Seeds and Trees: An Insight into Agriculture, Biotechnology and Intellectual Property Rights

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Abstract

The role of intellectual property rights (IPRs) has lately become a key issue in agricultural and resource economics. As the scope and power of IPRs in biotechnology have grown, their international reach has expanded. These developments raise many fascinating and important issues: optimal patent design and licensing; the implications of IPRs under cumulative innovation, typical of agriculture and biotechnology; the effects of the TRIPS agreement on developing countries; etc. The paper finds that any system of IPR protection must take into account the needs of the community as well as the services provided to the commercial or highly productive sector, including limitations that may be imposed on a farmer's ability and rights to replant saved seed. It also finds that there are specific needs to achieve a balance between efficient protection of genetic resources, efficient protection of IPRs and mechanisms to regulate the access to genetic resources and traditional knowledge.

***Keywords*:** IPR, PVR, Biotechnology, Patent protection, Farmers' rights.

Introduction

The most important mechanisms for legally protecting agricultural innovations are plant variety rights (PVR)[1] and patents (extended to cover plants, animals, and microorganisms). Other forms of protection can be provided through trademarks, trade secrets and copyright. Alternatives to these include material transfer agreements (MTAs) of a private contractual nature. If no form of protection is taken, then research results are generally placed in the public domain, mostly in the form of publications, making results available to all without restrictions on use.

1. PVR

Patent law was originally considered unsuitable for protecting new plant varieties developed by traditional breeding methods. Some countries therefore introduced special national laws for PVR in the 1960s, as did the International Union for the Protection of New Varieties of Plants (UPOV[2]), established in 1961. These rights are granted by the state to plant breeders to exclude others from producing or commercialising material of a specific plant variety for a minimum of 15 to 20 years.To be eligible for PVR, the variety must be novel, distinct from existing varieties, and uniform and stable in its essential characteristics. At first, this form of legal protection was limited to commercialising reproductive or vegetatively propagated material taken from a new variety. It was implied or specified that certain exemptions were allowed to farmers and researchers (breeders). Such exemptions under PVR systems are termed farmers' privilege and breeders' privilege (or research exemption).

2. PVR under UPOV

The original 1961 version of UPOV was revised in 1972, 1978, and 1991. The 1991 version has come into force in most of the countries and a few others are about to implement it. Originally, the scope of PVR concerned 'the production for purposes of commercial marketing, the offering for sale, the marketing of the reproductive or vegetative propagating material, of the variety' (UPOV, 1978). This has been broadened under UPOV 1991.UPOV 1978 specified that any member state could provide *either* patent protection *or* PVR protection for the same botanical species or genus. This prohibition of double protection is not present in UPOV 1991. Researchers using biotechnology techniques alongside traditional breeding methods will be able to obtain both types of protection as appropriate.

3. Scope of Protection

Under UPOV 1991, a plant breeder is conferred the exclusive right to do or to license the following acts in relation to propagating material of the variety:

i) produce or reproduce the material;
ii) condition the material for the purpose of propagation;
iii) offer the material for sale;

iv) sell the material;
v) import the material;
vi) export the material;
vii) stock the material for the purposes described above.

The general duration of PVR is 25 years in the case of trees and vines and 20 years for any other variety.

4. Registrable Plant Varieties

As with patents, PVR are established after a registration process. A plant variety is considered to be registrable if it has a breeder; if it is distinct, uniform and stable; and if it has not been or only recently been exploited. A plant variety is considered *distinct* if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge. It is *uniform* if, subject to the variation that may be expected from the particular features of its propagation, it is uniform in its relevant characteristics on propagation. A plant variety is *stable* if its relevant characteristics remain unchanged after repeated propagation. A plant variety is taken *not* to have been *exploited* if it or propagating material has not been sold to another person by or with the consent of the breeder. The test of no commercial exploitation is easier to satisfy than the test for novelty under patent law, and the choice between the two forms of IPR is a matter to be considered by the agricultural research institute.

The most important procedure in getting PVR is examining the biological material itself. Extensive field trials are necessary to determine whether the variety meets the legal requirements of distinctiveness, uniformity, and stability. The breeder must also supply an objective description of the new variety and list its characteristics in a qualitative or quantitative way so that it can be clearly distinguished from already known varieties. Each country must have a means of registering and certifying material selected for PVR to guarantee that seed or planting material distributed to growers remains 'true to type' (retains the qualities originally stated on the application). To maintain confidence in the PVR system, there must be agreement among breeders and growers on the validity and usefulness of the system, with the benefits of compliance fully understood. The system must ensure that a variety for which protection is sought meets the requirements of distinctiveness, uniformity, and stability. Apart from the financial constraints in maintaining a PVR system, finding technically qualified personnel to staff a PVR office may present a major difficulty.

