Commission on Intellectual Property Rights

Study Paper 3a

Access to Genetic Resources, Gene-based Inventions and Agriculture

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Executive Summary and Recommendations

I. Seeds and Seed System Transformations

Identifying the key properties of the 'seed' is a useful starting point for a study on intellectual property rights in plant genetic resources as it brings together the literature on seed systems with that of intellectual property rights. Embedded in the seed are two distinct and separable properties: (a) genetic information and (b) physical properties. Of particular significance is the malleability of plants, on account of changes achieved in its genetic software (i.e. varietal characteristics), which lead seeds to occupy the unique position of the platform for the techno-economic transformation of agriculture.

Varietal development, i.e. plant breeding, is the core purpose of seed systems. However, a number of other activities, viz. seed production and multiplication, and processing, storing and marketing seeds, are also crucial in delivering new varieties to the farmer. In addition, the public sector performs many supporting activities (e.g. germplasm collection and documentation, background research) that enable plant breeding. Strong recommendations for putting in place policies to promote increasing privatisation of different components of seed systems have been made in the literature. These recommendations require urgent re-evaluation in light of awareness of (a) factors defining the demand conditions for seeds and (b) the supporting role of public sector breeding-related activities.

Recommendations

1. Donor agencies (e.g. World Bank, NGOs and relevant developed country government departments) should closely review policies aimed at fostering the privatisation of seed systems in developing countries. This should focus on the farmers' seed sourcing behaviour and the state of public sector breeding-related activities and evolve a strategy of long-term support of national and international public agricultural research.

2. Donor agencies (e.g. World Bank, NGOs and relevant developed country government departments) should either undertake or commission studies that focus on science/technology developments in plant breeding and farm-based activities to highlight strategies aimed at tying-in seeds with other farm inputs.

3. Donor organisations and agencies, government departments associated with rural developmental activities and non-governmental organisations, should commit to widening participation and partnership in agricultural research so as to include farmers.

II. The Economic Impact of Plant Variety Protection

Economists studying plant breeders' rights tend to be less theoretically sophisticated when compared to available analysis in the area of patents. In particular, the absence of a theoretical approach, the literature only provides empirical research. In the case of developed countries this literature can be reviewed along three themes:

R&D Impact: It is often claimed the availability of PBRs incentivised private investments in plant breeding. The evidence, as recent contributors note, is that of a modest and uneven impact of PBRs on private sector breeding investments. First, older companies, i.e. companies with breeding expertise and pre-existed the legislation, reveal higher R&D-intensities and broader crop portfolios. Second, the investment spread unevenly across crops, with wheat and soybean attracted the most investment. Yet, economists have failed to analyse a range of factors that must have contributed to the change in investment patterns, viz., scientific opportunities (e.g. discovery of heterosis in wheat), appropriability conditions (i.e. the fragility of the soybean seed), demand (e.g. international trade in these crops).

New Varieties Released: A common claim in the literature is that the availability of PBRs leads to an increase in the number of new varieties released. Empirical evidence from the US and the UK do seem to support this claim; however, deeper methodological issues remain in terms of confirming the role of IPRs. First, there is mixed evidence about the changes in the *historical* rate of release of varieties in a pre- and post-PBR world, which suggests that other factors are also important. Second, it is quite obvious that a general increase in the number of varieties released is of meaningless value; rather of importance are the agronomic qualities of the varieties. Field trial data confirms a general view that more recent vintages of varieties are more productive; though questions remain about the role of varieties and the package of inputs. Third, increases in the rate of release of varieties are part of wider appropriation strategies of breeding companies and directed at reducing the useful economic life of varieties. Evidence from wheat in the UK shows that average age of varieties has fallen from 12 years to about 6 years in the 1960-95 period.

