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# PLANT PATENTS AND BREEDERS' RIGHTS

Protection of Breeders' Rights in Selected Countries and the International Breeders' Rights System

MOSST University Branch December 1982

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### SUMMARY

Basically, the same considerations that resulted in the adoption of the ordinary patent systems have led to their extention to patenting living matter such as bacteria and plants. In some countries, for example, in the United States since 1930, and in France before 1970, some plants (asexually reproducible in the first case and mainly a decorative species in the second) became patentable under the ordinary patent laws. The same solution to providing legal protection to breeders' proprietary rights, not only in plants regardless of the manner of their reproduction but also in methods of breeding the plant varieties, were adopted in 1976 in The accommodation of plant patents under ordinary patent laws required that the patentability criteria be suitably revised and special examination standards and procedures be established.

The alternative approach, adopted in Europe and various other countries including the United States (for sexually reproducible plants), was to provide patent-like protection for plant breeding by way of special plant breeders' rights legislation. Similar legislation in the form of a Plant Breeders' Rights Act is also proposed to be enacted in Canada.

The international legal framework for the recognition and protection of national plant patents is provided through the International Convention for the Protection of New Varieties of Plants (U.P.O.V.) negotiated in 1961 and in force since August 1968 (by September 1982 in some 16 states including Japan and the United States).

Under plant breeders' rights legislation, legal protection to the breeder's "invention" of a new plant variety is granted providing that such variety is distinct from all other known varieties with respect to at least one important morphological or physiological characteristic, sufficiently uniform that is, apart from

minor divergencies, the plants involved are identical in all their essential characteristics, and stable that is its plants remain, in their essential characteristics, true to the definition of the variety after each successive propagation or the required propagation cycle, and providing that the claimed variety is appropriately named. In some jurisdictions (i.e. U.S.A.) these requirements are satisfied on the basis of breeders' claims while in others they are verified by grow-out tests conducted under control of the organization administering plant breeders! rights legislation. In either case, cecisions as to "importance" of distinguishing characteristics and of "sufficiency" of uniformity and stability are left to the discretion of the authorities charged with granting breeders' rights.

Breeders' protection provided under the national plant variety protection laws is in the form of the exclusive right to control the commercial exploitation of new plant varieties usually by extraction of an

appropriate, once only, royalty. Such rights are not as broad as those associated with ordinary patents. are restricted to control of commercial exploitation of reproductive material only, such as seeds for growing, cuttings for planting, etc. as opposed to "consumption" material such as grain for milling or vegetables, etc. used as food or industrial material. They do not apply to production and use of seeds saved from current crops for subsequent sowing or reproduction and propagation of plants of the protected variety for pleasure. consist of two categories of rights, the basic or fundamental rights which give the plant breeder the exclusive right to, and to authorize others to, sell the reproductive material of the protected variety and to produce that material for the purpose of sale and in the case of ornamental plants of secondary breeders' rights. The latter provide, in addition, that the holder shall have the exclusive right to commercially use for the production of ornamental plants or cut flowers, such plants or parts thereof which are normally commercialized for purposes other than propagation.

Legal protection of proprietary rights to new plants is usually argued for on the ground that as a matter of equity the plant breeder deserves as much of an opportunity to obtain a reward for his work as is provided to other inventors. Moreover, the governments regard the plant patent system as the means of supporting plant breeding as a vital economic activity.

Lately, the adoption of a patent-like system and creation of special monopoly rights for plant breeders' have become a matter of considerable dispute. One of the main objections stems from the concern that a plant patent system will lead to economic concentration in the seed industry and produce undesirable socio-economic effects. The other refers to the possibility that such a system will tie up and hide germplasm at a time when diversity of germplasm is badly needed.

The first set of objections fails to take into account that legal monopoly is not identical with economic monopoly. In any case, plant breeders' laws provide for automatic and compulsory licenses and there are other legal instruments to control the use of

economic power. The second issue, that of preservation of genetic diversity is a problem in its own right. If anything, patenting of plants and associated requirements for disclosure, should be of help in this connection. This is not to say that patenting of plants raises no problems or issues.

The plant breeders' laws provide, for example, that the seeds of a protected variety be placed into a specified germplasm repository or available from the owner of breeders' rights. The practical significance of such collections is not known for the scientific basis for conclusively determining whether two plants are identical or different is lacking. Plant breeding, whether patented or not, does favour genetic uniformity and in this way increases crops' vulnerability to unforeseen diseases or pests. Perhaps the plant breeders' rights laws should allow for protecting mixtures for use within single fields.\*

<sup>\*</sup> Agriculture Canada notes that such a mixture when planted will not reproduce itself in the sense that the proportions of its various components will be different from those found in the starting seed stock.

Much more serious with regard to the arrangements for patenting plants under plant variety protection laws are the issues resulting from research and advances in genetic technologies. There are becoming available, for example, new cell- and gene-manipulation techniques (DNA engineering or regeneration of plants from protoplasts) which are capable of producing genetic improvements of crop plants and which are bound to complement, compete, or supercede the conventional breeding methods. techniques, however, are patentable and are being patented under the basic patent laws. What is the legal status of new seed lines produced by such patented processes? Another feature of this situation which is worth considering is the fact that ordinary patent laws, confer rights which are far broader than those under plant breeders' rights systems and which lack the special protection for farmers and for further breeding.

