Transitions in Agbiotech: Economics of Strategy and Policy

EDITED BY
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Proceedings of NE-165 Conference
June 24-25, 1999
Washington, D.C.

Including papers presented at the:

International Consortium on Agricultural Biotechnology
Research Conference
June 17-19, 1999
Rome Tor Vergata, Italy

PART THREE:
Intellectual Property Rights

17. An Economic Approach to Identifying an 'Effective *Sui Generis* System' for Plant Variety Protection Under TRIPs

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An Economic Approach to Identifying an 'Effective *Sui Generis* System' for Plant Variety Protection Under TRIPs

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Chapter 17

An Economic Approach to Identifying an 'Effective *Sui Generis* System' for Plant Variety Protection Under TRIPs

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I. Introduction and Objectives

The U.S. Patent Act of 1790 is often thought of as the first of the 'modern' patent systems. It, along with the slightly later acts of France (1791) and subsequently Germany's unified law (1877) among others, have over the ensuing 200 plus years shaped an intellectual property rights (IPR) system which is carefully crafted to strike a balance between public costs and benefits (see e.g., Dam, 1994). For sure, there remains much to do to make the balance optimal for little is known about the detailed functions of IP law and its consequences both domestic and international. The systems will continue to evolve to accommodate new needs and technologies, such as, in recent years, biotechnology. And there has been acknowledgment of major errors, as in the U.S., the issuing of the 1895 Selden patents for the engine, transmission, and differential configuration for motor cars (see Allen, 1990) and possibly the granting of rights for all transgenic cotton. Another example is the conundrum of the European Patent Convention's Article 53(b) wording, "plant and animal varieties and essentially biological processes for the production of plants and animals" - whatever that may mean.

With a number of issues, well-argued matters have been raised about system operation. Deardorff (1992), for example, raises questions about the benefits of patent systems to developing countries with limited technological competence. Others have been less analytical and more vociferous in their critiques, particularly as applies to developing countries (see e.g., Nijar and Ling, 1994). But overall the system is a carefully crafted one with numerous checks and balances. For that reason it provides an appropriate model for developing countries which, by the end of this calendar year (1999), are committed under the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Appendix to the World Trade Organization (WTO) agreement to adopt a form of IP protection for plants[2]. A choice may be made among patents or Plant Breeders' Rights (PBRs), or both (Article 27.3(b)), but most countries are selecting the PBR option. However, the complete direction accorded to countries is the option of "an effective *sui generis* system for the protection of plant varieties."

Now, the meaning of *sui generis* is known - it refers to a special purpose system; hence, my shorthand use of PBR. Regrettably though, just what is meant by 'effective' and 'plant variety' is anything but clear. Here, I do not attempt the definition of plant variety[3] but do attempt to construct an 'effective,' in an economic context, PBR system which parallels patent

systems, making due adjustments for biological and institutional differences between the classes of products. I focus particularly on the kinds of checks and balances in patent legislation to understand their possible roles in PBR systems. A PBR system which parallels the checks and balances of major patent systems is, for the purposes of this paper, considered to be 'effective' within the TRIPs context. From an economic perspective, the next step is identifying what makes a system efficient as well as effective in terms of achieving its objectives.

Section II presents in a general way the components of the checks and balances of patent systems, while Section III 'constructs' a Plant Breeders' Rights system structured on the patent system while making adjustments for the technical and institutional differences between the two. Section III also examines the requirements of the International Convention for the Protection of New Varieties of Plants (UPOV), the only existing international *sui generis* system for the protection of plant materials, for its concurrence with the identified 'effective' system. Section IV also considers what is known about the 'effectiveness' of that constructed system. Section IV makes proposals for a system which is both effective and efficient.

II. Checks and Balances of Patent Systems

The purpose of patent systems is to provide an incentive for investment in inventive activities and to enhance technology transfer.[4] Hence, patent systems provide the inventor or successor-in-title a limited period to exploit the invention free from direct copying. That is the benefit to the inventor -- a negative one for sure, as it allows only the right to prevent others from practicing the invention without permission. In exchange, society receives additional investment in inventive activities plus the revealing of the practice of the invention through the disclosure requirement. The outcome, however, is economically inefficient, for placing a charge on new inventions slows their dissemination compared to the economically efficient zero marginal cost solution (see Carlton and Perloff, 1994, Chap. 17).

In order to limit the monopoly grant offered, patent law and practice restrict the scope and breadth of the grant in multiple ways. These may be grouped into (a) patentability requirements and (b) rights and limitations of the patent holder. Here these components will be reviewed in brief, then compared to a possible *sui generis* system for plant varieties.

Patentability Requirements

Essentially all patent law requires that patentability inventions satisfy the novelty, inventive step (non-obviousness under US law), utility, and disclosure requirements. General requirements are specified below, with the reader directed to national law for specific mandates.

Novelty: An invention must be new so that society is not providing privileges for materials already in the public domain. Some systems specify absolute novelty (no prior

disclosure, e.g., EPC) while others allow up to one year following initial public announcement (e.g., US). Detailed stipulations specify the exact terms and conditions under which a patent is judged to be revealed for novelty purposes.

Inventive Step: An invention must encompass more than an obvious extension of what was previously known. Combined with novelty, inventive step (non-obviousness under the U.S. system) determines the scope of a patent grant. Scope defines the degree of difference which is required for a related non-infringing invention - the 'doctrine of equivalents' in patent terminology.

Utility: Utility requirements specify that a use for the invention must be identified. The use need not be economically viable in any way – a worse mouse trap is just as patentable as a better one – but it must function as described. Depending on the type of patent granted – *per se* use; product-by-process; process – as defined by the patent claims, additional uses may or may not be covered under the patent grant.