Market Concentration: Concerns about changing levels of market concentration are integral to this issue. Evidence from the US and UK adequately demonstrate a high and increasing level of concentration in the number of granted issued in a crop. This concentration in grants acts as a deterrent to market entry; thus, the evidence of concentration in the seed market, which has increased with the consolidation in the industry. It is the exercise of the resulting market power that raises public policy questions. Evidence of increases in seed price suggests an undue exercise of market power by breeding companies.

Many commentators recognise the differing circumstances in developing countries; thus questioning the appropriateness of existing models of PVP. This report reviews the limited evidence of private sector breeding activities in developing countries.

Research Priorities: Private sector breeding tends to limit itself to high value/low volume crops and hybrids. Further, the agronomic qualities indicate that the target areas are characteristically the post-Green Revolution areas. Accordingly, it appears unlikely that the crop and agronomic needs of the wider farming populations, particularly low external-input use communities, are consistent with this research priority. Neither is there convincing evidence that dominant trends from the release of genetically-modified field crops are directed at these populations. As such, a 'chicken-and-egg' problem persists: 'is it that an absence of effective demand is the hurdle for the supply of suitable varieties? Or is that lack of suitable varieties has inhibited the generation of demand in these areas?'

Access to Varieties: It is said that the availability of PBRs will allow legitimate access to foreign-bred genetic material. This appears to be the case from studies based in Latin America and Kenya. The case of Kenya raise public policy questions: has the access to foreign bred genetic material enhanced national capacity in plant breeding and what is the impact on food security. Existing literature on Kenya does not provide encouraging evidence on either of these two issues. Finally, there remain questions about the impact of PBRs on the terms of access to finished varieties by farmers. Given established seed exchange networks and its role in distributing varieties and maintaining diversity, there are apprehensions about the adverse impact of PBRs.

National and international public plant breeding is the mainstay of most developing countries. Not only does develop new varieties, but it also provides the general scientific and technological environment for plant breeding. Many policy analysts raise questions about the future role and orientation of public sector breeding in an era that is increasingly being characterised by the presence of the private sector. Discouraging trends in funding patterns for public agriculture research indicate that a smaller role might be one key result. The report identifies three salient points. First, research conducted in the private and the public sector are non-substitutable as they are targeted at different farming groups. The shrinking resource base of the public sector and the low possibility of cost recovery, place ever greater demand for external revenues. Second, closer institutional linkages between the public and the private sector raise public welfare questions in terms of accountability and transparency. Third, the spread of proprietary control in research tools and uncertainty in the limits of ownership make the conduct of agricultural research all the more difficult by requiring complicated negotiations.

Recommendations

4. A substantive review of the functioning of plant breeders' rights, at national and international levels, must be conducted to identify and analyse the impact on agricultural research, agronomic qualities of new varieties released and market concentration. This work can be conducted through relevant international organisations (e.g. UPOV, UNCTAD, and FAO)

5. Developing country governments are recommended to review the evidence from the above-mentioned report as a first-step towards conducting similar national-level study. This study should inform the policy process of making new law to implement article 27.3b.

6. National and international agricultural research centres are recommended to review the impact of intellectual property rights on their conduct of agricultural research (e.g. ISNAR studies) and evaluate their collaborations with the private sector.

7. Donor agencies (e.g. World Bank and developed country departments of international development) are recommended to strengthen their long-term commitment to funding public sector agricultural research.

III. The TRIPs Agreement and Plant Innovations

The TRIPs Agreement aims at establishing minimum standards and does not seek to globally harmonise standards and norms of intellectual property protection. Yet, there are examples of political and economic pressure being applied on developing countries to secure the implementation of 'TRIPs-plus' legislation.

With respect to plant genetic resources, three central legal and technical issues require close scrutiny: (a) what is the criterion for granting patents? (b) what is the scope of, and limits to, the exclusions from patentability in the Agreement? and (c) what are 'plant varieties' for the purpose of article 27.3b?

