2] Michael K. Hansen, GENETIC ENGINEERING IS NOT AN EXTENSION OF CONVENTIONAL PLANT BREEDING, CONSUMER POLICY INSTITUTE/CONSUMERS UNION 1 (2000). However, as Hansen points out, there are exceptions to this general rule, which include species hybridization, wide crosses, and horizontal gene transfer.

[3] *Id.*

Genetic engineering, in contrast, enables scientists to insert carefully selected genetic material into a particular organism.[4] This process does not occur in nature, and it allows researchers to more precisely control the expression of certain genes. Furthermore, the genetic material inserted into a particular plant's genome (the genetic material of an organism) does not have to be present in the original species.[5] For example, researchers once introduced an antifreeze gene from Artic flounder into tobacco and tomato plants.[6] Genetic engineering also allows scientists to create *new* genetic material, the expression of which leads to new plant characteristics.

Accordingly, conventional breeding and genetically engineering plants differ in three principal respects. First, while traditional breeding only permits the movement of genetic material between different varieties of the same species, closely related species, or closely related genera, genetic engineering allow scientists to insert genetic material from one species into a completely distinct species. Second, genetic engineering allows scientists to create new, non-naturally occurring genetic material, and then insert that material into plants' DNA for expression. Conventional breeders must generate new plants from an existing pool of genetic material.[7] Third, genetic engineering enables scientists to more precisely control characteristics of the resulting product than do conventional breeding techniques.[8]

Patent Rights versus Plant Variety Protection

What is a Patent?

A patent grants an individual the right to exclude all other people from manufacturing, using, or selling the product on which the patent was granted. Although patent law differs from country to country, 160 nations have signed the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and, accordingly, recognize the minimum standards of patent protection sets forth in this agreement.

In terms of subject matter, the TRIPS agreement requires nations to make patents available for "any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[9] The agreement further explains that the terms "inventive step" and "capable of industrial application" may be deemed by a member nation to be synonymous with the terms "non-obvious" and "useful,"

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[4] *Id.*; Peggy G. Lemaux, *Genetically Engineered Plants and Foods: A Scientist's Analysis of the Issues (Part I)*, 59 Ann. R. Plant. Bio. 771, 773 (2008).

[5] Hansen, *supra* note 2, at 1-2.

[6] R. Hightower, et al., *Expression of Antifreeze Proteins in Transgenic Plants*, 17 PLANT MOL. BIOL. 1013 (1991). These products were never commercialized.

[7] Note that genetic mutation can occur in nature, therein creating "new" genetic material. However, these mutations are not the direct and intended consequences of conventional breeding techniques.

[8] Lemaux, *supra* note 4, at 774.

[9] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 1197, 1869 U.N.T.S. 299.

respectively.[10] The agreement then lists a number of categories of inventions that member states may exclude from patentability, including "diagnostic, therapeutic and surgical methods for the treatment of humans or animals; plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."[11] Nevertheless, member nations may choose to make patents available for such inventions. Some nations chose to make patents on plants available.

Under the TRIPS agreement, a patent confers on its holder the exclusive right to: make, use, offer for sale, sell, or import the product or process protected by that patent.[12] Patent owners also have the right "to assign, or transfer by succession, the patent and to conclude licensing contracts."[13] The minimum term of patent protection provided by the TRIPS agreement is twenty years, counted from the filing date.[14] Although the TRIPS agreement does afford limited exceptions to these exclusive rights (namely, the TRIPS agreement allows nations to issue compulsory licenses on particular patented products or processes), the patent rights conferred by the TRIPS agreement are strong.

What is Plant Variety Protection?

Plant variety protection (PVP) grants breeders some degree of exclusive rights over the vegetative and reproductive materials of plant varieties they have invented or discovered. Because the objective of PVP systems is protection of the propagating materials of protected varieties, plant breeders' rights do not cover "technical processes for the production of those varieties."[15] In other words, breeders cannot obtain exclusive rights over particular breeding methods through PVP systems, whereas they could, hypothetically, obtain a patent on such a process under a nation's patent laws.

Plant Variety Protection systems vary widely from country to country. However, the International Convention for the Protection of New Varieties of Plants (UPOV) has attempted to create an international standard for Plant Variety Protection. Currently, 72 nations are UPOV signatories: 52 have ascended to the 1991 version of the UPOV, 19 to the 1978 version of the UPOV, and 1 to a 1972 version.