Disclosure: A patentable invention must be disclosed fully and completely, whereas with life forms if a written disclosure is judged inadequate by the patent examiner, a deposit of the material may be required (see Straus and Moufang, 1990). The decision criterion is if the disclosure is 'enabling', that is, if it allows for a relatively direct re-creation of the invention. If the description is overly general, or the re-creation requires a protracted trial and error process - undue experimentation in patent terminology - then the deposit is mandated (unless the material is presently and openly available from other sources). Under U.S. law, the "best method" of practicing the invention must be disclosed. Other systems allow the disclosure of a less efficient but still workable method.

Patent disclosures serve multiple functions, the revealing of the invention, the provision of information which allows the invention to be duplicated on patent expiration, and a contribution to the 'storehouse' of technical information which the patent system provides. Indeed, full disclosure to a large degree separates patents from trade secrets, which are perpetual as long as the information remains secret.

Duration: All patent laws provide a point when rights expire. Under the TRIPs agreements (Article 33), that period is being standardized as 20 years from date of first filing.

Rights and Limitations of the Patent Holder

Many of the factors which determine the effective scope of protection lie outside the formal patentability requirements. The more significant of those, summarized here, include the research exemption, exhaustion of rights, and compulsory licenses and related antitrust applications, as well as general factors involved with determining patent scope and reciprocal rights in other countries.

Research Exemption: The research exemption delineates the ways and forms of research which can be done on patented products and processes. As the exemption is based on the case law in most systems, it is often difficult to characterize in detail. Within the U.S. system, reference is often made to *Roche Products v. Bolar Pharmaceutical Co.* which established the principle that only 'idle curiosity' is protected by the exemption. From that decision, a narrow exemption is often inferred. However, *Roche* was not dicta as regards the broader interpretation of the experimental use exemption (i.e., was not part of the case so the decision does not set precedent) as regards research use, so that the actual latitude is likely greater (see Bent, 1989). Goldstein (1985), for example, distinguishes between research *with* a patented product (generally disallowed) and research *on* one (often permitted).

A broad research exemption expedites the process of incremental improvements whereas a narrow exemption effectively extends the scope of protection around an invention. Despite the allegedly narrow U.S. research exemption, studies have shown that many inventions have been 'invented around' (see e.g., Harabi, 1995).

Exhaustion of Rights: The exhaustion of rights refers to the point at which the rights of the patent holder are terminated. In general, this occurs at point-of-first-sale, for with the exchange goes an implied right to use the invention as intended. It makes little sense to purchase, say, a cream separator if the sale does not confer the right actually to use the device for the separation of cream.

Several caveats need to be added to this general principle. First, additional rights or grants of permission may be required for use, particularly of more complex process inventions. Second is the issue of the resale rights of the purchaser, particularly as regards the right to export to a third country. Most laws are silent on such 'gray market' exports, while TRIPs Article 6 also allows full national discretion on this matter. In general, permitting international exhaustion of rights allows arbitrage to keep prices in line transnationally. Conversely, not permitting patent owners to maximize revenues through any price discrimination encourages a uniform price policy worldwide, which as a general matter could raise prices or reduce availability for developing countries.

Compulsory Licenses and Antitrust Applications: All patent systems have a means of granting a patent license without the consent of the patent owner, a system known as compulsory licensing. Terms and requirements for these licenses vary considerably across countries. The U.S., for example, grants licenses only to the government and only for matters of national security (Patent Act, Sections 181, 183). In Canada grounds are broader, including non-national use on a commercial scale after three years with no adequate justification given, or if demand in Canada is not being met to an adequate extent. Under these circumstances, a compulsory license may be granted (Section 65-66). (In Canada, special conditions apply to food and pharmaceuticals). Most developing countries have requirements closer to those of Canada than to those of the U.S., with maximum permitted terms based on the Paris Convention of 1883 (Article 5).

TRIPs allows specific rights to limit the extent of a patent grant, including the option to provide "limited exceptions" to the rights conferred by patents (Article 30) and including the granting of compulsory cross licenses (Article 31). The grounds for granting compulsory licenses are quite broad. They are limited primarily in procedural terms by the requirement to negotiate first in good faith with the patent owner, to be evaluated on individual merits, to be non-exclusive and non-assignable, and to provide for equitable remuneration for the patent owner. In the case of a cross license for the dependent patent, which cannot be exploited without infringing the rights of the first, a license may be granted when:

> (i) the invention claimed in the second patent shall involve an important technical advance ... (Article 31(l))

Patent revocation must be subject to judicial review (Article 32).

The effects of compulsory licenses are very uncertain. The most recent thorough review of applications date to the 1970s during a period of quite different attitudes toward technology transfer (UNCTAD, 1975). They indicated very limited grants of compulsory licenses, which some have taken as an indication of their ineffectiveness. Just as plausibly, the mere threat of the granting of licenses could be curbing much opportunistic behavior, voiding much of the need for actual license grants.

Compulsory licensing provisions tend to be broader in developing countries than in industrialized countries. This appears to be the case, in part, because smaller economies are understandably concerned about the economic power of multinational firms, yet many such countries lack the legislation and legal processes for administering antitrust law. Thus, they rely on compulsory licenses to curb some possible applications of excessive market power. The U.S. is again towards the extreme with a broad body of antitrust legislation, so that it is instructive to know if any relief from delays would be forthcoming from that source.

Antitrust issues related to patents can be, and have been, brought under both the Sherman and Clayton Acts (especially Section 3). In general, what has been found illegal is the use of patents as a mechanism for price fixing, or the treatment of a patented product as a tying good. Receiving particular scrutiny is the patent pool – if it can be construed that the pool was structured primarily to limit horizontal competition. Similarly, patents may not be used to mandate retail price maintenance or otherwise impede vertical competition if the intent of the actions was to limit competition. While the underlying decisions were reached in the context of cases involving patents, the offense is the conduct of limiting competition, not the existence of patents *per se*. Thus, the same decisions could apply to the use of Material Transfer Agreements (MTAs) and other contractual arrangements. Indeed, the only decisions which specifically require patents in their case development are those which forbid the continuation of royalty payments following a patent's expiration.

