



North-South Policy Brief

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Framework for the Introduction of Plant Variety Protection in Developing Countries

The Agreement on Trade Related aspects of Intellectual Property Rights (TRIPs) requires member states of the World Trade Organisation to comply with basic rules on intellectual property rights. The Agreement, which provides for the protection of plant varieties by "patents or an effective *sui generis* system", has initiated the development of their legal protection systems for plant varieties by many developing countries. Most international discussions on this issue fully concentrate on the legal issues. We, however, stress that more emphasis is needed on the institutional options, technical issues and commercial aspects of plant variety protection, including the costs involved for governments and other stakeholders.

Legal issues concentrate around the balance between the rights and obligations of breeders and farmers, and in creating a mutually reinforcing system of national regulatory systems derived from the TRIPs Agreement, the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Agriculture (IT/PGRFA). We conclude that the patent system is not suitable for developing countries to protect plant varieties. The UPOV-system deserves close attention.

Institutional options deal with the placement of the PVP-office in the Ministry of Agriculture or the patent office. Furthermore, decisions have to be made as to what extent the government has to be involved in the testing of the new varieties. Independence of the testing process, human and technical resources within public institutions, the capacities of the breeder/applicant and the courts system, and possibilities for international cooperation are the key issues that have to be examined.

Capacity building has to accompany the development of an effective system. This involves breeders, seed producers, farmers and their advisers (extension), and lawyers and judges.

Even though commercialisation of the protected varieties is the responsibility of the right holder (the breeder in most cases), the involvement of (public or private) organisations may be looked into in making effective arrangements for royalty collection.



1. Introduction

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) was signed by 125 countries in 1994 as part of the new General Agreement on Tariffs and Trade (GATT) and established minimum standards for intellectual property rights (IPR). The agreement requires in Article 27 (3) b the member states of the World Trade Organisation (WTO) - the succeeding organisation of GATT - to provide protection for plant varieties by patent or "an effective *sui generis* system, or a combination thereof". *Sui generis* means "of its own class", "tailor made".

All WTO members (145 as of February 2003) are obliged to implement the provisions of the TRIPs agreement. All developing countries other than those categorised as least developed countries (LDC's) were required to provide intellectual property rights protection for plant varieties by January 1, 2000. The LDC's have until January 1, 2006. As a consequence, many developing countries have ventured into the development of a legal basis for the protection of plant varieties, followed by the development of an administrative and technical system to implement the law. The introduction of a sound Plant Variety Protection (PVP) system has far reaching consequences of a legal, institutional, technical, financial and commercial nature.

The present paper intends to analyse these consequences and discusses the main options in the various fields that are affected by the system. It concentrates on the *sui generis* option of PVP since the majority of countries consider the utility-patent system inappropriate for the protection of varieties. This paper is aimed at assisting policy makers and other stakeholders in the public and private sector in developing and transition countries that are setting up their protection system for plant varieties.

2. Objectives for protecting varieties

Plant breeding may be undertaken and financed by government agencies as part of a policy to secure an adequate supply of food, feed and industrial needs. Plant breeding can also be undertaken by commercial seed producers as a profit-yielding investment. But, when farmers and other seed producers can easily

reproduce the variety, commercial breeders may not be able to reap a sufficient share of the benefits of their work to justify the investment. The introduction of such a protection system is thus justified by the following considerations:

Promotion of breeding

Intellectual property rights on plant varieties provides the breeder of a new plant variety with the exclusive rights to exploit it and to attempt to recover the investment. This is an incentive to invest in local plant breeding. The promotion of plant breeding is part of a policy to improve food security. Increased investments in breeding efforts have generally been observed in countries that have introduced effective protection systems for plant varieties (Lesser, 1997; Eaton, 2002).

Access to foreign varieties

The absence of an effective system for the protection of plant varieties is likely to deter foreign breeders from introducing their varieties in a particular country. This effect of PVP is especially relevant for developing countries with smaller domestic breeding sectors. Introduction of foreign varieties adds to the choice that farmers have to select the best variety for their conditions and thus supports agricultural development and food security policies.

Production for export

Export products that meet the needs of the foreign markets are often based on foreign breeding, particularly in ornamental plants. An importing country may block the product from entering the country when the breeder has not given permission to multiply the crop in the exporting country. Since breeders do not easily send their most valuable new varieties (that command the highest prices in the markets) to countries where their interests are not secured, countries tend to lose potential export income when an acceptable level of protection cannot be guaranteed.