The patentability of plant genetic resources depends on the subject matter fulfilling the normal tests for patent grant, viz. novelty, inventive step and industrial applicability. While the Agreement does not provide any explicit definition, wide variations exist between different jurisdictions in the application of these principles, reflecting differences in interpretations and subjectivity in application. While many countries grant patents on subject matter involving genetic material – on the grounds that adequate human intervention has occurred – there is nothing in the Agreement that oblige members to accept the isolation of genetic material as qualifying for a patent.

Article 27.3b obliges member countries to provide intellectual property protection (patents, or sui generis or some combination) for plant varieties. However, there is no definition of plant variety in the Agreement nor does it refer to the pre-existing international template – UPOV. Consequently, there is no obligation to join this or any other, multilateral treaty on plant variety protection. It is useful to consider a variety of options in establishing a legal definition of plant variety, keeping in mind national priorities. In this respect, a simultaneous analysis of the conditions for the grant of protection is considered useful.

Recommendations

8. Developing countries should take full opportunity to exercise their national sovereignty in developing and implementing national intellectual property right legislation. In this respect, the TRIPs Council should review the use of bilateral treaties as mechanisms to secure 'TRIPs-plus' standards in developing countries.

9. A clear agreed interpretation of the obligation with respect to the patentability of plant genetic resources should be developed at the TRIPs Council, wherein the non-patentability of naturally occurring plant genetic resources (including gene sequences and genes) should be established. Countries should be free in opting to disallow patents on plants.

10. Member countries of the WTO should direct the TRIPs Council to take cognition of the different, and at times conflicting, views on the patentability of plant genetic resources and the difficulties facing developing countries in implementing their obligation under art. 27.3b of the Agreement. Appropriate extension periods for compliance to the Agreement should be made available.

IV. Implementing Article 27.3b – The Case of Plant Varieties

The obligation under article 27.3b is for an intellectual property right and must include provisions for national treatment, most favoured nation and (as yet unclear) requirement for effective protection. A variety of options are available for developing countries: (a) exclude plants (including plant varieties) from patentability, (b) not exclude plants (including plant varieties) from patentability, (c) not exclude plants from patentability and simultaneously provide for the protection of plant varieties via a dual system (i.e. patents and *sui generis*), and (d) exclude only plant varieties from patentability, thus providing for a *sui generis* system. These options must be examined in terms of national priorities, in particular the need to maintain access to genetic material for breeders to continue plant breeding and for farmers to ensure seed diffusion. Consequently, the sui generis option is considered the best alternative.

The paper reviews three key components of the sui generis system, viz. coverage of the law, the conditions for protection, and the scope of protection, which are all undefined in the Agreement. In addition, the term 'effective sui generis system' is undefined in the Agreement and has led to wide speculation on the required scope of protection. In contrast, there are views suggesting that it will be the standards of protection that determine whether a sui generis system is effective. With respect to the three components, the following points are made:

Coverage of the law: The Agreement does not indicate the required coverage, nor does it state that protection should be limited to a defined list of plant species or botanical genera. Consequently, the popular interpretation that all plant species and botanical genera must be

included within the ambit of the law. In contrast, UPOV78 and UPOV91 provide a more gradual approach to expanded coverage of the law. In this respect, it appears unreasonable that the TRIPs obligation requires immediate and maximum coverage. The analysis here explores an alternative interpretation of the Agreement, where a gradual expansion, such as the one existing within UPOV78, might be deemed consistent with the Agreement. As such, this is a grey area which will be ultimately decided either through dispute settlement at WTO or an agreed interpretation at the TRIPs Council.

Conditions for Protection: As this is undefined in the Agreement, most commentators have focussed attention on the UPOV system where the requirements are distinctness, uniformity and stability. Three problems with the UPOV system are noted in the literature: (a) the demand on uniformity is an excessive burden which has, at times, deleterious effects on biodiversity; (b) the exclusive focus on distinctness of characteristics is considered a low threshold for 'inventive step' which tends to enable the easy grant of protection (e.g. cosmetic breeding), and (c) the high demand on stability is considered an economic deterrent to the quick release of new varieties. Following from this critical evaluation of the DUS system, some modifications are presented as possible systems for developing countries to consider. These include the following:

- Enhancing distinctness by introducing a qualification for 'important characteristics' (which existed in UPOV78) such as 'traits of agronomic value'. This would raise the 'inventive step' threshold and could act as an incentive for the breeding of useful varieties.