The position of the Department of Justice as regards licensing of intellectual property (IP) was codified in 1995 in the Antitrust Division's *Antitrust Guidelines for the Licensing of Intellectual Property*. Those Guidelines recognize "the principle that 'antitrust concerns may arise when a licensing arrangement harms competition among entities that would have been actual or likely potential competitors in a relevant market in the absence of the license.'" As research and development (R&D) is a scarce factor, the Guidelines recognize the potential for harm from license-based restraints which could reduce competition from related inventive activity and the integration of complementary research. Nonetheless, recognizing that antitrust applications in that area are according to the Rule of Reason, a 'safety zone' has been established, under which, excluding extraordinary cases, action will not be taken for exclusive licenses if:

(1) license restraints are not of the type typically found to be *per se* violations of antitrust laws, and
(2) the aggregate market share of the licensor and licensee does not exceed 20 percent of each relevant market affected by the restraint.

As a general matter, nonexclusive licensees will rarely result in antitrust action.

What of exclusive licenses if utilized within a concentrated market? The Antitrust Division defines exclusivity according to its character. There is no presumption of exclusivity "merely because a party chooses to deal with a single licensee or licensor, or confines his activities to a single field of use or location, or because only a single licensee has been chosen to take a license."

Thus the Guidelines reflect the prevailing view at the Justice Department that vertical licenses, such as the type considered here, seldom have the capacity to harm competition. Even when there is evidence of vertical restraints, such as the practice of tying, the terms will be challenged under the Guidelines only if:

(1) the seller has market power in the tying good,
(2) the arrangement has an adverse effect on competition in the market for the tied good, and
(3) the anti-competitive effects are not outweighed by the efficiency justifications.

Overall, it is as difficult to prevail with an antitrust action which *mandates* licensing. For sure, some antitrust cases have been resolved by requiring licensing,[5] but in general if the argument is for enhancing the public good, the vehicle is compulsory licenses, not antitrust law.

Patent Scope: Formally, scope is determined by the patent claims in combination with novelty. In practice, patent scope is an outcome of patent office practice and negotiations between the applicant and examiner. Perhaps the most relevant practice for purposes here is that of placing the burden of proof for the exclusion of a claim on the patent office — an examiner must show within the allowed novelty sources or based on prior grants why a claim

should be denied. As a result of this practice, early, pathbreaking applications for a new technology tend to be quite broad and narrow naturally as the technology matures. Certainly this has occurred with agricultural biotechnology patents in such cases as the grant in the U.S. of the rights to methods to transform all soybeans, since rescinded. More generally though, optimal scope choices, made on an application-by-application basis, effectively determine the social balance which defines the patent system.

Merges and Nelson (1990), using a case study method, show that broad grants tend to limit subsequent innovation. That however begs the issue of whether the initial breadth of grants was necessary to attract the needed investment. Studies have tended to show that the lottery-like atmosphere of R&D tends to require the potential of large payoffs, however small the probability of success might be, as Schumpeter (1950) observed fifty years ago. An important caveat was noting (not surprisingly) that open, non-exclusive licenses led to more rapid technological advancement than restrictive practices. Often the openness of licensing practices was a response to governmental pressure, as is demonstrated in the case of airplane design during World War II. More economic theoretical approaches lead to less intuitive results, but are of sufficient abstraction to limit their application.

Klemperer (1990), for example, considers both patent width (scope) and length factors under the assumption that consumers prefer variety but differ in their demands and costs of substituting among products (treated as transport costs). Welfare losses are attributable to two sources: (a) switching to less preferred products sold at competitive prices, and (b) foregoing consumption of a class of products altogether. Klemperer shows that when all consumers have the same costs of substitution, patents should be 'narrow' but of infinite duration. Conversely, when preferences are strong so that the value of consuming the preferred variety is greater than not consuming that product class altogether, then patents should be 'wide' but of short duration. More formally, as the elasticity for the cost of substituting among goods increases, welfare losses from substitution intensify. In cases where valuation of preferred varieties becomes more elastic, the significance of this second form of welfare loss becomes more important.

Reciprocal Rights: Patent laws are strictly national, meaning owners have rights only in countries where patents have been secured. Even regional systems like the European Patent Convention operate based on the awarding of a 'bundle' of national patents compared to a single multinational one. Hence it is critical for inventors to be able to secure roughly similar types of protection in multiple countries, as indicated by the market potential of each invention.

National laws typically do not make reference to reciprocal rights as those rights are a key component of the Paris Convention of 1883. Article 2.1 guarantees that nationals of any country in the Union "enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals; all without prejudice...." In the absence of national rights, patent systems break down into a series of bilateral agreements, creating uncertainty and different standards for inventors.

Subsection Conclusions

This section has summarized the multiple checks and balances of patent systems to emphasize the careful balance which has emerged over centuries of use. No attempt is made to demonstrate the balance is optimal, but rather the intent is to use it as a basis for constructing an 'effective' Plant Breeders' Rights system.

III. Constructing an Effective *Sui Generis* System for Plant Varieties from Patent Systems

This section considers first the transition of patent system efficacy requirements to an effective system for PBR, and then evaluates the current acts of UPOV, the Convention for the Protection of New Varieties of Plants, for compatibility with that constructed system.

Comparable Requirements for an Effective Sui Generis System

In this subsection, the minimal effective patent requirements identified above are applied to construct an 'effective' PBR system.