Although the 1991 version of the UPOV grants significantly greater rights to plant breeders than the 1978 version, both grant breeders the exclusive right to produce the protected plant for purposes of commercial marketing, to offer the plant for sale, and to market the plant.[16] While

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[10] *Id.*
[11] *Id.*
[12] *Id.* art. 28.
[13] *Id.*
[14] *Id.* art. 33.
[15] Claudio Chiarolla, *Commodifying Agricultural Biodiversity and Development-Related Issues*, 9 J. WORLD INTELL. PROP. 25, 28 (2006).
[16] International Convention for the Protection of New Varieties of Plants art. 14(1)(a), Mar. 19, 1991; International Convention for the Protection of New Varieties of Plants art. 5(1), Oct. 23, 1978.

the 1978 UPOV does not extend breeders' exclusive rights to materials harvested from the plant variety, the 1991 UPOV gives breeders some control over the harvests of protected plants.[17] The term of protection granted by the two versions of the UPOV also differs: the 1978 Act requires a minimum term of protection of fifteen years (with the exception of vines, forest trees, fruit trees and ornamental trees, which are to be protected for no less than eighteen years),[18] while the 1991 UPOV requires a twenty-year term of protection (with a twenty-five year term for tree and vine varieties).[19]

To qualify for protection under the 1991 and 1978 UPOVs, a plant variety must be new, distinct from existing or commonly known varieties, homogenous or uniform, and stable.[20] A plant variety cannot qualify as "new" if it has been sold on the market for more than a specified period of years prior to the date of application for protection. The UPOV defines "distinct" as "clearly distinguishable by one or more important characteristics from any other variety whose existence is a matter of common knowledge at the time when protection is applied for."[21] Homogeneity refers to "the particular features of [the plant's] sexual reproduction or vegetative propagation,"[22] and the UPOV Guidelines state that, to qualify as homogeneous, a variation displayed by a plant variety must be "as limited as necessary to permit accurate description and assessment of distinctness and to ensure stability."[23] Finally, the stability requirement "is a temporal one, requiring the breeder to show that the essential characteristics of its variety are homogeneous or uniform over time, even after repeated reproduction or propagation."[24]

Finally, both versions of the UPOV provide for certain exceptions and limitations to the exclusive rights they confer. Nevertheless, the scope of these exceptions and limitations is much greater in the 1978 UPOV. Briefly, the UPOVs provide for a breeders' exemption[25] and a farmers' privilege. The breeders' exemption precludes member states from granting breeders the right to authorize or refrain from authorizing other breeders' use of their protected variety to create new varieties or to market those new varieties.[26] In other words, breeders may not wield their rights to prevent other breeders from ***creating new varieties*** or marketing those

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[17] GAIA/ GRAIN, Ten Reasons not To Join UPOV, GRAIN (May 1998), http://www.grain.org/article/entries/1-ten-reasons-not-to-join-upov.

[18] International Convention for the Protection of New Varieties of Plants art. 8, Oct. 23, 1978.

[19] International Convention for the Protection of New Varieties of Plants art. 19(2), Mar. 19, 1991.

[20] International Convention for the Protection of New Varieties of Plants art. 6-9, Mar. 19, 1991; International Convention for the Protection of New Varieties of Plants art. 6, Oct. 23, 1978.

[21] International Convention for the Protection of New Varieties of Plants art. 6(1)(a), Oct. 23, 1978.

[22] *Id.* art. 6(1)(c).

[23] LAURENCE R. HELFER, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, INTELLECTUAL PROPERTY RIGHTS IN PLANT VARIETIES INTERNATIONAL LEGAL REGIMES AND POLICY OPTIONS FOR NATIONAL GOVERNMENTS 23, (2004), *available at* http://www.fao.org/3/a-y5714e.pdf.

[24] *Id.* at 23.

[25] International Convention for the Protection of New Varieties of Plants arts. 14(5)(a) & 15(1)(ii), Mar. 19, 1991; International Convention for the Protection of New Varieties of Plants art. 5(3), Oct. 23, 1978.