The DNA techniques may also be exploited for genetic improvements of microbial crop symbiants or associates such as bacteria, fungi, etc., which live in the vicinity of plant roots and which are able to supply growing plants with desirable nutrients such as fixed

nitrogen and phosphorus or protect roots against pathogens. Which law should apply to a case of new nitrogen-fixing process that includes traditionally bred host plant and DNA produced nitrogen-fixing bacterium? Should such a new combination of host plant and nitrogen fixing organism be patented as a single invention and under what law?

Problems and issues such as these appear to require that the present approaches to patenting DNA processes, plants and microorganisms be reviewed and the anomalies resulting from the existence of two patent systems, one for plants and the other for other inventions, remedied. It would seem best that such a review be undertaken independently from, and does not interfere with the current plans to legislate the Plant Breeders' Rights Act proposed for Canada and the already government approved amendments to the Patent Act. Its results can be acted upon when available.

A.S. Bandzierz
December 1982

# PLANT PATENTS AND BREEDERS' RIGHTS

Protection of Breeders' Rights in Selected Countries and the International Breeders' Rights System

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#### GLOSSARY OF TERMS

Asexual or vegetative reproduction

Reproduction by way of grafting, budding, or rooting from stems or underground bulbs, etc.

Diotechnology

The utilization of biological processes, be it microbial, plant or animal cells, or their constituents, to provide goods and services.

Budding

Production of daughter cells in the form of rounded outgrowth characteristic of yeasts and other fungi

or

means of artificial propagation in which a bud taken from one plant is inserted under the bark of another subsequently developing into a shoot.

Bud sport

The production of an abnormal branch, inflorescence, or flower from a bud as a result of mutation.

Class, species variety of plants

In classifying living things all animals and plants are grouped into categories according to their similarities and relationships. They are placed into different serially graded groups often called taxa. In order of increasing specificity, plants are grouped into division, class, order, family, genus, species and variety. For plant breeders the operational categories are species, i.e. wheat, potatoes, etc. and their subdivisions into varieties.

Clone

A collection of genetically identical cells or organisms which have been derived asexually from a common ancestor; all cells in the clone have the same genetic material and are exact copies of the original.

Cultivar

An organism developed and persistent under cultivation.

DNA (deoxyribonucleic aciā) The genetic material found in all living organisms. Every inherited characteristic has its origin somewhere in the code of each individual's complement of DNA.

Gene

The hereditary unit; a segment of DNA coding for a specific protein.

Gene mapping

Determining the relative location of different genes on a given chromosome.

Genetic engineering

A technology used at the laboratory level to alter the hereditary apparatus of a living cell so that the cell can produce more, or different chemicals, or perform completely new functions. These altered cells are then used in industrial production.

Germplasm.

The total genetic variability available to an organism, represented by the pool of germ cells or seed. The term as used in the text refers to all the reproductive material in the kingdom of plants. For the purposes of conservation it is usual to speak about

- wild species of plants, which may or may not be the progenitors of cultivated plants;
- primitive cultivars or land races which although evolving have remained relatively stable and which constitute the genetic stock for nearly all crops or species of economic interest;
- current or recently used cultivars;
- obsolete cultivars, the old varieties which are no longer in widespread use;

- special genetic stocks or breeding lines, including mutants produced by mutation breeding and certain mutant lines which are extremely useful now and will remain so in the future.

Germ cell

The sex cell of an organism (sperm or egg, pollen or ovum). It differs from other cells in that it contains only half the usual number of chromozones. Germ cells fuse during fertilization.

Graft

A plant consisting of a rooted part (stock) into which another part (scion) has been inserted so as to make organic union.

Hybrid

A new variety of plant or animal that results from cross-breeding two different existing varieties.

Mutant

Organism whose visible properties with respect to some traits differ from the norm of the population due to mutation in its DNA.

Mutation

Any change that alters the sequence of bases along DNA, changing the genetic material.

Pathogen

A specific causative agent of disease.

Protoplast

A cell without a wall.

Recombinant DNA

The hybrid DNA produced by joining pieces of DNA from different sources.

Sexual reproduction

Reproduction from seeds produced through pollination. (The union of gametes or gametic nuclei preceding the formation of a new individual.)

Sport

Any plant differing markedly from the normal by reason of genetical factors; it may be due to a mutation or to other causes such as a rare combination of factors.

Stock

The rooted stem into which the scion is inserted in grafting,

or

direct line descendant: an individual originating a line of descendants.

Tuber

A swollen, underground stem, or less often a root, consisting mainly of (parenchijmalous) cells containing much

stored food material.

some time now, the breeders' property rights in some plant varieties have become protectable under ordinary patent laws.

The traditional patent laws, however, did not envisage the possibility of patenting living matter and their patentability criteria and patenting procedures were not designed to accommodate this eventuality. In order to allow for plant patents, the definition of patentable subject matter had to be revised, and the patentability criteria changed or relaxed. Even then, the protection provided has been confined to "product by process" patents only, namely, to plant varieties developed by asexual reproduction (excluding certain species of this category).

The ordinary patent laws are still being adjusted to provide for patenting of such living matter as microorganisms. Moreover, they are still intended to provide patent protection to products and processes employed in manufacture rather than agriculture.

More recently, the successes of plant breeding and the growing appreciation of its importance to productivity of agriculture, has led many developed countries to create new monopoly rights for plant breeders. These, although more constrained than the property rights conferred by the traditional patent system, are nevertheless similar in purpose. Just as in the case of patent rights, such plant breeders' rights are intended to provide encouragement, reward and protection for the discovery or breeding and disclosure of new plant varieties of use in agriculture.