Making new varieties public

Protection of a good variety may create a strong argument for investment in seed production and sales.

Political considerations

Having an effective protection system for plant varieties enables a country to be regarded as a reliable partner in various international forums.

3. Legal options

UPOV *sui generis* plant variety protection

Most countries with a protection system for varieties currently opt for a *sui generis* system that is in harmony with the International Convention for the Protection of New Varieties of Plants, administered by its International Union (UPOV). The Convention came into force in 1968 and was revised in 1978 and 1991 in order to cater for changes in the seed sector in the member states over time. UPOV (52 members early 2003) provides a basis for an internationally harmonised *sui generis* system that has proven its value in Western countries over 3 decades. The following principles are central in the Convention:

Harmonised conditions

There are three technical (distinctness, uniformity and stability) and two non-technical (novelty and acceptable denomination) conditions for the granting of rights, while the applicant should have a justifiable claim on the variety. Additional conditions for the granting of protection are forbidden. Harmonisation in testing is achieved by standardised guidelines and protocols.

Scope of protection

The protection covers all aspects of commercialisation of seeds and planting materials, and may extend to harvested materials. It does, however, not extend to 'non-commercial use', the use for further breeding (breeders' exemption), and member countries can allow seed production for own use (farmers' privilege).

Duration of protection

The duration of the protection is chosen in such a manner that the breeder is expected to have enough time to recover his investments, i.e. minimum 25 years for trees and vines and 20 years for all other plants.

Plant species

Member countries have to extend the protection for at least 15 plant genera/species upon accession and to all species within 10 years.

National treatment & right of priority

This rule stipulates that breeders from other UPOV-member states are treated as if they are national breeders. A right of priority, based on an earlier application in another UPOV member-state is currently discussed.

Other *sui generis* systems

In many developing countries the seed sector is composed of a combination of a formal seed sector and farmer-produced seed of both "traditional" and "improved" varieties. Many countries have promoted the farmer-to-farmer exchange of new varieties in order to rapidly spread new varieties. Such exchange is severely limited under a UPOV-law, which is a major argument for countries not to accede to the Convention. Moreover many countries want to combine PVP and farmers' rights in one regulatory system. The TRIPs agreement does not specify explicitly the requirements of an effective *sui generis* system and does not prescribe WTO-members to follow UPOV. An example of a specific *sui generis* system that does not comply with the 1991 UPOV model is the Indian Protection of Plant Varieties and Farmers' Rights Act of 2001 (Ramana, 2003). The Indian Act serves to provide rights to both farmers and breeders. The farmers are to be remunerated for their contribution to conserving, improving and making available plant genetic resources. PVP is granted to stimulate



investment. The Act covers four classes of varieties (new, extant, essentially derived and farmers' varieties), describes the principle of benefit sharing, and recognises farmers' rights and research rights. Other examples of (draft) laws that combine PVP and farmers' rights have been prepared in e.g. Thailand, Bangladesh and Namibia (the latter is based on the model law of the African Union for the protection of the rights of local communities, farmers and breeders. The efficacy of these laws and the efficiency of their implementation still need to be proven.

Plant patents have been granted in the USA since 1930 for vegetatively multiplied crops, excluding plants producing edible tubers, such as potato. Since this is a system that is specifically designed for plant varieties, this should also be considered a *sui generis* system. The application for plant patent requires a detailed description, photographs and drawings of the variety. The requirements for granting a plant patent are based on the following criteria:

- invented or discovered in a "cultivated" area and not in nature
- the plant variety must be new, i.e. not sold, released or published in the USA
- the plant variety must be distinguishable
- the plant variety must be non-obvious, meaning that a skilled person in the art would not have arrived at the same variety.

Utility patents

Utility patents are granted to products or processes that are:

- new in respect to the "state of the art", i.e. published or used world wide
- useful, having a practical purpose in any kind of industry, including agriculture
- inventive or non-obvious to a person skilled in the art. This is a vague and difficult criterion, predominantly subject to the judgement of the patent examiner.

Utility patents have long been considered unsuitable for protecting living matter. Most patent laws in the world forbid the patenting of plants, animals or varieties of plants and animals (e.g. European Patent Convention of 1973). However, in the USA the utility patent system extends to conventionally bred plant varieties. Three options for plant variety protection are therefore available in the USA: plant variety protection for seed crops and asexually reproduced crops; plant patent for

asexually reproduced crops except edible tubers; and utility patent for all crops. There is neither a link nor any form of coherence or co-operation between the three systems. A single variety can be protected by more than one system in the USA.