National Treatment: The national treatment issue under PBR is identical to that for patents — the thwarting of the home country incentive to restrict protection to nationals, which in the longer term undermines the system. To be fully effective, PBR must grant full and equal rights to nonresidents and residents alike.

Identification of Protectable Subject Matter: The minimal TRIPs statutes require the definition of protectable subject matter be broad within the context of plant varieties, with only a few restrictions allowed. In this context, the definition of 'plant variety' and 'plant' are central, but such definitions lie outside the scope of this paper. Yet some limiter may be needed to distinguish what within the plant kingdom is protectable by PBR, particularly as PBR has been applied to varieties of use in agriculture and horticulture, although cultural terms are not used. One approach is the patent law distinction often made between inventions and discoveries, where inventions require some human effort beyond identification. Another aspect is the utility/industrial application requirement, limiting protection to those varieties with some identified application beyond mere existence (see below). However, many important plant improvements result from discoveries, and it is important that useful discoveries, such as mutants, are reproduced and made available to growers. In particular, it is notable that the U.S. Plant Patent Act makes provision for the protection of "cultivated sports, mutants, hybrids and newly found seedlings" (Section 161 of the Patent Act of 1952).

Protection Requirements: The patentability requirements identified in Section II.A are novelty, inventive step (non-obviousness) and capability of industrial application (utility), plus

disclosure. The novelty requirement has direct correspondence with PBR, but the inventive step/non-obviousness requires somewhat different considerations (see UPOV, 1989). At one level, a traditional process of developing a new variety - cross and select - is a formulated one, with ingenuity applied in identifying the crosses for further development[6]. The inventive step requirement for PBR could be specified by requiring a showing of some unique contribution, some distinctness. That would be sufficient for genera and species for which a reference variety is known, and to which the applicant variety could be compared. However, in the case of, say, a previously unknown wild relative, no reference variety would exist. In that case, an input measure - human effort - would have to be submitted for the standard output measure - distinctness.

Industrial application/utility at a minimum requires some use for the invention to be identified in the application, but the use need not be efficient in the sense of being commercially viable compared to competing products. For plant varieties capable of being used in agriculture and horticulture, even indirectly as pure lines for subsequent breeding, the utility is self-evident. This is not necessarily so for wild discovered materials, although wild relatives, for example, could contain useful resistance or other beneficial traits. In such cases the identified distinctness characteristics of applicant varieties would presumably specify the useful attributes. Thus, effective PBR requires some specification of utility to prevent the potential protection of a large mass of discovered materials of no known use.

Disclosure likewise serves a somewhat more limited role for PBR compared to patents. The storehouse of technical knowledge and access components for patents do not strictly apply, for the general techniques are widely known and materials can be generated from those purchased on the market. Disclosure also occurs as soon as varieties are placed on the market, although this does not occur in the case of the inbred parent lines of hybrids which do not become publicly available. Thus, PBR disclosure is largely for the purpose of identifying the protected variety, a critical element in an operational system. However, new technologies, like genetic markers, may have reduced the need to use a visual description for identification purposes.

Rights Granted: Producers of plant varieties as a general matter must have the same rights to exclude unauthorized use for making, using, offering for sale, and selling or importing for those purposes as do other inventors. And because plant varieties combine attributes of products and technologies, it is essential the exclusionary rights extend at least to products directly produced, such as flowers. Here though the biological attributes of plants and the practical considerations of agriculture necessitate additional considerations.

It is the practice with many open pollinated crops for farmers to retain part of the harvest as a seed source for subsequent plantings, something which would generally be an infringement under patents. For commercial scale row crop farmers, new seeds are purchased about every third generation, while at the more subsistence level the periods would be far longer. Such reuse of seed is very efficient for farmers as it avoids the handling costs associated with producing and selling seed annually, and its allowance does avoid the costly task of

attempting to enforce rights among dispersed customers. But farmer-saved seed does limit breeders' revenue. The amount of the loss is debated; industry sources claim large amounts, but studies in the U.S. indicate the price of seed to be used for more than one crop season is higher. Stated more formally, seed producers can appropriate part of the value for the stream of benefits from seeds (Hansen and Knudson, 1996). Thus, the incentive effect of farmer-saved seed is an empirical issue by crop, location and type of farmer so that operationally it seems appropriate optionally to allow farmers the legal right to such use, known as the farmers' privilege. Sale of saved seed, originally allowed in the U.S. (PVPA of 1970, Sec. 113), is inappropriate however and an unnecessary loss for rights holders.

More significant overall is the sequential nature of plant breeding where current generations of seed stock are used as a basis for subsequent generations. To maintain the process of improvements requires free access to protected materials as the basis for initial variation. This right, known as the breeders' exemption, combines aspects of the (non-statutory) research exemption in patent law with compulsory licensing privileges.

Inclusion of the breeders' exemption removes much of the role for compulsory licenses. Once a variety is marketed it can be improved and marketed independently, bypassing the control of the original rights holder. However, access to a new variety of great public importance could still be inhibited (a) if it were never marketed and (b) for the period required to improve and market a substitute variety. Given these considerations, compulsory licensing provisions for public needs are still appropriate.

A Constructed 'Effective Sui Generis System for Plant Varieties'

Based on the preceding discussion, it is possible to construct a *sui generis* system for plant varieties mimicking the TRIPs requirements, as follows:

National and Most-Favored-Nation Treatment: National treatment is central, at minimum for the WTO member states: most-favored-nation treatment is a less essential component.