The creation of such new monopoly rights to basic reproductive processes and matter has raised issues of some sensitivity. For some time now there has been considerable pressure building up which challenges the social desirability of the national and international systems of plant breeders' rights. The controversies generated by the proposed Plant Breeders' Rights Act (Bill C-32) for Canada, the 1980 amendments to the U.S. Plant Variety Protection Act of 1970, and the Australian Plant Variety Bill introduced a year ago, are but some of its examples.

### PLANT PATENTS AND BREEDERS' RIGHTS

Protection of breeders' rights in selected countries and the international breeders' rights system

Plant breeding is undertaken to develop new varieties of plants with improved characteristics regarding such features as resistance to disease and crop pests, yield, size, shape, colcur, time of maturity, tolerance to heat, frost, wetness, acidity and other adverse climatic and soil conditions, handling and packaging. It depends and draws upon knowledge from such scientific disciplines as genetics, physiology, chemistry and nutrition. It requires continuing research and development and remains a long, costly and often a very risky venture. Its results, except that they are in the form of living plants with self-reproducing capability, are in the nature of inventions as much as those embodied in written specifications and claims protected under the traditional patent laws.

Indeed, in some countries (i.e. U.S.A., Cuba, South Korea, France before 1970 and some other states) and for

Quite apart from the issues of social desirability, the very basis upon which the plant breeders' rights system had been established may also have to be examined in the light of continuing advances in genetics and biotechnology. The present breeders' rights refer to plant varieties which have to be named and offer protection on a trademark-type basis. It should soon be possible to map the entire gene structure of an organism and thus define the plant perfectly. Moreover, progress in the gene mapping and genetic engineering includes the possibility of artificially transferring genes (governing the development of various plant characteristics) in a more directly controlled manner than in the present natural breeding processes. Such an advance may permit the transfer to plants of useful genes which are not found in any plant species. These developments may, in due course, permit placing plant breeders' protection on a technical basis as it is done under patent laws.

In less distant future, available for exploitation are cellular manipulation techniques which make it

possible to produce mutants and hybrids in the laboratory and provide an advantageous alternative to conventional plant breeding. Equally promising are the possibilities of improving biological nitrogen fixation in plants and modification of bacteria not only for that purpose but also for the production of agriculturally useful substances, including vitamins and amino acids for feed supplements, animal growth hormones and vaccines.

These advances in biotechnology also reveal the areas of convergence between the two patent systems and raise the question of complimentary protection under the ordinary patent laws and plant breeders' rights systems.

The purpose of this paper is to outline the main elements of the prevailing system for protecting breeders' rights, highlight its substantive provisions

and features of operation, and to draw attention to various issues raised by its opponents and advances in biotechnology.

# 1. NATIONAL AND INTERNATIONAL LEGAL FRAMEWORK FOR PROTECTING BREEDERS' PROPERTY RIGHTS IN PLANTS

In the <u>United States</u> specific provisions for plant patents were enacted by the Patent Law Amendment of 1930. In their current version they are contained in U.S. Code, Title 35, Chapter 15, Sections 161-164, and provide that a patent may be granted to whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant in an uncultivated state. The claim in the specification must be in formal terms to the plant shown and described. The plant patent granted gives "the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced for the term of 17 years from the date of issue".

The protection for sexually reproduced plant varieties is provided by the Plant Variety Protection Act of 1970 as revised in 1980. Expressly excluded from protection under this legislation are "fungi, bacteria or first generation hybrids". The Act provides for a specialized review procedure and awards of "Certificates of Plant Variety Protection" with effective meaning of a patent for up to 18 years (from the date of issue) to a protectable variety defined by its distinctness, unitormity and stability (c.u.s.). Since hybrids are not stable they are not "patentable". The effective protection for hybrids however, is provided by allowing for control of the direct use of "patentable" inbred lines in the production of hybrids. The legislation explicitly limits the rights of certificate holders to those needed to prevent unauthorized sale of the protected seed for seed purposes or for use in producing hybrids. Thus, a farmer can, without infringing upon certificate holders' rights, save the seed from his lawfully acquired seed and use it to grow a new crop, providing he does not sell it for seed purposes.

It may be of interest to note that neither of the two laws applies to potatoes.

In <u>Japan</u>, the development of a new variety of plant was formally recognized as an invention under the revised Patent Law in effect from January 1, 1976.\* The related Examination Standard for New Variety of Plant permits patenting the invention of the variety of plant per se "produced by means of breeding" regardless of the manner of their reproduction as well as patents for the invention of the method for breeding the variety of plant "produced by means of breeding". The term "produced by means of breeding" is said to mean "bred" or "created".

The arrangements for protecting plant breeders' rights by way of legislation other than patent laws had been adopted in the sixties and seventies by a number of Western European countries. They are exemplified in a complex of national "patent" systems and certification procedures such as those established under the British Plant Varieties and Seeds Act of 1964 (Part 1), German Law on the Protection of Plant Varieties of 1968 as

<sup>\*</sup> Subsequently, further measures for the protection of new plant varieties were adopted in the 1978 amendment to the Agricultural Seeds and Seedling Law of 1947.

revised and in effect on January 4, 1977, French Law on the Protection of New Plant Varieties (No. 70489) of June 11, 1970 and those under similar legislation in Italy (Decree No. 974 of August 12, 1975), Belgium (May 20, 1975), Switzerland (with effect from June 1, 1977) or the Netherlands.