- The uniformity requirement could be replaced by a requirement for identifiability that fulfils the legal need for identifying the protected subject matter, whilst potentially avoiding the adverse biodiversity implications. In addition, this may also allow the inclusion of farmer-varieties.

- Other requirements that could implement principles of the CBD are also worthy of consideration. Of relevance are the submission of certificates declaring the geographical origin of the genetic material involved in the application and certificates confirming prior informed consent.

The literature on the conditions for grant of protection is relatively new and it is important that developing countries examine these models closely before implementing the provisions.

Scope of protection: It is here that public policy comes to bear in its effort to balance the interests of different segments of society, crudely put as a tension between the incentives demanded by inventors and the need for wide/quick diffusion. Developing countries need

to consider different approaches in terms of balancing the measures required by TRIPs with national priorities, there being no a priori guarantee that the two are identical. The paper considers a range of questions that will ultimately define the scope of protection being offered; e.g. the duration of protection, possibilities of differential scope of protection; exceptions from the scope for farmers and breeders. The options available are quite diverse and developing countries need to make a proper assessment of an appropriate scope of protection. What is clear is that a 'one-size fits all' approach is counter-productive.

Recommendations

11. The option to fulfil the obligation under article 27.3b by implementing an effective sui generis system for plant variety protection should be retained without modifications aimed at establishing a possible benchmark (e.g. UPOV).

12. Developing countries are recommended to undertake an extensive review of policies on agricultural development as a first step towards formulating and implementing an effective sui generis system for plant variety protection. This review exercise should be conducted in a participatory manner with the full and active involvement of all segments of society that are impacted by transformations in agriculture.

13. It is recommended that developing countries should reiterate their demand for the TRIPs Council to complete its substantive review of article 27.3b, which should also bring on board evidence of the impact (actual and/or potential) of IPRs in genetic resources and survey the issue of capacity-building as pre-requisite to effective implementation.

14. Developing countries are strongly recommended to examine key components of a sui generis system (e.g. the coverage of the legislation, the scope of, and conditions for, protection) to assess what might be appropriate and in the national interest.

1. Introduction

The TRIPs Agreement has led to a highly politically charged debate on the issue of property rights in plant genetic resources. The social, ethical and moral questions extend beyond the legal and technical questions about whether 'inventions' involving pre-existing subject matter qualify for intellectual property protection. For developing countries[1] the obligation under the TRIPs Agreement has led to strong political reactions that have cut across ideological differences. At issue, in a narrow policy sense, is whether implementation of the TRIPs Agreement with respect to plant genetic resources will result in any net social benefits? This report attempts to systematically present empirical evidence to allow for informed and evidence-based policy making in developing countries.

The report covers the following four areas of the literature:

- A discussion of the properties of seeds and the transformations taking place in seed provision systems in developing countries
- An assessment of the empirical evidence of the economic impact of plant variety protection in developed and developing countries, with a brief discussion of the pressures on public plant breeding
- An introduction to the TRIPs Agreement obligation with respect to plant genetic resources that highlights some grey areas and ambiguities
- Review of options available in formulating an effective sui generis system for the protection of plant varieties, such as the coverage of the legislation, the scope of protection and conditions for grant of protection.

2. Seeds and Seed System Transformations: A Conceptual Precursor

2.1 Introduction[2]

Identifying key properties of the 'seed' is a useful starting point for a study on intellectual properties rights in plant genetic resources. Not only is it important to identify and appreciate the complex properties embedded in the seed, it is also crucial to recognise the

[1] 'Developing countries' is used to refer to both categories of 'developing countries' and 'least developed countries'.