The two exceptions to the breeders' rights have been modified in the latest amendment to the UPOV convention (1991). Article 14(1) extends the breeders' rights to all acts pertaining to production and reproduction of seeds and other planting material. Thus, unlike the provisions of UPOV 1978, there is no longer an implicit right of farmers to save and reuse seed from protected varieties without the breeders' authorisation. Article 15(2) does, however, provide some leeway for farmers: 'each Contracting Party (to UPOV 1991) may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeders' right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product'.

5. Patent Protection

The international standard for the domestic protection of inventions is prescribed in Article 27 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which is binding for all members of the World Trade Organization (WTO). Article 27(1) provides that 'patents shall be 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'. Article 27(2) envisages that inventions may be excluded from patentability to protect '*ordre public*' or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment'. Article 27(3) permits signatories to exclude from patentability 'plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological or microbiological processes'. Additionally, Article 27(3) requires that 'members shall provide for the protection of plant varieties either by patents or by an effective *sui generis*[3] system or by any combination thereof.'

6. Intellectual Property Rights and Living Systems

The first requirement that a biotechnological innovation has to satisfy, if it is to be patented, is that it constitutes an invention. In this regard a distinction is often drawn between an invention and a discovery, which is considered not patentable. The development of a number of new biotechnologies is based on the discoveries of researchers, which initially provided a problem for potential patentees. A turning point occurred when patent applications involving living organisms began to be filed on a regular basis.

Although there was already a predisposition to regard patenting biological resources as no different from patenting anything else, the decisions of theUS Supreme Court in the landmark *Diamond vs. Chakrabarty* case[4] established a principle that "the relevant distinction was not between living and inanimate"things but whether living products could be seen as "human made inventions". In the USA this narrow majority in *Diamond vs. Chakrabarty* laid the foundation for granting intellectual property protection for products of modern biotechnology. Relying on this decision, the United States Patent Office was prepared to grant broad patents for hybridized and genetically engineered organisms. This was part of a major but invisible cultural change, expressed by a senior UK patent expert, R. S. Crespi [5] :*Historically, the patent system came to birth to meet industrial needs. Industry was perceived as activities carried on inside factories… Manufacture was the key word. Agriculture was felt to be outside the realm of patent law. Living things were also assumed to be excluded as being products of nature rather than products of manufacture… This restricted view no longer persists in most industrialised countries. Thus the European Patent Convention of 1973 declares agriculture to be a kind of industry.*

The European Union (EU) Biopatenting Directive strongly affirmed the principle of patenting almost everything biological. It merely added a set of arbitrary exclusion clauses for applications such as human cloning known to be politically sensitive to the European Parliament. It did not respond appropriately to the full range of relevant ethical concerns, and made clear that its prime concern was European economic growth and competitiveness. This drive to patent everything biological turns the commercial paradigm into an idol. The second distinction concerns what has been invented. Where genetic modifications to an animal or plant are an issue, the addition of two or three genes to an animal with perhaps 100,000 genes does not turn the animal into a human invention. The inventive step is to add the new gene construct to the animal. The novel construct might be rewarded by a patent, or the inventive application of a modified animal to a specific purpose.

7. Farmers' Rights

Although not formally a part of the Convention on Biological Diversity, farmers' rights[6] were seen as a related concept in public debate. First formulated in Resolution 5/89 of a 1989 conference of the Food and Agriculture Organization of the United Nations (FAO), " 'farmers' rights' means rights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources, particularly those in the centers of origin/diversity…" (FAO, 1989).The original intent of farmers' rights was to recognise farmers and members of indigenous rural or traditional communities for their role in creating, domesticating, and building sources of agricultural varieties and diversity for food and agriculture. However, it is not clear how farmers' rights are to be given practical legal expression. It may prove difficult to graft this kind of right to traditional intellectual property law, in which case it will almost certainly be necessary to create a specialised new legal framework. Focusing on developing countries in particular, Article 27(3) of the

8. Impact on Farmers' Livelihoods

Patents and PVR were developed for institutional breeders serving commercial farmers in the industrialised countries, not for developing countries. In developing countries poor farmers, the majority of them women, practise mainly subsistence farming; crops are mostly local food crops which are not widely traded with seed saved from year to year and exchanged between local farmers. The crops grown are often not uniform commercial varieties but farmers' varieties (landraces[7]) which have a wide range of genetic characteristics and ensure a food supply by guaranteeing at least some yield, even in difficult conditions. Food security for most small-scale farmers is based on access to land and water, seeds and tools. Their meagre cash incomes are already stretched by other costs, such as school fees and health charges. Complete dependence on the market for their agricultural inputs or food needs is simply too risky and is likely to be so for the foreseeable future.