Since the patent system does not cater for farmers' privilege, breeder's exemption and non-commercial use, we consider that the patent system does not provide a suitable balance of rights among the stakeholders.

Costs

The costs for applicants of PVP and patents can vary considerably, depending on how the systems are set up. For PVP, costs usually also vary according to the type of crop. The total fees for applying for and maintaining a PVP for ten years for an ornamental plant variety is currently €4606 in the Netherlands, for vegetables €10,899, and field crops €5564. The total fees for applying for and maintaining a patent in this country for a period of ten years is at least €5100. Patent applications, however, involve additional fees for the preparation of the relevant forms, and the legal costs of prosecuting infringements are generally higher in patent system where conflicts arise more frequently. Rights based on results from independent, official field testing are less frequently challenged than rights based on written information from the inventor. The unavailability of information on these other legal costs incurred by the applicant makes a full comparison of the costs between PVP and patents difficult.

Relationship with CBD and IT/PGRFA

The Convention on Biological Diversity is based on the principles that the conservation of biological diversity is a common concern of mankind and that states have sovereign rights over their own biological resources. States are responsible for conserving their biological resources, facilitating access, promoting sustainable use, and stimulating the fair and equitable sharing of benefits arising from this use.

The International Treaty on Plant Genetic Resources for Food and Agriculture recognises the past, present and future contributions of farmers, in conserving, improving and making available plant genetic resources for food and agriculture (the basis of Farmers' Rights), and it provides for a multilateral system for the major

food crops in order to facilitate access and benefit-sharing.

Even though the objectives are very different, TRIPs (promote innovation) and CBD and IT/PGRFA (stimulate conservation) provide a framework for a remuneration for the party that contributed to the genetic resource. The CBD furthermore focuses on the rights of states, the IT/PGRFA on the rights of farmers, and TRIPs on inventors/breeders.

4. Institutional arrangements

National authority on PVP

Similar to most intellectual property rights regimes, a plant variety has to be registered before the protection can be granted. This requires a national authority to decide on applications and grants, (and variety denominations and descriptions), requests for compulsory licences or annulment of a right, and claims for the property of a right by another party. This National Authority can either be constituted by a PVP-Board consisting of independent experts, that is supported by a secretariat for administrative issues. Alternatively, one office is responsible for both administration and decisions. A PVP authority is usually located either under the Ministry of Agriculture or within the patent office.

When attaching a PVP authority to a patent office, it should be realised that both systems are independent and fundamentally different. Patent offices need to establish a separate capacity in the biological sciences to operate a PVP system. In countries where plant breeding is done mainly within the Ministry of Agriculture, a PVP-authority within that same Ministry may not be sufficiently independent. Very few countries however have opted for including PVP in the patent office.

Funding a PVP system

A plant variety protection system serves two clients:

- society, to support agricultural development, and to meet international obligations
- the breeder, to protect his long term investment in breeding

It therefore seems reasonable that state and breeder/applicant jointly finance the PVP system. In a situation where the private breeding sector is well developed, all costs of the system may be covered in full by the breeder through fees. Where the private breeding sector is less developed, the input from the

state might be larger in order to stimulate the sector and to reduce increased seed costs. A distinction has to be made between establishment and operational costs of the system, whereby the former may have to be borne completely by the Government. Breeders should not be charged for inefficiencies of public operations.

DUS Testing

Four options for organising the testing of varieties are currently known:

- official examination on behalf of the PVP authority (e.g. most EU-countries)
- official examination of the breeders' own data (e.g. USA)
- mixed systems (e.g. Australia, France)
- co-operation between countries (e.g. Slovenia)

Official examination has the advantages of avoiding disputes among breeders after the granting of rights (reducing the involvement of courts). It also reduces the costs of maintaining a reference collection of all relevant existing varieties that a new application has to be tested against. Disadvantage in a developing country is that it requires that scarce human resources (botanists/breeders) are necessary to operate the system and that independence from public breeding stations is often not guaranteed.

Breeder testing with official examination of the 'paper work' has the advantage that the breeder reduces dependence on the inefficiencies of public institutions. It opens the way, however, for the manipulation of data, which may have to be corrected in court. Breeder testing may be more difficult to organise for small breeding enterprises compared to their larger competitors.