Protectable Subject Matter and Exclusions: One approach, not attempted here, is the use of the definition of 'plant variety' to distinguish between protectable and non-protectable types of plants. Another approach, more in line with an economics-based system, is to separate discovered materials from those to which human effort and ingenuity have been applied - the discover versus invent issue under patent law (see Reed, 1993). Patent laws, however, do not define the term 'invent', raising some interpretation issues, particularly if a word like 'breeding' is substituted in a *sui generis* system. Perhaps a comparable approach is to use an operable definition such as "any form of plant which has been subject to a systematic effort to enhance one group of traits relative to another" or plants which have been "bred or discovered and

developed". This restricts protection to the class of plants which has been subject to human efforts, but not artificially to any specified species.

Protection Requirements

Novelty: not previously known for some specified period. However, unlike inventions which can be accessed by a written description, plant varieties exist physically and only become available when physical material is accessed. Accordingly, novelty should only be lost when physical material of the variety is made freely available. This will usually occur when a variety is commercialized.

Inventive Step/Non-obviousness: as discussed above, the threshold needs to be changed compared to patents to an operational one of some observable distinctness when a reference variety is available and human developmental effort otherwise.

Industrial Application/Utility: in most instances the utility will be obvious - a new soybean variety or rose. But if there is a doubt, a line of commerce could be identified for the applicant variety. Otherwise, the specified distinctness characteristics can identify the useful attributes.

Disclosure: at minimum, the description should clearly identify the protected variety and its parts for enforcement purposes. The matter of providing for replication is largely resolved through the allowance of a breeders' exemption (see below).

Rights Granted and Limitations: rights granted can be the same as under patents, including unauthorized use, offering for sale, and selling or importing with the intent of using for those purposes the product directly obtained, such as seeds or flowers. Limitations can include the limited restrictions and compulsory licensing provisions as in TRIPs (Articles 30 and 31). Additionally, the characteristics of plant varieties and their use necessitate the provision of an optional additional limitation of farmers' privilege, and a breeders' exemption.

Is UPOV 'Effective'?

In Table 1 a comparison is made between the derived effective PBR system and the UPOV Acts of 1978 and 1991. The UPOV Acts are selected as a basis of comparison for they are the only existent international form of PBR protection, adhered to by 43 countries.[7] Areas where there is a substantial difference between the constructed system and UPOV are discussed further below.

TABLE 1 Comparisons Between the "Constructed" *Sui Generis* System and the UPOV 1978 and 1991 Acts

Component	**Constructed TRIPs**	**UPOV 1978**	**UPOV 1991**
National and MFN treatment	Equal rights for WTO members	Nationals of member states (3.1) Nationals of non-member states on condition of varietal examination (3.2) Above applicable on a reciprocal basis with states protecting a genus or species (3.3)	Nationals of contracting parties (4.1)
Protectable subject matter:			
Protection	All plants subject to systematic effort	May be applied to all genera and species, but minimum requirement is 24 within eight years (4)	Existing members: all genera and species within 5 years (3.1) New members: all genera and species with 10 years (3.2)
Exclusions	Ordre public, morality and protect environment	None – except as above	None – following phase-in period
Protection Requirements	**TRIPs**	**UPOV 1978**	**UPOV 1991**
Novelty	Must be new	Novelty: for protected genera and species not sold in territory of member for more than 1 year and elsewhere more than 4 years (6 for vines and trees) (6.1(b))	Same (6.1)
Inventive Step	Observable differences	Distinguishable by one or more important characteristics from any other variety of common knowledge (6.1)	Clearly distinguishable from any other variety of common knowledge (7)
Utility	Must serve industrial application	--	--
Disclosure	Describe for identification purposes	Distinguishing characteristic capable of precise recognition and description (6.1); other description requirements in application	
Uniformity	--	Sufficiently homogenous (6.1(c))	Sufficiently uniform in its relevant characteristics (8)
Stability	--	Stable in essential characteristics (6.1(d))	Relevant characteristics remain unchanged after repeated propagation (9)

Rights Granted and Limitations:	**TRIPs**	**UPOV 1978**	**UPOV 1991**
Granted	Permission to make, sell, etc. including products produced directly	Permission for production of reproductive materials for marketing or offering or marketing such material – including ornamental plants or parts (5.1)	Permission required for: Propagating material: production, sale, importing, exporting (141(a)) Harvested material: including plants and plant parts - as above (14.2) Certain products: made directly as above (14.3)
Limitations	Compulsory licenses	Restrictions of rights allowed only for public interest with equitable remuneration (9)	Same (17)
Breeders' Exemption	Change – add	Permission not required for use as source of variation for creating new varieties or marketing such varieties (5.3)	Permission not required for acts for experimental purposes or for breeding other varieties (15.1) (optional) Allow for initial varieties which require permission for commercialization (14.5)
Farmers' Privilege	Change – add provisionally	Implicit in not being covered under rights granted	(optional) Permit farmers to use for propagating purposes on own holdings (15.2)
Duration	20 years from filing date	Min. 15 years from grant, 18 years for vines and trees (8)	Min. 20 years from grant, 25 years for vines and trees (19.2)

National Treatment: The UPOV Acts are considerably more restrictive in their minimum requirements as regards national treatment than the Paris Convention requirements, raising the issue of whether UPOV is TRIPs-effective. However, all UPOV member States are free to grant national treatment to States which are not UPOV members, and some do so, e.g., the United Kingdom.

Protectable Subject Matter: UPOV 1978 with its minimal requirement of 24 species and genera falls far short of the TRIPs mandate for a very broad treatment of protectable subject matter, and appears TRIPs-incompatible. The 1991 Act eases that requirement by requiring all species and genera be protected, but over a 10-year period.

Inventive Step: The 1978 Act (Article 6.1) requires a variety be distinguishable in "one or more important characteristics from any other variety of common knowledge". If the scope of protectable subject matter is extended to include plant genera and species varieties not in commercial use, then, at least initially, examiners will have no reference variety with which to compare. This may present some practical considerations, but no fundamental ones. However, for non-cultivated materials where the dimensions of the population might not even be known, this means of measuring the inventive step is not applicable.