The general extension of the patents and PVR regime will promote commercialisation of farming in developing countries. This is rapidly undermining the whole base of small-scale mixed subsistence and local market-based production systems. For example, in the Philippines credit institutions tend no longer to support traditional agriculture. If private R&D produces varieties and methods most suitable for medium and large-scale farmers who can afford to invest in them, many small farmers will be squeezed out. They will be unable to risk innovation unless there are appropriate safeguards for them to do so. The impact of such a result would be first felt by small farmers, especially those with precarious title to their land, increasing landlessness, social dislocation and swelling population movements to urban centres. Despite the greater productivity of small-scale agriculture in terms of unit area, which also fulfils multiple roles [8], too often national policy makers see production as the key issue, millions of small farmers as a problem, and larger farms as highly preferable.

But unless there are alternative livelihoods, the new agricultural regimes could impoverish millions and reduce their food security dramatically. Any changes in R&D and IPRs must be sensitive to these realities and aimed at promoting the needs of poorer farmers.

9. The Continuing Debate on IPR

Agricultural development, including the release of improved planting materials through formal breeding and production, has benefited from a long history of public-sector/ public-good investment. At the core of this system has been the wide availability of plant genetic resources.But such public-good investments face an uncertain future. First, an increased emphasis on market mechanisms has forced publicly funded organisations to respond to broader economic and market opportunities and to position themselves to be part of the future global agricultural research system. Secondly, there is a tendency to restrict the free availability of germplasm to breeders working in publicly funded national agricultural research programmes.While many of those representing the formal and informal sectors oppose the use of patents on agricultural improvements, public institutions are increasingly being encouraged to protect their intellectual property (Baenziger et al., 1993). But many developing countries are being cautious about extending intellectual property protection to agricultural crops (Rai, 1994). For example, current thinking in India on the country's IPR framework attempts to take into account the interests of those using planting material. The preference is to continue to leave research results in the public domain.

These problems and issues arise as IPR generally and patents in particular are adapted to cover living organisms, genes, and biological processes related to agriculture. But even early on, many countries judged patent systems to be inappropriate for protecting living organisms because they imposed practical restrictions (ODI, 1993). The increased use of IPR protection in agricultural research does not seem to account fully either for the long-standing tradition of public-sector investment or for the innovations contributed by international agricultural research and by informal or indigenous communities. It is feared that such protection destroys the public-good nature of agriculture, especially as it relates to the needs of the rural poor. MTAs (if carefully prepared to ensure agreed-on use) and research exemptions could allay fears regarding access to material protected by patents. The WTO agreement on TRIPS provided impetus for domestic intellectual property legislation to comply with international norms. Applicants for membership of the WTO have to sign this agreement. The TRIPS Agreement promulgated minimum standards for intellectual property laws and enforcement regimes (Blakeney, 1996). Industrialised countries were obliged to give effect to the agreement's provisions within one year of its commencement in 1995. Developing countries had an additional four years and least developed countries a total of 10 years within which to bring their laws into line with the TRIPS norms. The TRIPS norms also form the basis for the intellectual property rules for a number of regional commercial unions such as the Association of South-East Asian Nations (ASEAN), the European Union, Mercado Comÿn del Sur (Mercosur), and the North American Free Trade Agreement (NAFTA) (see Blakeney, 1998).

10. *Sui generis* Systems

There has been a vigorous debate on the sorts of *sui generis* systems that might comply with Article 27.3(b) of the TRIPS agreement. The TRIPS provision makes no reference to UPOV, which is considered to provide some leeway in the formulation of *sui generis* systems. Furthermore, key elements for the shaping of *sui generis* systems are either unclear or not defined. First, there could be several ways of defining the term plant variety. For granting protection under the traditional PVR system, plant varieties must meet the criteria of being distinct, uniform, and stable. It has been suggested that 'uniformity' and 'stability' could be replaced by the criterion of identifiability, allowing the inclusion of plant populations that are more heterogeneous, thus taking into account the interests of local communities. The scope of protection could be limited to cover only the reproductive parts of plants, or could be extended to include harvested plant materials also.