[2] This section is based on Rangnekar (2000: chapters 5 and 6).

role played by seeds in the techno-economic transformation of agriculture. Equally important, particularly for policy deliberations, is the need to establish a link between concerns regarding IPRs and the literature on seed systems. The following two sections are directed at these conceptual issues.

2.2 Seeds: The Primacy of Genetic Software

Agriculture is an example of a 'complex technology system' of varied techno-economic institutions that exhibits subtle interdependencies and component compatibility. Inputs build the environment and provide the general conditions in which seeds perform; and it is necessary for seeds and inputs to be compatible for an effective exploitation of the latent economies in the technological package. However, seeds occupy a particular primacy in that they establish the upper limit to the productivity of all other agricultural inputs. (Cromwell, 1990; Jaffee and Srivastava, 1992) The primacy of seeds is on account of the dual properties embedded in the 'seed'. A packet of seeds is composed of two distinct and separable properties: (a) genetic information, i.e. *software*, which is the result of breeding programmes, and (b) physical properties, i.e. *diskette-like* features that are determined by seed production process[3] (Lewontin and Berlan, 1990).

In reality is the genetic software, i.e. the varietal characteristics, that is of crucial importance in substantially determining the productivity limits of agricultural inputs. For example, while the introduction of inorganic chemicals relax the constraints of renewing soil fertility after each cycle of cultivation, transformations at the varietal level are necessary to enable crops to withstand and effectively utilise such applications. Economic returns associated with the use of these inputs depend on the adoption of varieties that are bred to respond to the application of these inputs. A similar argument can be made for the case of mechanisation, where effective mechanisation of farm practices requires specific transformations in the biology (e.g. uniform maturing) and architecture (e.g. strong stalks) of the plant. Consequently, mechanised harvesting of certain crops (e.g. tomatoes) had to await a breeding achievement (e.g. hard exteriors). Yet, neither specific input packages, nor particular types of varieties (e.g. dwarfs) can independently proliferate as the dominant mode of agriculture. Rather, it is a technology package consisting of specific varieties that are compatible with defined inputs and agronomic practices. However, the malleability of plants, on account of changes achieved in its genetic software give it (i.e. the 'seed') a unique position of being a platform for the techno-economic transformation of agriculture.

[3] This internal duality in seeds is reflected in an industrial division of labour between firms that are primarily plant breeders and those that are mainly seed producers. A similar distinction exists in the regulatory system where plant variety protection focuses on genetic software (i.e. plant breeding) and seed certification concentrates on the diskette (i.e. seed production).

The characterisation of 'seeds' as platforms for technical change highlights another aspect of the component-interdependencies of the technology system. Changes achieved in genetic software that tie together variety and input enable the creation of markets for industrially produced agricultural inputs. Because of the systems nature of agricultural technology, these different markets are increasingly interlinked. In the era of biotechnology, evidence of the interlinking of agricultural product markets via transformation achieved at the level of the genetic *software* is more transparent. Take for example the breeding focus on herbicide-tolerance: adoption of a particular variety ties the farmer to an input package consisting of brand-name herbicides. Not surprisingly, herbicide tolerance is the dominant trait being tested across all genetically modified crops: the proportion of transgenic crops with this single trait increased from 23% to 54% of the total global area under transgenic crops between 1996-97. (James, 1998)

2.3 Seed Systems: Changing Roles of the Public and Private Sectors

Producing plant varieties for use by farmers require a number of different activities, each with its distinct techno-economic resource requirements[4]. Plant breeding is but one of the many steps to be accomplished. The following schema appears well accepted within the literature: (Gregg et al., 1980; Pray and Ramaswami, 1991; Jaffee and Srivastava, 1992; Jaffee and Srivastava, 1994)

- Varietal development: The development of genetic software (i.e. new varieties) involves assembling diverse genetic material, crossing the genetic material to generate variation, selecting recombinations from the variation, and stabilising the preferred characteristics as a new variety. The specific method of selecting preferred characteristics differs according to the mode of propagation of the species (e.g. cross or self-pollinating) and the type of breeding method (e.g. hybrid or pure line). The varieties are tested and evaluated for specific characteristics and than released as breeders' seed.