Plant breeders' rights in those countries are available to whoever breeds or discovers a plant variety being any culture, class, line, stock or hybrid, whatever the origin, whether artificial or natural, of the variation from which it resulted, provided the variety for which the protection is being sought belongs to a species or group of species to which the relevant law has been extended. In the U.K., for example, the application of the 1964 Act is progressively extended by specific regulations. By 1980, these regulations covered over 350 operational schemes, each covering protection provided to a species or other convenient group of plants. It should be noted that (as indicated by the German court) discovery referred to above can be of a plant growing in the wild or occurring as a genetic variant, whether artificially induced or not.

The global, but not uncontested trend toward plant "patents" is reflected in the International Convention for the Protection of New Varieties of Plants (U.P.O.V.). The Convention was negotiated at the initiative of France in 1961 and came into force in Its initial members were nine European countries and South Africa. Its revisions were participated by some 27 other states, including some developing countries. By March 1, 1981 the revised text was signed by 26 states, including Canada. At this time, joined in the Union are 16 states,\* including, by executive decision, the United States. The Convention applies to all botanical genera and species and defines the minimum requirements and conditions for granting plant breeders' rights and the substance of such rights within their minimum scope which must be provided for in the national legislation so that those rights could be recognized by the Members of the Union. On the basis of reciprocity, the Convention also obliges that for the purposes of

<sup>\*</sup> By September 1982 the Union comprised the following countries: Belgium, Denmark, France, F.D.R. of Germany, Israel, Italy, Netherlands, Spain, South Africa, Sweden, Switzerland, United Kingdom, Japan, New Zealand, United States and Ireland.

granting breeders' rights, the countries of the Union treat the nationals of other member states the same way as they do their own.

In the case of plant patents provided for under ordinary patent laws their international recognition and protection is provided for under <a href="The Paris Convention">The Paris Convention</a> for the Protection of Industrial Property of March 20, 1883 as revised to date.

# 2. STATUTORY CONDITIONS FOR PLANT VARIETY PROTECTION Criteria of Protectability:

For plant species to which the national plant breeders' rights or patent laws apply, property rights in a plant variety can be granted to its breeder or discoverer providing that such a plant is distinctly new, uniform and stable, as determined (with or without the aid of growing out trials) by the body designated in the relevant legislation and providing that the claimed variety has not been commercialized, except as allowed for under relevant law, and that it is designated by a denomination suitable for registration.

### Distinctness and Novelty

In order to be considered for protection, the claimed variety must be clearly distinguishable by at least one important morphological or physiological characteristic from any other variety whose existence is a matter of common knowledge at the time of application.

Morphological characteristics may include such features as leaf shape, colour of flowers; while physiological aspects may cover such things as disease resistance, temperature tolerance and the like. The Danish Act of 1962, for example, mentions "such internal characteristics as resistance, content of valuable matter (dry matter, oil, etc.) and suitability for special modes of treatment". The U.S. Act of 1970 refers to processing or product characteristics or milling and baking characteristics in the case of wheat.

Important characteristics mean characteristics important for distinguishing purposes between plant varieties considered for protection and varieties whose existence is a matter of common knowledge. The assessment of such characteristics is independent from

assessments of economic or agronomic merits required by seed certification procedures under seed control laws. The latter are quite separate and independent from those governing plant breeders' protection. They provide, among other things, for determination by way of statutory trials, whether given varieties (patented or not) are of sufficient merit and value to allow for their cultivation and use in the country concerned.

Common knowledge may be established by reference to plant varieties already in cultivation and exploited for commercial purposes, those entered into official registers of "plant patenting" countries or included in botanical or commercial reference collections, or precisely described in any publication.

Except, as explicitly allowed under relevant laws (i.e. one year grace period under U.S. law), prior marketing in a country of application may make a variety ineligible for protection because of lack of novelty.

### Uniformity

According to the U.K. Plant Varieties and Seed Act, 1964, (Section 2) the variety must be sufficiently homogeneous, having regard to the particular features of its sexual reproduction or vegetative propagation. The German Law on the Protection of Plant Varieties (Section 5) deems a variety to be sufficiently homogeneous "when apart from a limited number of divergencies, the plants thereof are identical in all their essential characteristics". Similar requirements for sufficient homogeneity are included in pertinent legislation of other countries.

### Stability

The variety considered for protection must remain sufficiently true to its description when multiplied through such numbers of generations as is required to produce seeds for commerce. In the German Act of 1968, for example, a variety is deemed to be stable "when its plants remain, in their essential characteristics, true to the definition of the variety after each successive

propagation or at the end of each cycle in those cases where the breeding of such variety requires a particular propagation cycle".

### Varietal Name

One of the statutory requirements for granting breeders' rights is that the variety in which such rights are sought be named. This is to register the "patented" variety and to assist in protecting its breeder's rights. Under the British Act of 1964, a proposed variety name may be rejected on a number of statutory grounds, i.e. as liable to deceive or cause confusion as to the characteristics or value of the plant variety or as to the identity of the breeder or that such a name is the same as, or likely to be confused with, the trademark, registered or applied for, or a trade name used for reproductive material of the variety being "patented" or of another but belonging to the same species.

Use of a registered varietal name is restricted to trade in plants of the protected variety. Its use by any person when trading in a different plant variety

constitutes an infringement of the rights of the breeder of the registered variety.