Uniformity and Stability: These requirements have no parallel under patent systems due in part to the different subject matter. There are at least two justifications for their inclusion in the UPOV Acts, (a) description and identification, and (b) practicality - uniform and stable varieties are generally more useful in commercial agriculture. As to (b), practicality is a consideration, but there is no requirement in patent law that a patented invention be competitive with other products on the market. Indeed, survey reports that only some 15 percent of patents achieve commercial success underscore that point (Nogues, 1989). Presumably an inventor would wish to make the product commercially viable, but it is not the task of the patent examination process to require it be so. Thus justification (b) can be rejected.

Regarding (a), uniformity and stability are important aspects of the distinguishing characteristics for without them a variety is not distinguishable over time, making a protection system inoperative. However, those requirements have attracted comment particularly from those who link the requirements with the uniformity and vulnerability of major crops. Recent work by Olufowote *et al*. (1997) among others has shown that non-inbred materials display a wide variation in heterogeneity at randomly selected alleles, but any material which has been selected, even using less formal techniques (such as might be applied by local farmers in selecting landraces), to be useful would presumably be stable in its target characteristics, say stress resistance. It is presently possible to specify that level of stability in a probabilistic sense, but only following considerable investment. In the more distant future, it is conceivable that marker technology - microsatellite markers give evidence of particular promise - can assist in the process.

The UPOV terminology of "sufficiently uniform in its relevant characteristics" and "relevant characteristics remain unchanged after repeated propagation" (UPOV 1991, Articles 7 and 8) is sufficiently flexible to allow for changing interpretations. Thus it is possible to protect at least some landraces under the current systems, but the practical effect will be minimal as the costs of specifying the variety will be high.

Farmers' Privilege: The use of the crop as a seed source for a subsequent season would be an infringement under patent systems. The farmers' privilege is allowed (indirectly, by not being identified as an infringing use) under UPOV 1978, and made optional under UPOV 1991. Countries have responded differently; the U.S. for example adopted a blanket authorization for the privilege, while the EU grants the privilege only for small farms. Larger operations are required to pay royalties.

International Exhaustion of Rights: PBR systems are silent as regards international exhaustion of rights, but the matter has limited practical importance due to the general need to adapt seeds to local growing conditions and market requirements.

Subsection Conclusions

Existing PBR systems, as exemplified by the UPOV Acts of 1978 and 1991, parallel closely the functioning of patent systems. This is not surprising, for the two systems have similar objectives, and the framers of PBR would of course be conscious of the operation of patent systems. Nonetheless, there are important differences in the additional exemptions allowed under PBR in national treatment and protectable subject matter and in application of the systems. Thus it is to those matters we turn for a final judgment on efficacy, and its economic definition.

IV. But Is the Constructed System Effective?

In order to make a judgment on whether the constructed system is indeed effective, it is necessary to examine its operation in addition to the legal text. That is undertaken here, first by examining what is known of the breeding investment response to PBR, and then considering the administrative application of the law in detail.

Investment Responses to PBR Legislation

Being comparatively recent and restricted in geographic scope provides both benefits and limits for the analysis of the economic effects of legislation. The limitation is that to date few studies have been conducted, but for those available there is a better accounting of cause and effect.

A detailed early study was commissioned by the U.S. Department of Agriculture to investigate expressed concerns about the possible negative effects of PBR (Butler and Marion, 1985). Regarding the effect on private R&D investments, significant increases in the number of plant breeding programs were recorded while investments increased most rapidly in the 1967-70 period, provisionally in anticipation of the passage of the Act in 1970. Expenditures were (and remain) unevenly distributed across crops with major investments directed to soybeans. That allocation has been explained as an economic response to relative profit opportunities (Foster and Perrin, 1991). Wheat breeding on the other hand remains dominated by the public sector with little evident effect of PBR (Alston and Venner, 1998).

There has been no systematic effort to evaluate the effects of PBR in Europe or Canada. But the development of one key Canadian crop, canola, has been documented in detail. Following 1985 there was a sharp increase in private sector canola development attributable to several factors of which "perhaps the most critical factor was the introduction of intellectual property rights for biological inventions." (Phillips, 1998).

For developing countries in Latin America, Jaffé and van Wijk (1995) found only Argentina combined several years of experience under PBR with effective enforcement. There, PBR appears to have restrained "companies from reducing or even eliminating their breeding programs and enabled the reactivation of soybean breeding." But those effects occurred only after rights could be effectively enforced. To date, no systematic efforts have been made to document the effects of PBR on access to materials developed elsewhere, but both Canada and Chile justified enacting the legislation in part to enhance that access.

Application of PBR Systems

Scope Issues: The application of any legal/economic system allows for a myriad of approaches. For the purposes of this paper it is primarily important to distinguish between two, referred to here as the European (examination) and U.S. (registration) systems. In Europe, for major crops, commodity committees are empanelled with the responsibility to identify relevant attributes for protection, and in some cases to establish a minimum statistical standard for meeting that requirement compared to the reference variety. Thus, for example, storability of onions could be set as a distinctness criteria with a protectable variety required to show one percent less sprouting than the reference. Growout trials are then undertaken to measure performance in field conditions.

The EU operates with a legally separate registration system for row crops known as Value in Cultivation and Use (VCU). Under that system, varieties must demonstrate superiority in economically important traits to be placed in the Common Catalog and be eligible for sale. That is, VCU acts as a form of quality certification. Operationally, the VCU testing is done concurrently with distinctiveness, uniformity and stability (DUS) testing (see Lesser, 1987) and is operationally indistinguishable from European PBR systems when effects are evaluated.