Various mixed systems are possible: Australia operates a breeder testing system where officials monitor the trials. Different breeders tend to jointly organise DUS-trials to minimise costs. This is a useful approach where sufficient independent (!!) officials can be recruited. France mixes the systems in a different way: for maize, the first year of testing is the breeder's responsibility, whereas officials operate the 2nd year trials, thus confirming the first years' results. For developing countries this may not be the ideal option because it would still entail setting up a complete independent testing infrastructure.

Finally, trials may be grown at the applicants' premises, and observations done by the national authority. This option is interesting where the know-how for growing the species is specific (minor crops) or time-consuming (estate crops), that it would be too expensive to develop separate trials and expertise.



International co-operation is one of the most obvious options. Bilateral co-operation is the most common form, whereby a national PVP office may request another country to carry out the trials for a certain variety or crop under a formal agreement between the two states. Some countries do this for all crops, and do not have their own DUS-testing infrastructure (e.g. Slovenia). PVP offices may also purchase the DUS report from another country when the filed variety has already been presented there. The national PVP-office remains responsible for granting of the rights. A further level of co-operation can be found in the European Union, where one joint system offers protection in all EU countries through a single application.

These options are possible only when countries have the same technical requirements for granting rights (not necessarily only among UPOV-members).

5. Technical and human capacity aspects

Criteria

The technical requirements are very similar among existing PVP-systems.

The **novelty** examination is based on market information. The variety should not have been marketed anywhere within a certain period before application. In countries with compulsory variety registration for market access this may be simple. Where this is not the case and where the variety may have been marketed in (distant) foreign countries, an effective system of market information and international co-operation are needed.

Distinctness is assessed by comparing the candidate variety with all varieties whose existence is a matter of common knowledge at the time of the filing of the application.

A new variety has to be **uniform and stable**: the essential characteristics of the variety have to be constant after repeated multiplication. Stability is essential in the settlement of disputes and is largely based on the level of uniformity. The description format is designed in such a way as to minimise influences by the environment and trials have to be performed in a maximally uniform environment. This makes DUS-testing essentially different from multi-locational testing of varieties for cultivation and use, and these do not necessarily have to be replicated over various locations.

Design of the tests

Excellent facilities have to be available, both in terms of well-managed and uniform trial fields and certain laboratory facilities. Furthermore, the presence of trained staff is essential. This poses specific challenges. In most countries, government agricultural research stations offer the best facilities, and breeding programmes offer the best qualified staff. However, in the case of centralised testing a conflict of interest is likely where the breeders are made responsible for DUS testing. Strict quality management systems could be designed to avoid such conflicts.

The most important aspect for trial design of the DUS tests is the distinctiveness requirement. Based on the information provided by the applicant, the differences with the existing varieties have to be established. The applicant variety thus has to be planted next to these similar ones.

In order to choose the right varieties for comparison, a thorough knowledge of the existing varieties is essential. This requires very experienced staff, databases, collections of photographs (mainly ornamentals), and/or databases of genetic fingerprints. Maintenance and use of reference varieties may add up to 75% of the costs in vegetatively propagated crops.

Human resources

DUS testing requires special skills. It requires detailed observations of characteristics that plant breeders are rarely accustomed to doing. Botanists may be better equipped, but are often scarce in any given country. Moreover, the crop expert needs to have the expertise to make a distinction between crop variation caused by genotypic differences and crop variation caused by environmental diversity.

In countries with few releases every year and limited numbers of trained staff in the national research systems, the human resource capacity can be the main limiting factor. Regional co-operation seems to be the most obvious solution whereby different countries may test different crop groups.

6. Commercial aspects

The common objective of a plant variety protection system is to offer the breeder an exclusive right to market and sell the variety, thus providing the plant breeder with the incentive not only to develop the variety, but also to actively market it. The breeder is responsible for the exploitation of the variety and to monitor infringements on his exclusive right.

Exploiting the variety

The breeder can decide to exploit the variety himself, he can decide to exploit the variety through a third party or he may sell his rights. The breeder may thus produce and market the seeds himself and include a mark-up on the seed price in order to recover his investments in breeding.

It is more common, however, that the breeder provides licenses to seed producers to multiply and sell seed of

his variety. The license contract has to be advantageous for both the breeder (licensor) and the seed producer (licensee). The licensee normally gets the exclusive right to sell seed of the variety in a certain market (region/country/quantity) against the payment of an agreed fee (royalty). Licensees are often charged with monitoring the market for illegal multiplication of the same variety and report this to the breeder or act on his behalf. This is in the joint interest of both parties, since illegal multiplication and sales reduces the market for the licensee and the royalty incomes for the breeder.