[26] *Id.*

new varieties. The farmers' privilege enables farmers to use the seeds (and other propagating materials) of protected plant varieties for noncommercial purposes without the breeders' prior authorization. However, the 1991 UPOV, unlike the 1978 UPOV, prohibits farmers from selling or exchanging seeds with other farmers for propagating purposes.[27]

Critical Differences between Plant Variety Protection and Patent Protection

Subject Matter

- As previously mentioned, the objective of plant variety protection systems is to grant breeders control over the *propagating* material of protected varieties. Thus, plant breeders' rights do not cover technical processes for the production of those varieties. In contrast, patent protection is available for both *products* and *processes*. Therefore, in a nation that grants patent protection for plants, a breeder could hypothetically obtain a patent on both the plant itself and the process used to make that plant.
- Moreover, plant variety protection focuses on the vegetative and reproductive materials of a plant—only that material is eligible for protection. In contrast, some patent protection systems allow breeders to obtain patents on both plants and the key genetic material expressed by those plants.
    - Thus, under PVP systems, plant genetic material remains unprotected and available to the public for further research and development. In patent systems, such genetic information can be removed from the public domain and held exclusively by one individual or corporation.

Scope

- The scope of the exclusive rights granted to a breeder under a TRIPS-compliant patent system is much greater than that of a typical plant variety protection system due to the exceptions and limitations present in most PVP systems.
- Although both systems grant breeders similar exclusionary rights (the exclusive right to produce, sell, and market), most PVP systems provide for important exceptions and limitations to these exclusive rights, such as the farmers' privilege and the breeders' exemption. Because TRIPS-compliant patent systems do not allow for similar exceptions and limitations, the scope of exclusive rights conferred by patent protection is more absolute than that provided by PVP systems.

Eligibility Requirements

- Qualification for protection is easier under PVP systems than under patent systems because plant breeders' rights are specifically crafted to accommodate the peculiar needs of plant breeding. "Therefore, the criteria of distinctness, uniformity and stability [] are generally adapted to the mode of reproduction of the variety and can provide more flexibilities than requirements for patentability."[28]
- Furthermore, "neither the equivalent of utility/industrial application, nor inventive step/non-obviousness is required [under PVP systems]. Thus, no definite amount of

[27] J. WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 141 (2000).
[28] Chiarolla, *supra* note 15, 29.

human intervention is necessary in order to qualify for protection. Therefore, in principle, plant varieties, including plants growing in the wild, may be eligible for protection simply if they are distinct from earlier known species."[29]

Can Plant Breeders' Rights and Patent Rights Overlap?

In short, yes. Some nations understand their PVP and patent systems as overlapping, and, accordingly, have allowed breeders to obtain plant variety protection and patent protection on the same exact plant. For example, the United States Supreme Court has held that a breeder can obtain a patent and PVP protection on the same plant without issue.[30]

Plant Plants versus Patents on Plant-related inventions

Put simply, a plant patent can be described as a patent on the plant as a whole, whereas a patent on a plant-related invention would be a patent on a particular aspect or feature of a plant, such as a particular plant gene.

Some patent systems allow individuals to obtain patents on both plants and features of those plants. For example, if a manufacturer creates a new gene that enables plants to become resistant to a certain type of pesticide and then implants that gene into a particular plant's genome, the manufacturer may be able to obtain patent protection on both the pesticide resistant ***gene*** and the ***plant genome*** into which it was inserted. The patent on the plant would prevent any person, other than the patent holder, to make, use, offer for sale, sell, or import the pesticide-resistant ***plant***. The patent on the gene would prevent any person, other than the patent holder, to make, use, offer for sale, sell, or import any organism containing that ***gene***. Thus, the patent on the gene—the plant-related invention—actually has a broader scope than the plant patent. Because the gene patent provides the patent holder with an exclusive right to the gene, any plant genome into which the gene is inserted becomes effectively patent protected. **The functional difference between patents on plants and plant-related inventions is largely non-existent. Therefore, even if a nation does not make patents on plants available, if that nation permits patents on plant-related matter, manufacturers will be able to obtain exclusive rights to the plants they sell in effectively the same way.**

Plant-Patent Rights in the United States versus Canada

A comparative case study helps clarify this point. The United States allows inventors to obtain patents on plants and plant-related inventions. On May 27, 1997,[31] the United States Patent and Trademark Office granted Monsanto a patent on: (1) **plants** that are tolerant to a particular type of herbicide, (2) the **genetically modified seeds** for such plants, (3) the **specific modified genes**, (4) the **method of producing the genetically-modified plants,** and (5) the **method of**

[29] *Id.*

[30] *J.E.M. Ag Supply, Inc. v Pioneer Hi-Breed Int'l, Inc*, 534 U.S. 124, 144 (2001).