The U.S. system is quite different in that essentially no variety testing is undertaken, and further, distinctness can be established in any dimension, even far from something of practical value, say a flower color shade not detectable by the human eye. As a result, many similar competing varieties are available on the market, a situation known as 'cosmetic breeding'. That has previously led to a reference to the U.S. system as one of registration which protects the variety name, not the germplasm *per se* (Lesser, 1986). Canada and Australia operate hybrid systems with European-type growouts conducted by the applicant under government supervision.

From this perspective, it is possible the scope of coverage in the U.S. is too limited, potentially not 'effective.' Stated more formally, farmers' substitution functions among closely related varieties can be expected to be highly elastic as they share similar objective functions for varieties, and comparative performance information is available. Under those conditions, owners of rights will price competitively to minimize lost sales. With limited profits, protection must be of long duration to allow the recovery of the R&D investment. However, variety life is typically more limited by natural factors such as increasing susceptibility to insects and diseases co-evolving with the varieties than by statutory limits. Indeed, the commercial life of a variety in the U.S. has been placed at seven years, but is declining due to competition. Thus we can tentatively conclude U.S. protection is too limited to be effective.

Partial corroborative information comes from complaints of breeders, efforts to find alternative protection mechanisms, including utility patents for varieties, and projections of low estimated values for certificates of plant variety protection (PVP). For soybeans sold in New York State, the estimated return for a certificate of plant variety protection was 2.3 percent of the variety value (as contrasted with the large portion of the seed price which reflects the crop value). While the percentage may seem large, the value per bag of seed amounted to only $.32. That analysis needs to be replicated in other areas and times, but is suggestive of the low value of PVP in the United States.

However, this approach also raises social costs by delaying the introduction of more efficient technology. As an alternative, it is possible selectively to increase the scope of protection for more significant contributions. That goal was effectively accomplished with the distinction between 'initial' and 'derived' varieties in the 1991 UPOV Act, although for different reasons. Article 14(5) allows for the permission of the breeder to be required for a variety which is "essentially derived from [a] protected variety, where the protected variety is not itself an essentially derived variety." A variety is essentially derived when "it is predominately derived from an initial variety, or from a variety that is itself predominately derived from the initial variety, while retaining the expression of the essential characteristics." Essentially derived varieties may be obtained in a number of identified ways, including "transformation by genetic engineering." And that is, of course, a principal objective of the new approach — preventing agbiotech companies from usurping a variety by inserting genes into it, while having no responsibility to the breeder.

Operationally, 'essentially derived' behaves as a limit to the breeders' exemption, itself a form of research exemption. Article 15.1(iii) allows the use of a protected variety for the "purpose of breeding another variety"; but when the resultant new variety is derived, permission of the owner of the initial variety is required for commercialization. Rights are non-pyramiding; that is, if A is an initial variety and B is derived from it and C from B, owners of both B and C varieties must have the permission of variety A's owner before commercialization.

Clearly, this process will prevent biotech firms from appropriating protected varieties, as is intended. The effects of this approach are not known; I am unaware of any cases having been brought to date. In most countries, the owner of an initial variety must assert his/her rights by suing the derived variety's owner for infringement. This is how patent rights are enforced. It means that until court challenges have been made, the scope of protection granted to initial varieties will be unclear.

Initial variety legislation can however have additional effects. Consider, for example, a case in which annual varietal improvement is at the rate of one percent annually, while a three percent improvement is needed to qualify as an initial variety. All benefits go to the owner of initial varieties. Producers of essentially derived varieties act as royalty collectors for the owner of the initial variety. The initial owners (under competitive conditions) receive only the value of their contribution, and then only until it is superseded by an improved one. What to do? Why not delay the release of a new variety until it qualifies as an initial one, in our example withholding release for three generations? That approach would have the social cost of delaying access to improved technologies.

Farmers' Exemption: Another aspect of PBR legislation which makes it weaker than comparable patent protection is the allowance of the right to hold back harvested material for use as a seed source, that is, the farmers' privilege. Here reference is made only to open pollinated materials, for the use of asexually propagating materials like tree cuttings would clearly obviate any profit potential for breeders, while first generation hybrids (which do not reproduce true to form) cannot be economically used as a seed source. The 1978 UPOV Act allows a universal farmers' privilege - indirectly by not classifying such use as an infringement (see Section III.B(e)). The 1991 Act (Article 15.2), however, makes the farmers' exemption optional at the national level. The U.S. has decided to allow a full Farmers' Exemption, while the EU requires that large farms pay a royalty.

Breeders have long and understandably complained that the exemption significantly reduces their sales and profits. The latter point is valid; row crop seeds in the U.S. are replaced only every third year as saved seed becomes contaminated while new seed has the benefit of additional breeding work. Small seeds like alfalfa and vegetables are typically purchased annually due to handling difficulties. But are breeders' *profits* reduced as a result of the use of the privilege? Hansen and Knudson (1996) argue, not by much. They use a field-level model for U.S. soybean production to show that seed companies can indirectly appropriate rents by charging a sufficiently high price for the parent seed.

Higher seed prices which allow breeders to capture multi-year profits, however, have an indirect societal effect. Knudson and Hansen (1991) show that U.S. farmers sometimes under-invest in new seed, suffering a yield and profit loss as a consequence. Considering seed sources in a regional production model for wheat, the authors show that lower quantities of purchased seed led on average to an eleven percent yield loss. As the proportion of purchased seed varied according to the crop price, it seems likely that farmers were responding to cash flow rather than profitability factors. Raising seed prices would exacerbate this matter, particularly under current low crop prices, while disallowing farmer seed saving could enhance production efficiency and profitability. If indeed seed companies are appropriating most of the net new seed value anyway, then costs to farmers would rise only in respect to the costs of new seed distribution compared to on farm handling and conditioning costs, plus those for enforcement. Yet enforcement would be simplified if seed saving were banned for then farmers would have some documentable seed source annually. Data on the net cost difference, however, are not available at this time.