- Seed production and multiplication: It is here that the diskette (i.e. the seed) carrying the selected genetic software (i.e. varietal characteristics) is produced through the sequential multiplication of breeder seeds. The preferred method of multiplication depends on the mode of propagation of the crop, while the number of multiplications depends on the regulatory system. It is quite common to have a three-stage process that sequentially produces 'foundation seed', 'certified seed' and 'commercial seed'.

[4] The exposition here is necessarily historically contingent and reflective of contemporary regulations. If, by way of argument, the discussion concerned seed production systems prior to the early 20th century re-discovery of Mendelian genetics or the mid-20th century implementation of seed certification schemes in Europe, than the number of stages and activities would be quite different.

It is important to maintain the distinguishing characteristics of the variety, so that the farmer plants a *diskette* (i.e. seed) that corresponds to the advertised claims of the *software* (i.e. variety).

- Seed processing and storage: Given that seeds are living organism, a number of precautionary steps need to be undertaken to maintain the viability of the seed over a period of time between production and eventual utilisation. These precautions involve steps like drying, cleaning, and chemical treatment.

- Seed marketing and distribution: This involves a number of activities, such as transportation, promotion, field demonstrations, advertising, etc., to ensure that the right amount of seed of the appropriate variety reaches the farmer at the correct time. Equally crucial is the requirement of informing farmers of the characteristics and agronomic performance of available varieties so as to enable appropriate and informed decision-making by farmers.

In addition to the activities listed above are functions like germplasm collection and documentation and fundamental research. These wider activities provide the environment within which plant breeding can take place and are invariably performed by the public sector.

TABLE 1
Techno-economic Factors and Appropriate Role for Public and Private Sector

Activity	Scope for Appropriability	Externalities	Scale Economies	Private Sector Incentives	Public Sector Provision
Varietal Development					
- Self-Pollinated	Low	X	X	Low	High
- Hybrids	High	X	X	High	Variable*
Varietal Maintenance	Medium	X	X	Medium	High
Seed Production					
- Self-Pollinated	Low	-	-	Medium	Variable**
- Hybrids	High	-	X	High	Low
Seed Certification	Low	X	X	Medium	High
Seed Marketing					
- Storage	Variable	-	X	Variable	Variable
- Promotion	Medium		-	High	Medium
- Distribution	Medium	X	-	High	Low

* Depending on level of scientific development, early stages suitable for public sector involvement.
** High justification for public sector in foundation seed production and at early stages of seed industry development.
X – indicates the presence of the relevant property.

Source: (Jaffee, 1992)

The literature on seed systems makes policy prescriptions on the appropriate role for the public and private sector in terms of the activities identified above (see table 1). The analysis is based on mapping seed system development across countries, which has led to

the identification of three broad stages. (Jaffee and Srivastava, 1992; Jaffee and Srivastava, 1994) In the early stages of seed system development farmers tend to be the primary and dominant source for varietal improvement. The transitory middle stages are characterised by the dominating presence of public sector breeding activities and mixed presence of private-public agencies in downstream seed system activities. At this stage, as far as varietal development is concerned, private sector investments tend to focus on high-value/low-volume commercial crops and hybrids. The final stage of a *mature* seed system is distinguished by the presence of private sector companies in varietal development. Underlying this analysis are stereotypical characterisations of the private and the public sectors. Thus, the public sector is presented as being 'inefficient or ineffective'. (Jaffee and Srivastava, 1992; Jaffee and Srivastava, 1994) In contrast, the "private sector is normally flexible, [and] responsive to changing requirements" (Gregg, 1980: 224). However, there is little disagreement that, following the adoption of policies of liberalisation, the public sector and parastatal organisations are under significant budgetary pressure, which undermines its capacity to deliver varietal improvements. (Morris et al., 1998; Mruthyunjaya and Ranjitha, 1998; Tripp and Pal, 2001)