Royalty collection

Since PVP offers a private right, breeders are responsible for organising the collection of royalties arising from the license contract. The breeder may however request the services of other organisations. In some countries the certification agencies play a major role in providing data and/or administrative services for royalty collection (e.g. The Netherlands). In other countries national seed associations can organise a central royalty collection system on behalf of the breeders. Involvement of the PVP-Office or the Ministry of Agriculture in royalty collection should be avoided due to conflicts of interests.

Identifying and prosecuting breaches

Licensors will normally pay their dues to the breeder. It is, however, of interest for the seed producer to produce and sell more than is stipulated in the contract. Also the marketing of seed without a license may be very profitable (but illegal when the variety is protected). Also in such cases, there is no official authority to act as a policeman and the breeder is responsible for pursuing infringements. Once a PVP system has been fully implemented in a country, it will become largely self-regulating with respect to infringements. The most common forms of action taken included: direct correspondence, letter from a lawyer, intervention by a breeders association. Only as a last resort, will breeders use the courts to secure their rights.

7. Public acceptance

It is essential that the various stakeholders understand and accept the objectives and operation of a plant variety protection system. Early participation of such

stakeholders in the design of the system can be extremely useful. This is relatively easy when they have organised themselves in breeders', seed producers' and/or farmers' associations.

An extensive effort is usually needed to familiarise stakeholders with the rules and operations, and especially with their specific rights and obligations. In most industrialised countries, stakeholders have had the chance to adjust with an ever-refining system over several decades – in many developing countries, a rather advanced system is developed overnight. One consequence may be that private plant breeding companies with experience with PVP elsewhere may have an advantage compared to local seed producers and farmers, or even national authorities.

Such differences should be resolved as early as possible through consultations, training and extension programmes.

Such programmes should target:

- **breeders**, including public, private and community plant breeders (and those in international research organisations). Plant breeders typically understand the purpose and operation of a PVP system. However, they tend to think that having the rights to a variety will automatically lead to royalties. Individual breeders may also not be aware that the employer (public or private) actually holds the right. In some countries only, the individual breeder has the legal right to a minimum percentage of the royalties. Breeders should also be aware of their obligations under the system, i.e. towards right holders of existing varieties and holders of plant genetic resources (ref: CBD and IT/PGRFA), especially where PVP and farmers' rights are combined in one system. Furthermore, PVP fit in a system of commercial plant breeding, based on cost-benefit analysis of the costs of application/maintenance and commercialisation of the variety versus the expected revenues; plant breeders in the public sector operate differently.
- **seed producers and contract growers** must understand that they are not permitted to multiply and sell seed of a protected variety without the consent of the breeder. This is a significant change for seed producers who, in the absence of PVP, may have been strongly encouraged to multiply and distribute improved varieties to promote widespread diffusion. Seed producers need to be convinced that the

payment of royalties will form the basis for new and better varieties in the future. Furthermore, seed producers may benefit from a more stable seed market in which they can reduce the number of competitors by signing a licence agreement with a breeder. Seed producers may be inclined to avoid such contracts or not to adhere to all stipulations in order to reduce costs.

- **farmers, as both users and producers of seed** (on either a non-commercial or semi-commercial scale) need to be informed about their obligations and their rights, especially in terms of their right (or not) to produce, exchange and sell seed of non-protected and protected varieties. In the early stages of a protection system, farmers can easily be approached by impostors who claim to represent either the breeder or the state and collect royalties on their behalf.
- **lawyers and judges**. As with any other law, judges and lawyers have to be made aware of the details of a PVP-system, especially the differences with other forms of intellectual property rights and the peculiar issues related to the biological nature of the protected subject matter. Especially the latter issue is a continuous 'learning process', even in well-developed systems, requiring the support of the PVP-office by a group of independent advisors.

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This brief is based on a larger report that is available with the authors. The information has been gathered throughout several years of international cooperation projects, executed by staff of the Centre for Genetic Resources, The Netherlands and their partners within Wageningen UR and abroad. This Centre also organises an international PVP-course in Wageningen annually since 1996: http://www.iac.wageningen-ur.nl/services/training/regular/brochurepvp_2003.pdf