### 3. PROCEDURES FOR GRANTING PLANT BREEDERS' PROTECTION

The applications for protection are processed by organizations designated to administer the relevant legislation; i.e., the Federal Office of Plant Varieties in Germany, Plant Variety Rights Office in Great Britain or the Department of Agriculture in the United States. In the European countries of the U.P.O.V. Convention the rights granting procedures involve verification of d.u.s. claims by way of growing out trials for the claimed variety. Such trials are controlled by the organizations administering the national plant breeders' rights laws. In the U.S.A., the Department of Agriculture relies on a description by the breeder for distinguishing a variety and his statement that the variety is homogeneous and stable. In either case, decisions as to "importance" of distinguishing characteristics and of "sufficiency" of uniformity and of stability are left to the discretion of the authorities charged with granting breeders' rights.

### 4. SCOPE AND NATURE OF PLANT EREEDERS' RIGHTS

Protection of plant breeders provided under the national plant breeders' rights laws is in the form of the exclusive right to control the commercial exploitation of a new plant variety usually by extraction of an appropriate, once only, royalty.

Such breecers' rights are restricted to control of commercial exploitation of reproductive or propagating material only, such as seeds for growing, cuttings for planting, etc. as opposed to "consumption materials" such as grain for milling, potatoes or vegetables used as foce or industrial materials.

For the purpose of defining their scope "commer-cialization" or "commercial exploitations" is (according to the German Act of 1968) understood to be "offering for sale, placing on sale, sale, and any other form of distribution". With regard to "reproductive" or "propagating" material it is taken to include:

- "l. seeds;
  - 2. plants and parts of plants in the case of plants whose species are normally vegetatively propagated;

when intended for plant production".

Thus, the determination as to what transactions the plant breeders' rights apply to is not dependent on the fact that they involve the protected plant variety but on their purpose. Such an approach to defining plant breeders' rights is hardly problem free since the purpose of the various transactions involved is not always clear at the time they take place. Moreover, the original intention may, for all kinds of valid reasons, have to be changed.

In addition to the fact that the plant breeders' rights do not apply to transactions involving protected varieties traded as consumption materials they are also not intended to affect non-trading activities. Thus, excluded from the purview of breeders' rights is the production and use of seeds saved from current crops for subsequent sowing or reproduction and propagation of the protected variety for pleasure.

In the U.P.O.V. terminology, there are two categories of breeders' rights, fundamental and secondary rights. The first, that is basic or fundamental rights, give the plant breeder the exclusive right to, and to authorize others to, sell the reproductive material of the variety and to produce that material in the territory to which the law applies for the purpose of sale.

In the case of certain plant species the definition of "reproductive materials" is extended giving rise to secondary breeders' rights.\* Thus, in the German plant breeders' legislation, in the case of ornamental plants, the holder shall have, in addition, the exclusive right to commercially use for the production of ornamental plants or cut flowers, such plants or parts thereof, which are normally commercialized for purposes other than propagation.

<sup>\*</sup> Agriculture Canada wishes to note that the U.P.O.V. Convention does not require that member-states grant such rights.

In some jurisdictions, such secondary rights are conferred by regulatory authorities on a crop by crop basis. In Eritain, for example, the regulations pertaining to "The Plant Breeders' Rights (Roses) Scheme 1965" provide that plant breeders' rights exercizable in respect of the Rose varieties, shall include the right to propagate and to authorize others to propagate any such variety for the purpose of selling cut blooms of that variety, while those pertaining to Carnations and Chrysanthemums give the exclusive right to produce or propagate such plant varieties for the purpose of selling cut blooms.

It should be noted that this extention of breeders' rights cuts across one of the fundamental principles of the plant breeders' legislation in Europe since cut blooms or other fruiting material are essentially in the consumption materials category. It should also be noted that in the United States the plant varieties to which European governments extend secondary breeders' rights are usually patented under the Plant Patent Act of 1930 and not under the Plant Variety Protection Act of 1970.

Both in the European countries and the United
States, breeders' rights include the exclusive right to,
and to authorize others to, use the reproductive
material of the plant variety to which the rights
relate, for the purpose of producing, in order to sell
it, the reproductive material of another variety but
only if the production of that other variety is not
possible without the repeated use of the reproductive
material of the plant variety to which the rights
relate, i.e., for commercial production of the first
generation hybrids. Other than for commercialization,
the protected variety can be freely used for breeding
purposes. Except as stated above the resulting plant
variety can be marketed without tribute to the
monopolist of the parent variety.

The plant breeders' rights are confined to national jurisdictions and do not give the plant breeder rights over sales outside his own country. Nevertheless, in many actual circumstances, the import of (and transborder trade in) seeds and seedlings for use as such is subject to the control of the breeder.

In Britain for example, a purchase of reproductive material outside the country coupled with its use as reproductive material in the territories under British jurisdiction would, together, constitute an infringement.

In the United States unauthorized propagation of seeds for sale abroad is not likely to constitute an intringement of the U.S. Certificate of Protection, although imports of these seeds, if detected, could probably be barred as an unfair trace practice.

Nith regard to exports, the Cerman Law on the Protection of Plant Varieties explicitly states (Section 15(4)) that "authorization, by the holder shall be required whenever it is proposed to transfer propagating material of the protected variety outside the territory where the Law is in force to a territory where equivalent protection is not provided for the varieties of the species to which the said variety belongs".