Secondly, the TRIPS Agreement does not prohibit the development of additional protection systems, nor does it prohibit the protection of additional subject matter to safeguard local knowledge systems and informal innovations as well as to prevent their illegal appropriation. Several elements could be added, such as community gene funds and the establishment of mediation procedures (public defender) for the protection of local interests or local registers.Darrell A. Posey and Graham Dutfield have conceived of traditional resource rights as an approach to *sui generis* protection. Traditional resource rights are posited as "a process and framework to develop multiple, locally appropriate systems and 'solutions' that reflect the diversity of contexts where *sui generis* systems are required" (Posey, 1996). 'Traditional resources' include tangible and intangible assets and attributes deemed to indigenous and local communities.

Traditional resource rights are described as 'an integrated rights concept that recognises the inextricable link between cultural and biological diversity' delineating a constellation of 'overlapping and mutually supporting bundles of rights' that 'can be used for protection, compensation and conservation' (Posey & Dutfield, 1996).

11. Conclusion

Selecting among the types of protection to be applied to innovations arising from agricultural research is a complex management decision. In many public organisations, research liaison officers or offices of intellectual property help with these decisions. These individuals will help assess the accountability requirements and public expectations regarding innovations produced with public funds. Such offices can also help the national research programme to anticipate means to license, develop and move its innovations into production. Since such technology transfer agreements are especially important for new products serving farmers who rely on purchased inputs and make capital expenditures, technology transfer will usually include the licensing of some proprietary right.In deciding on which forms of IPR protection to adopt, it is important to consider whether an innovation will have only national application or perhaps wider, even global, relevance. Applying innovations to the needs of farming communities that do not traditionally rely on purchased inputs requires no IPR protection. In fact, the costs of such protection would far outweigh any commercial benefit. However, if that same innovation has global implications, then some form of protection may well be advised.

Decisions to extend IPR protection to agriculture will also depend on the assessment of the impact such decisions may have on farmers who use farmer-saved seed for planting in subsequent years. In most developing countries, small and medium-scale farmers and those operating in a resource-limited environment form the core of the agricultural system. Any system of IPR protection must take into account the needs of this community as well as the services provided to the commercial or highly productive sector, including limitations that may be imposed on a farmer's ability and rights to replant saved seed. It should be noted that the application of IPR to agricultural products is a very recent phenomenon. There is little record of the overall utility or success of patenting innovations. Revenues gained from IPR protection may help pay the costs of maintaining the structures necessary for providing researchers with advice on IPR, documenting innovations and preparing applications, but not necessarily much more.

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[1] The terms "plant variety rights" and "plant breeders' rights" are synonymous. For purposes of clarity, only the term "plant variety rights" is used here, because this corresponds most closely to the nature of the legal protection that is obtained.

[2] *UPOV* is the French acronym of the said organisation, having the full form *Union Internationale Pour la Protection des Obtentions Vegetales*.

[3] *Sui generis* means that national governments can decide on the legislation to provide effective protection, without having to follow a template used by other countries. Article 1.1 of the TRIPS Agreement leaves individual WTO members free to determine the appropriate method of implementing TRIPS within their own legal system, leaving room for different interpretations. Many developing countries believe that there exists considerable ambiguity over the wording of the flexibilities within the Agreement and seek further clarification. They fear that their interpretation of the Agreement (and therefore their legislation) may differ from another country's interpretation, which could lead to a costly WTO dispute settlement panel and other difficulties. The court case sought by a group of pharmaceutical companies in South Africa against the South African Government's medicines legislation on compulsory licensing highlighted the problem of interpretation.

[4] In 1971 General Electric Company and Ananda Chakrabarty applied for a patent on a genetically modified microbe which could digest hydrocarbons. After long debate, the US Supreme Court eventually decided, by five votes to four, that the oil eating microbe was not a product of nature and therefore patentable. See also Bruce and Bruce (1998): 219-220.

[5] R.S. Crespi (1989). Patents in biotechnology: the legal background. In *Proceedings of International Conference on Patenting Life Forms in Europe*, Brussels, 7-8 February 1989.

[6] Farmers' rights should not be confused with farmers' privilege, mentioned earlier.
TRIPS Agreement of April 1994 envisaged special types of legal systems for plant and animal varieties.

[7] Landraces **:** Crops which are often not uniform commercial varieties but farmers' varieties with a broad range of genetic characteristics to ensure a food supply by guaranteeing at least some yield, even in difficult conditions.

[8] See Peter Rosset, FAO Conference on multifunctional agriculture, Maastricht, Netherlands. September 1999. Web: http://www.fao.org/mfcal/welcome.htm

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