[31] U.S. Patent No. 5,633,435.

controlling weeds by planting the herbicide-tolerant plant seed. The herbicide in question is called glyphosate, although it is better known by its trademarked name: Roundup®. This Monsanto patent protects a variety of plants that contain the herbicide-tolerant gene, including genetically-modified corn, wheat, rice, barley, soybean, cotton, sugarbeet, oilseed rape, canola, flax, sunflower, potato, tobacco, tomato, alfalfa, poplar, pine, eukalyptus, apple, lettuce, peas, lentils, grape and turf grasses. Glyphosate can be sprayed broadly in fields planted with the Roundup®-tolerant seed, killing weeds but not harming the resistant soybeans. The box below reproduces Monsanto's patent claims to the Roundup®-tolerant plants, genes, and method for creating such plants.

U.S. Patent No. 5,633,435—Glyphosate-Tolerant 5-Enolpyruvylshikimate-3-Phosphate[32]

1. An **isolated DNA molecule** which encodes an EPSPS enzyme having the sequence of SEQ ID NO:3.

2. A **DNA molecule of claim 1** having the sequence of SEQ ID NO:2.

3. A **DNA molecule of claim 1** having the sequence of SEQ ID NO:9.

. . .

15. A **method of producing genetically transformed plants** which are tolerant toward glyphosate herbicide, comprising the steps of:

a) inserting into the genome of a plant cell a recombinant, double-stranded DNA molecule comprising:

i) a promoter which functions in plant cells to cause the production of an RNA sequence,

ii) a structural DNA sequence that causes the production of an RNA sequence

. . .

iii) a 3' non-translated DNA sequence which functions in plant cells to cause the addition of a stretch of polyadenyl nucleotides to the 3' end of the RNA sequence;

where the promoter is heterologous with respect to the structural DNA sequence and adapted to cause sufficient expression of the polypeptide to enhance the glyphosate tolerance of a plant cell transformed with the DNA molecule;

[32] *Id.* (emphasis added).

b) obtaining a transformed plant cell; and

c) regenerating from the transformed plant cell a genetically transformed plant

which has increased tolerance to glyphosate herbicide.

. . .

24. A glyphosate-tolerant **plant cell** comprising a DNA molecule of claims 5, 8 or 10.

. . .

28. A glyphosate-tolerate **plant** comprising plant cells of claim 27.

29. A glyphosate-tolerant **plant** of claim 28 in which the promoter is from a DNA plant virus promoter.

30. A glyphosate-tolerant plant of claim 29 in which the promoter is selected from the group consisting of CaMV35S and FMV35S promoters.

31. A glyphosate-tolerant plant of claim 30 **selected from the group consisting of corn, wheat, rice, barley, soybean, cotton, sugarbeet, oilseed rape, canola, flax, sunflower, potato, tobacco, tomato, alfalfa, poplar, pine, eukalyptus, apple, lettuce, peas, lentils, grape and turf grasses**.

32. A **method for selectively controlling weeds in a field containing a crop having planted crop seeds or plants comprising the steps of**:

a) planting the crop seeds or plants which are glyphosate-tolerant as a result of a recombinant double-stranded DNA molecule being inserted into the crop seed or plant,

. . .

b) applying to the crop and weeds in the field a sufficient amount of glyphosate

herbicide to control the weeds without significantly affecting the crop.

The United States Court of Appeals for the Federal Circuit (Federal Circuit) has never questioned the validity of this Monsanto patent. In the early 2000s, Monsanto sued a number of farmers who purchased and planted Monsanto's patented soybean after these farmers saved and replanted the seeds from their initial soybean crop. The contract that the farmers signed when they initially purchased the soybeans specified that their purchase only covered

one planting season.[33] In other words, Monsanto granted the farmers a license to sow one season's worth of their patented soybean; any subsequent saving and replanting of their seeds would constitute patent-infringing conduct. After Monsanto sued, one of the farmers challenged the validity of the contract he signed with Monsanto. However, the Federal Circuit upheld the contract.[34]

In contrast with the United States, Canada does not offer patents on plants. Nevertheless, because Canada offers patents on *plant-related inventions*, Monsanto has been successful in preventing Canadian farmers from saving and replanting Monsanto seeds in the same way it has in the United States. The box below reproduces Monsanto's Canadian patent claims to the Roundup®-tolerant plant gene.