Finally, it must be repeated that the laws pertaining to the granting of plant breeders' rights are usually independent of those concerned with seed control regulations. Thus, although the breeder may be entitled to and receives plant rights in his variety, he may be unable to exercise them effectively in the granting state unless his variety is certified for use (with or without restrictions) in that state. Such certification is based on agroeconomic merits of the variety in question and not merely d.u.s. criteria used in granting breeders' rights. It requires separate procedures and tests which may or may not result in approval for unrestricted use. In consequence, the European EEC system of breeders' rights and seed and plant control measures involves not only registers of protected varieties, but also varietal control lists such as National Lists of plant varieties, two EEC Common Catalogues, one for vegetable plant species, one for agricultural plant species, as well as the Recommended List in Eritain.

Not unlike ordinary patent laws, the plant breeders' rights legislation also includes provisions concerning term of the rights, plant breeder's licences including automatic and compulsory licences, infringement of breeders' rights, their revocation and appeal procedures provided against the rulings of the bodies and organizations involved in administering and applying it.

## 5. PROPLEMS AND ISSUES IN PATENTING PLANTS

The adoption of a patent-like system and creation of special monopoly rights for plant breeders have, of late, become a matter of considerable dispute and controversy. There are questions being raised regarding the systems' socio-economic effects and its desirability in the national and international contexts. There are also matters and issues which are emerging as the result of advances in biotechnology.

# Sccio-economic Considerations Pertaining to Breeders' Rights System

The proponents of the plant patent systems point out that such legal arrangements give the plant breeder, as a matter of equity, an opportunity to obtain a reward for his work commensurate with its value to the community, provide incentive and support to the country's plant breeding and research which constitute a vital economic activity, and create favourable conditions for obtaining the best plant varieties produced by breeders in other countries and found suitable for use under climatic and farming conditions of the country in which plant breeders' rights are legally protected.

The evidence available from the United Kingdom and that presented in support of recent amendments to the U.S. Plant Variety Protection Act of 1970 suggests that plant breeders' rights systems have produced substantive benefits.

In Britain the plant breeding programs of private organizations have expanded significantly since 1964

when the new system of protecting breeders' rights was introduced. Associated with it was an increase in the flow of new varieties to the farmers and other users. The number of applications for variety protection rose from 107 in 1966 to 408 in 1978. Moreover, the international recognition of plant breeders' rights, particularly through U.P.C.V. is claimed to have produced substantial benefits in both private and public sectors. Royalties from abroad, particularly from other EEC states are said to represent a major source of income of the British companies concerned.

The U.S. statistics presented to Congress in 1980 are equally impressive. An analysis of the effects of the Plant Variety Protection Act indicated that it resulted in increased research by the private sector. Since the passage of the Act in 1970 the number of new varieties has increased from 94 to 227 for soybeans, from 139 to 231 for wheat and from 64 to 96 for cotton. There were three times more wheat, three times more soybeans and six times more cotton varieties developed since the enactment of the Act than in the ten years preceding this event.

It is, of course, too early to determine the degree of success of the research incentive created by the plant monopolies. Plant breeding is a long-term business and it often requires from 7 to 20 years of development prior to achieving results. Moreover, the benefits of the plant breeders' rights system must be related to the costs of the plant patent monopoly. The evidence regarding the latter is as yet less readily available than that for benefits.

The critics of the plant patent system raise two main objections. One of these concerns is a possible trend toward economic concentration in seed industry and some of its consequences. They point out that small seed firms are frequently being taken over by larger companies, sometimes internationals with interests in energy and agricultural chemicals. One of the consequences of this trend may well be a significant reduction in competition and increases in seed prices which otherwise might not have occurred. The U.S. seed prices did, in fact, rise sharply in the seventies.

Moreover, there are fears being expressed that firms with interests in energy and agricultural chemicals as well as in plant breeding may have little incentive to develop varieties which use less of their products; they may prefer hybrids which require that farmers purchase new seeds each year. There is also some concern that the pressure from larger companies to have their varieties licenced for sale under seed control laws may result in weakening, or the abolition of, the licensing system whose main objective is to indicate to the farmers the agricultural merits of the crop varieties suitable for their use.

It must be noted that some of the feared developments can hardly be viewed as a consequence of the plant patent system. In the case of fears regarding the future of the seed control system, it should be noted that it is guite separate and independent from

Plant patent systems. Lany countries, including
Canada,\* which have statutory seed control systems do
not have plant patents and grant no breeders' rights
while others, i.e. U.S.A. with plant patent legislation
have no seed control laws. Moreover, the EEC countries
all of which grant plant breeders' rights and certify
seeds for use in their jurisdictions, made the two
systems independent of each other. They are, in fact,
tightening the latter. The characteristics and
agronomic merits of the plant varieties included in the
countries' National Lists/EEC Common Catalogue must be
verified by statutory tests which are separate and
independent from those required for obtaining breeders'
rights.

<sup>\*</sup>According to the 1959 version of the Seeds Act "varieties may only be imported, advertised or sold if they are prescribed by the Minister". All applications for licensing of varieties must be submitted to the Seed Division of Agriculture Canada where they are examined and disposed of. When a licence is granted an official Description of the Variety is published. The basis on which each variety received its licence, is then made public. The licensing of a variety and subsequent prescription by the Minister of Agriculture in the Seeds Variety Order, is the official indicator that it has been tested and proven to have some advantage for Canadian agriculture.