The EU practice of requiring owners of large farms to pay royalties on saved seed is an intriguing alternative position, but one which begs more economic analysis. Presumably, the underlying concept is that large farms are more profitable and can afford to pay the royalties. This may be broadly true, as scale economies in production do exist. In general, however, U.S. experiences with basing policy on farm size considerations have been problematic, for ownership-of-record can be and is adjusted for cost purposes. Moreover, the prior version of U.S. PBR legislation allowed limited farm seed sales, not to exceed 50 percent of farm sales (PVPA of 1980, Section 113). That limitation proved unworkable as the practical definition of what constituted 'farm sales' for this purpose could not be specified effectively, and it was dropped in 1994 when the U.S. adopted the 1991 Act of UPOV. Conversely, the policy may focus on the higher efficiency of collecting royalties from large versus small farms. In either case, and depending on what royalty is charged, the practice of under-vesting in new seed would be reduced.

Subsection Conclusions

Seemingly, the European approach provides broader protection than is extended in the U.S., but both are socially inefficient. The one potentially provides a socially non-optimal broad protection, but the degree of protection likely necessary to attract investment, while the other provides narrow and short-term protection, probably too little overall for the optimal level of breeding investment. That certainly seems to have applied to wheat breeding.

The UPOV system provisions allowing for varietal dependency deal effectively with a target — preventing biotech firms from appropriating varieties through genetic engineering. Under the dependency approach, those firms must seek the permission of the variety owner for commercialization. However, excluding the consideration of biotech, if the non-dependency threshold is set too low, firms will have the incentive to avoid dependent status by withholding

multiple generations from sale. This would be a social loss. Better then that the bar be set relatively high.

Evidence indicates that farmers' privilege does not substantially reduce breeders' profits for open pollinated seed, and thus no restrictions are needed. However, requiring annual royalty payments for large farms, as is being practiced in the EU, will reduce the inefficient custom of replacing seeds infrequently. Placing the requirement on all farm sizes reduces the wasteful incentive to accommodate the legal stipulation of a farm size to avoid the payment.

V. Conclusions

It is relatively easy to derive a PBR system based on centuries of experience with patent systems. The public/private benefit balance, which characterizes IP, is well served by the long history of such a derived system. Indeed, it appears that UPOV, the international PBR convention, has accommodated institutional and biological differences between products. Reference is made in particular to the Breeders' Exemption (the right to use protected seed in breeding programs) and Farmers' Privilege (the right to use the harvest material as a seed source).

In the past, PBR systems have functioned well in increasing investment in plant breeding activities, particularly from the private sector. That is a highly important consequence in an era of worldwide reductions in public investment in agricultural research. It also is a necessary component of the TRIPs requirement for an "effective *sui generis* system." But the system should be efficient in terms of the public/private tradeoff as well. Globally, an IP tradeoff is inefficient due to welfare losses of delayed distribution of new varieties with a non-zero price. Locally, there are some possible improved efficiency tradeoffs. That is, PBR systems can be and are applied in multiple ways, with distinct efficacy and efficiency effects.

What can be said about ways to enhance the efficiency of PBR?

Situation: The U.S. registration approach with current distinctness requirements seemingly leads to quite weak protection, potentially too weak to be effective, to judge from firm efforts to find alternative mechanisms. Conversely, the European model allows far stronger protection, but is costly in administration and delays.

Enhancement: Perhaps an efficient hybrid would be the U.S. registration process with higher distinctness standards, but not limited to few varietal dimensions as is the case under the EU varietal committee systems.

Situation: The UPOV dependency provisions (depending on how implemented) provide incentives for delaying the release of new varieties, which is inefficient.

Enhancement: Setting high criteria for initial varieties would minimize that effect, for firms could not reasonably expect to withhold market release for several generations with the expectation of qualifying as an initial variety (and with the potential to earn rather than pay royalties).

Situation: The limited available research on the breeders' cost of farmers' privilege is convincing in that there is little need to restrict the privilege to provide greater royalty payments for breeders. Conversely, research shows that farmers sometimes under-invest in new seed purchases, leading to lost production potential. The two aspects are linked, for pricing varieties in a way which appropriates the royalty value for multiple years provides producers with an incentive to delay seed replacement.

Enhancement: Restricting the farmers' privilege under those circumstances - that is, requiring annual seed replacement - could actually improve agricultural productivity with little cost effect if previous research is substantiated by subsequent research.

Endnotes

[1]Professor, Dept. Agricultural, Resource and Managerial Economics, Cornell University. Parts of this paper are included in Lesser (1999).

[2]The least-developed countries are allowed an additional six years (until Jan. 1, 2006) to comply with this requirement.

[3]But see, for example, UPOV 1991, Article 1.

[4]See e.g., Machlup (1958). TRIPs specifies its objectives to be a contribution "to the promotion of technological innovation and to the transfer and dissemination of technology" (Article 7).

[5]Thus, the majority of consent decrees that involve patent-antitrust issues arise in the context of proposed mergers and acquisitions, rather than in the context of predatory behavior or *per se* illegal actions." (Khan, 1998, p. 25)

[6]Conceptually, there is no distinction from the production of traditional varieties in farmers' fields except the process is less systemized, but astute selection remains the key aspect for success (see e.g., Eyzaguirre and Iwanaga, 1996).

[7]Membership information is available from the UPOV web page, www.upov.int. Countries which are signatories to the 1978 or earlier Acts are not required to adopt the 1991 text, but for others the 1991 Act is the only one currently open for new members.

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