Canadian Patent No. 1,313,830

1. A chimeric plant gene which comprise:

(a) A promoter sequence which functions in plant cells;

(b) A coding sequence which causes the production of RNA, encoding a chloroplast transit peptide/5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) fusion polypeptide, which chloroplast transit peptide permits the fusion polypeptide to be important into a chloroplast of a plant cell; and

(c) A 3' non-translated region which encodes a polyadenylation signal which functions in plant cells to cause the addition of polyadenylate nucleotide to the 3' end of the RNA;

The promoter being heterologous with respect to the coding sequence and adapted to cause sufficient expression of the fusion polypeptide to enhance the glyphosate resistance of a plant cell transformed with the gene.

2. A chimeric gene of Claim 1 in which the promoter sequence is a plant virus promoter sequence.

3. A chimeric gene of Claim 2 in which the promoter sequence is a promoter sequence from cauliflower mosaic virus (CaMV)

4. A chimeric gene of Claim 3 in which the promoter sequence is the CaMV35S promoter sequence.

In 2001, Monsanto sued a Canadian farmer for planting seeds that grew from Monsanto plants that had blown onto his land as seeds. The farmer, Schmeiser, argued that (1) he was

[33] *Monsanto Co. v. McFarling*, 363 F.3d 1336, 1338 (Fed. Cir. 2004), *cert. denied*, 125 S.Ct. 2956 (2005).
[34] *Id.* at 1343.

cultivating his own traditionally bred canola strains; and (2) he made an extremely limited use of chemical herbicides and he did not knowingly acquire transgenic Monsanto seeds. "Moreover, he argued that, if the crops in his field were to be found to contain the technology patented by Monsanto, this was due to contamination by means of 'cross field breeding by wind or insects, seeds blowing by passing trucks, or dropping from farm equipment, or swaths blown from neighbours' fields'.'"[35] The Canadian Supreme Court held in Monsanto's favor, finding that Monsanto's patent on the plant gene was valid, and Schmeiser had infringed that patent.[36] Reproduced below is an excerpt of the Supreme Court of Canada's reasoning.

21. The appellant Schmeiser argues that the subject matter claimed in the patent is unpatentable. **While acknowledging that Monsanto claims protection only over a gene and a cell, Schmeiser contends that the result of extending such protection is to restrict use of a plant and a seed. This result, the argument goes, ought to render the subject matter unpatentable**, following the reasoning of the majority of this Court in Harvard College v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45, 2002 SCC 76 ("Harvard Mouse"). In that case, plants and seeds were found to be unpatentable "higher life forms".

22. This case is different from Harvard Mouse, where the patent refused was for a mammal. The Patent Commissioner, moreover, had allowed other claims, which were not at issue before the Court in that case, notably a plasmid and a somatic cell culture. The claims at issue in this case, for a gene and a cell, are somewhat analogous, suggesting that to find a gene and a cell to be patentable is in fact consistent with both the majority and the minority holdings in Harvard Mouse.

23. Further, all members of the Court in Harvard Mouse noted in obiter that a fertilized, genetically altered oncomouse egg would be patentable subject matter, regardless of its ultimate anticipated development into a mouse (at para. 3, per Binnie J. for the minority; at para. 162, per Bastarache J. for the majority).

24. 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, as we shall explain below. Monsanto's patent has already been issued, and the onus is thus on Schmeiser to show that the Commissioner erred in allowing the patent: Apotex Inc. v. Wellcome Foundation Ltd., [2002] 4 S.C.R. 153, 2002 SCC 77, at paras. 42-44. He has failed to discharge that onus. We therefore conclude that the patent is valid.[37]

As the emphasis above illustrates, the farmer did force the Supreme Court to consider that Monsanto's gene patent enabled Monsanto to achieve the same result as the company would have had Monsanto held a patent on the plant itself. Nevertheless, the Court was not

[35] Chiarolla, s*upra* note 15, at 34-35.
[36] *Monsanto Canada Inc. v. Schmeiser*, [2004] 1 S.C.R. 902, 2004 SCC 34.
[37] *Id.* (emphasis added).

persuaded by this argument and held that the farmer infringed Monsanto's patent. T**his case demonstrates that patents on plant-related inventions, such as genes, are just as harmful to farmers as patents on the plants themselves.**

In other countries, Monsanto's seeds only receive Plant Variety Protection.[38]

[38] Robert Tripp, Niels Louwaars, & Derek Eaton, *Plant Variety Protection in Developing Countries: A Report from the Field*, 32 FOOD POL'Y 354, 368 (2007).