Under the plant breeders' rights system the prices of seed may indeed be higher than without it. The cost of seeds, however, is not a large expenditure item within the total cost of raising the crop.

With regard to the issue of concentration, it is not clear whether such a development could be ascribed to the plant patent monopolies. It may well be that it is part of the normal pattern of economic change.

The new genetic technologies are likely to raise barriers to entry into the plant breeding business and may well result in increased concentration. In comparison to the current firms those based on new technology will require a number of staff biologists and substantial investment in the laboratory equipment.

Moreover, what could make the issue of concentration in seed industry particularly serious is the potential of genetic engineering to make the second generation of seed artificially sterile. Such an "innate plant patent system" in a concentrated industry could, indeed, result in enormous social costs to the affected economies.

Such a possibility must no doubt, be taken into account when providing for plant breeders' rights.

The second major concern of the opponents of the plant patents is the possibility that such a system will tie up and hide germplasm at a time when diversity of germplasm is badly needed. They also fear that plant patent systems will decrease the genetic diversity of plants and slow the creation of new varieties by limiting the exchange of information and of the plant germplasm.

The proponents of the system argue the opposite.

Their view is that the incentives created by the plant patent system support increased plant breeding activities. Such increased activities will increase genetic diversity of plants as more varieties are developed and will release public funds devoted to plant research for other uses, including preservation of plant genetic resources both of the cultivated varieties as well as of the wild species and primitive cultures.

The effect of plant breeders' rights legislation on genetic diversity of plants is probably one of the most crucial and confused issues in the debate.

There is no coubt that plant breeding led to the establishment of especially bred homogeneous cultures, the abandonment of land races from which they originated, a growing uniformity in the agricultural flora, and ultimately an increased "genetic vulnerability". This development, however, is the result of plant breeding, irrespective of whether such activity is protected by breeders' rights or not.

In any case, the need for genetic conservation has become fairly widely recognized to the point that there is now the International Foard for Plant Genetic Resources established in 1974 by the Consultative group on International Agricultural Resources (an inter-governmental body associated with the World Eank and Food and Agriculture Organization of the United Nations). The purpose of this organization is to promote the conservation of crop diversity by sponsoring an international network of germplasm collection. Included in this network are the International Agricultural Research Centres (some 13 in number), and numerous national institutions and organizations.

The issue of genetic conservation is independent of the plant patent system and of such critical importance that it should be reviewed and pursued in its own right, particularly with regard to wild species and primitive cultures. In the case of patented cultures and stocks, the plant patent systems usually require that the applicants for protection provide sample seeds which go into germplasm repositories. Alternatively, patent rights may be revoked if the owner of such rights fails to maintain the relevant reproductive material throughout the perioo for which such rights are exercisable. Whether in the case of recent, advanced varieties or the primitive cultures and land races, the evaluation of their practical significance still lacks the scientific basis for conclusively determining whether two plants are identical or different, i.e. information on the structure and sequence of plant genes.

With respect to genetic uniformity resulting from plant breeding and associated risk of reduced resistance to unforeseen diseases or pests the remedies are not to

be found in denial of breeders' rights protection but rather in a sound cultivation practice. In Britain, for example, advisory agencies associated under the Plant Varieties and Seeds Act of 1964 are now publishing "diversification groups" in which varieties are categorized into groups on the basis of their resistance factors. Varieties in the same group have similar resistance so they should not be grown in adjacent fields. Similar advice is available in other countries, including Canada and the U.S.A., for the plant varieties relevant to and used in those regions.

# Advances in biotechnology and protection of breeders' rights

kesearch in genetics and advances in genetic and cellular manipulation technologies are opening new ways of producing desirable plant varieties and adding new dimensions to the future crop production. In addition to presenting unique problems in handling the resulting inventions (i.e. patentability status, identification and disclosure requirements) they also raise issues pertaining to plant breeders' protection.

There are becoming available new cell- and gene-manipulating techniques (DNA engineering or regeneration of plants from protoplasts) which are capable of producing genetic improvements of crop plants and which are bound to expand, complement or supercede the conventional breeding and cultivation methods. Those techniques, however, are patentable under the basic patent laws and not under the plant patent legislation. What is the legal position of new seed lines produced through such patented processes is by no means clear. Will the patent for the product of such patented process be denied because the plant variety in question happens to be protected by the P.B.R. law? Moreover, the ordinary patent laws confer rights which are far broader than those under plant breeders' rights systems and which lack the special protection for farmers and for further breeding found under the latter.

Those and other new techniques may also affect adversely the existing, either de facto or legally conferred, protection. One ready illustration in this regard may be the case of Agrigenetics Research

Associates of Denver, Colorado who recently obtained a broad process patent for using cloning techniques to produce hybrid seeds which can be readied for marketing in as little as three years rather than the present eight to twelve years. They were also awarded another patent for applying those techniques to a specific species. Those seeds may be sold in competition to those produced by the hybrid's original developer. the United States hybrids are not protected under the Plant Variety Protection Act so that this development does not give rise to an infringement of breeders' rights. What may be the legalities of this situation under the proposed Canadian Plant Breeders' Rights Act or the European plant patent laws which provide preeders' rights for hybrids is not clear. The granting of those patents is certainly objected to by the British Association of Plant Breeders.