Consequently, the literature recommends the gradual withdrawal of the public sector from 'near-market' activities and from activities that allow high levels of appropriation (cf. table 1). These policy prescriptions are reflective of the continuous struggle to demarcate the private and the public domain whilst balancing the interests of different social groups engaged in agriculture. (Kloppenburg, 1988) No doubt, often there are strong views expressed on the policies that inhibit the development of a commercial seed industry, as expressed in the following quote,

> "The disincentives and uncertainty caused by seed distribution programs, the inefficiencies and privileges of public seed producers, and the existence of restrictive regulatory regimes all *conspire* to inhibit the development of a commercial seed sector in Africa". (Tripp and Rohrbach, 2001, p152, emphasis added)

Among the policies recommended for the promotion of a commercial seed industry is the introduction of intellectual property protection for plant varieties. (Perrin, 1994; Perrin, 1999) It is suggested that the availability of IPRs will enhance the scope of appropriability for commercial breeders, thus improving the incentives for investments in plant breeding, which will eventually lead to the development of better varieties.

However, this policy prescription misses two crucial factors that underpin the development of a commercial seed industry. First, on the demand side, it is necessary for the seed market to exhibit adequate and sustained purchasing capacity. At a global level, the commercial seed industry accounts for approximately a-third of the global market and is valued at US$30bn (cf. section 3.2[c]). The balance is divided equally between the public sector and a locally/farmer-supplied system. Disaggregating this to regional and local

levels reveals the marginal position of commercial seed providers. For example, only about 7% of wheat seed and 13% of rice seed in India is sourced from the formal (public and/or private) sector, and in many parts of Africa and Asia it is estimated that over 80% of total farmers' seed requirement are met from outside the formal sector. (ten Kate and Laird, 1999) In most instances, farmers source seed from a variety of outlets that include neighbours, farm-saved seed/grain, and local seed multipliers (cf. table 2).

Table 2 **Wheat Seed Sources in Bangladesh**

Source of seed	Farm Size			
	Marginal (< 0.5 acres)	Small (0.5-2.5 acres)	Medium (2.51-5.0 acres)	Large (> 5.0 acres)
Home storage	35.3	39.7	46.6	64.7
Neighbours	4.5	2.7	4.8	0
Seed producers	4.7	2.0	0.9	0
Market	34.9	29.6	19.1	10.1
Public seed company	20.6	23.9	28.7	24.0
Others	0	2.2	0	1.2

Source: O'Donoghue (1995) The Whole Family Training Programme on Post-Harvest Technologies. A Report for the Bangladesh-Australia Wheat Improvement Project, Dhaka. Based on table 2.1 in Tripp (1997)

In addition, most farmers do not regularly purchase seeds for each successive planting. This is not peculiar to farmers in developing countries, since wheat farmers in both industrialised and developing countries exhibit a varietal turnover rate that ranges between 5-10 years. (Brennan and Byerlee, 1991) Part of the relatively low and irregular demand for fresh seeds in developing countries is a reflection on the inappropriateness of breeding strategies within the formal sector (Tripp, 1997)and the pricing policies of commercial seed producers. (Tripp and Rohrbach, 2001)

Second, the viability of a commercial seed industry is significantly contingent on the pre-existing research base and enabling scientific environment. The technology studies literature has amply demonstrated that it is public science which substantially provides the leads and opportunities for the private sector to pick up and pursue. (Dosi, 1988; Rosenberg, 1994; Rosenberg, 1996; Freeman, 1997) In the case of plant breeding there are a number of activities that are mainly conducted by the public sector, such as germplasm documentation and maintenance, development of breeding lines, training of scientists and breeders. Unfortunately most accounts of seed system do not pay adequate attention to this factor. Thus, even in a 'mature' seed system such as the US, where PBRs have been

available since 1970[5], the dependence on the public sector is significant and apparent in the parentage of privately bred varieties: 50% of the wheat and soybean varieties, 90% of barley and dry bean varieties and 95% of rice varieties consist of publicly bred varieties; (Knudson, 1990) in 1979, 72% of hybrid corn varieties had at least one parent of public sector origin. (Butler and Marion, 1985) These parental lines have invariably been accessed at nominal costs of about US$5-20. (ten Kate and Laird, 1999, p125)