The DNA techniques may also be exploited for the genetic improvement of microbial crop symbiants or associates such as bacteria, fungi, etc. who live in, on, or in the vicinity of plant roots and which are able to supply growing plants with desirable nutrients such as fixed nitrogen and phosphorus. In addition,

microbial antagonists might secure vigorous growth of roots by protecting them against pathogens. This possibility raises the question as to which patent law is applicable to, for example, a case of a new nitrogen-fixing process in which the host plant is modified by traditional breeding while the nitrogen-fixing bacterium is produced by DNA manipulation.

Should such new combinations of hosts and nitrogen fixing organisms be patentable as a single invention, and under what patent law? Should the patent and/or seed control laws include provisions that the second generation seeds are not made artificially sterile? The present plant patent laws including the proposed Canadian P.B.R. Act, are concerned with single varieties and to the extent they result in increased reliance on genetically uniform plants' populations they also create conditions of increased vulnerability to crop failures. Should they be revised to accommodate more diversity

within a single field by, say, protecting mixtures?\*

Problems and issues such as these appear to require that the present approaches to patenting DNA inventions, plants and microorganisms are reviewed and the relevant changes confirmed by legislation. Moreover, such a review is called for, not merely in the context of protection of breeders' rights, but also because the new technologies and the legal rights to them are of direct consequence to the farmers themselves.

# 6. PROTECTION OF PLANT BREEDERS AND PLANT BREEDERS' RIGHTS LEGISLATION IN CANADA - STATUS AND PERSPECTIVES

With due regard to prevailing circumstances, it is important that the proposed review be carried out independently from, and not interfere with, the current plans to secure the passage of the proposed Plant Breeders' Rights Act and of the already approved amendments to the Patent Act. The results of the review may take some time to emerge and for that reason it is desirable that the task be proceeded with expeditiously.

<sup>\*</sup> Agriculture Canada notes in this connection that such mixtures will not reproduce themselves with the same proportions of constituent elements as found in the starting seed stock.

Its conclusions may be acted upon when they become available, irrespective of whether the currently planned establishment of the plant patent system envisaged in bill C-32 is proceeded with or not. Those plans for the enactment of new and of the revised patent laws represent an ambitious undertaking.

One of the proposed legislative actions concerns amendments to the Patent Act. Those amendments, as proposed to date, contain no changes in the definition of what constitutes the patentable subject matter and provide no clear legislative guidance for patenting microorganisms and other living entities. They also contain no set provisions for handling patent claims in biotechnology.

Another of the planned legislative actions is the passage of the Plant Breeders' Rights Act proposed by Agriculture Canada. There are at present no Canadian laws allowing patenting of plants so that plant breeders' proprietary rights to their new plant varieties and the opportunities to obtain a return on such "inventions" are legally unprotected. The only

plant breeders' protection that there is in Canada is by virtue of the Canadian Seed Growers' Association Regulations and Procedures for Peaigreed Crop Production and the Seeds Regulations under the Seeds Act. The combined effects of those regulations, according to Agriculture Canada, is that if "a breeder controls stock seed of his variety and sells only certified seed, then he controls the variety. He may then permit others to multiply and sell the variety for a royalty". This system recognizes plant breeders' rights by contract rather than by law. Moreover, it is limited to new varieties of some species only and its existence is of no consequence toward securing better access to plant varieties produced and patented in countries with plant breeders' rights legislation; it also does not allow for patenting the Canadian varieties in those states.

The proposed Canadian Plant Breeders' Rights Act is not unlike the existing legislation in Europe. It is to be administered somewhat differently to suit the Canadian conditions. Its purpose, just as of similar legislation elsewhere, is to encourage the Canadian plant breeding efforts, particularly by the private

sector, to improve Canadian access to plant varieties bred in other countries and to make it possible for Canadian breeders to patent their varieties in other countries and collect royalties when they are used there.

The best known reservations regarding this legislation are the same as those raised in other countries and mentioned in the section pertaining to socio-economic considerations regarding plant patent systems. Of major concern in the Canadian circumstances are also the effects of the proposed plant patent system on the publicly financed programs of agriculture related research and plant breeding, including the possibility that the results of such publicly supported programs will be patented and become available to Canadian farmers only under those conditions. Whether such a plant patent system would be of benefit to Canada depends on whether the research incentive created by plant monopolies is substantial enough to outweigh the relevant costs associated with such arrangements. Agriculture Canada is satisfied that the answer to this question is in the affirmative.

If it is worthwhile to enact such legislation for Canada, its full benefits may not be secured unless Canada joins, and progressively implements, the U.P.O.V. Convention. One of the conditions for joining the Convention is that Canada provide plant breeders' rights to at least five genera or species of plants.

Subsequently, in order to maintain her status, Canada must provide protection to additional genera or species within the following periods from the date of joining:

- "within three years, to at least ten genera or species in all;
- within six years, to at least eighteen genera or species in all;
- within eight years, to at least twenty-four genera or species in all;".

Indeed, the next stage of the plan to provide plant breeders' rights protection in this country is the legislation and other steps required for Canada to join the U.P.O.V. Convention. Also recommended in connection with the proposed Plant Breeders' Rights Act are the complementary amendments to the Seeds Act.

The prospects for the passage of the presently planned plant patent legislation are not known. One of the already mentioned options is to consider patenting of plants under a suitably revised Patent Act. The possibility that such an option may have to be considered makes it highly advisable that the review of the handling of biotechnological patents, pertaining not only to microorganisms, but also to plants, be accelerated.

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Lècember 1982

## PLANT PATENTS AND BREEDERS' RIGHTS

Protection of Breeders' Rights in Selected Countries and the International Breeders' Rights System

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