To sum up, recognition of the properties of the seed is of primary importance for a policy analysis of intellectual property rights in plant genetic resources. In this respect, it is important to recognise the malleability of plants, on account of changes achieved in at the level of its genetic software, which allow the seed to occupy a position of the platform for the techno-economic transformation of agriculture. The discussion also highlights the general policy prescription for increasing privatisation of different components of the seed system. These recommendations require urgent re-evaluation in light of (a) factors defining the demand conditions for seeds and (b) the supporting role of public sector breeding-related activities.

Recommendations

1. Donor agencies (e.g. World Bank, NGOs and relevant developed country government departments) should closely review policies aimed at fostering the privatisation of seed systems in developing countries. This should focus on the farmers' seed sourcing behaviour and the state of public sector breeding-related activities and evolve a strategy of long-term support of national and international public agricultural research.

2. Donor agencies (e.g. World Bank, NGOs and relevant developed country government departments) should either undertake or commission studies that focus on science/technology developments in plant breeding and farm-based activities to highlight strategies aimed at tying-in seeds with other farm inputs.

3. Donor organisations and agencies, government departments associated with rural developmental activities and non-governmental organisations, should commit to widening participation and partnership in agricultural research so as to include farmers.

[5] Add to this the other legal instruments that enable legal appropriation, such as the 1930 Plant Patent Act, the 1980 *Diamond v. Chakravarty* decision allowing patents on living matter (viz. microorganisms) and the *Ex parte Hibberd* decision in 1985 that allows patents on plants.

3. The Economic Impact of Plant Variety Protection: Assessing the Evidence

3.1 Introduction

The cornerstone and fundamental social logic of providing IPP is to promote socio-economic progress through granting temporary monopoly rights to inventors, which allows them to appropriate a rent from the use/exploitation of their inventions. This principle and intent is not entirely alien to the TRIPs Agreement, which states the following;

> *Recognising* the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives

The public policy imperative, and the fact that IPRs are instruments of temporary monopoly rights, has led to the development of checks and balances to ensure that the benefits are widely distributed. For some, these 'checks and balances' appear to be adequate. (Lesser, 2000) However, industrial economists studying the actual functioning and use of the IPRs system provide a more nuanced picture of economic reality,

> Although devised to solve an important incentive problem, the patent system is a crude and imperfect instrument. Because of diverse real-world complications, the patent protection given an innovator may be too little, too much, or of the wrong kind.
>
> The protection provided is often weak because there can be many viable solutions to a technical problem, so other firms can "invent around" a given patented solution. […] further complications emerge because the growth of technology is cumulative and richly interactive. […] For smaller and especially less-developed countries, patent holders' power to block use of their inventions by others poses a special problem. Multinational corporations commonly patent their most important inventions in dozens of national jurisdictions. The quest for scale economies leads them to produce in one or a few preferred locations … this typically means that high prices will be paid for imported patented products, while opportunities to build a home industry using first-line technology are restricted. (Scherer and Ross, 1990, pp624-26)

It is to issues like those referred to in the above quote that attention needs to be devoted – the evidence of the actual working of IPRs in agriculture. Again, a focus beyond the available 'checks and balances' in the letter of the law, is not novel. For example, in 1980 when in the US the Plant Variety Protection Act (1970) was being revised, attention focussed on the possible influence of high market concentration levels on seed prices and

the breeding effort. In a prescient article, John Barton (1982: 1072) drew attention to possible 'terminator technologies' being developed:

> What could make this concentration issue serious is the possibility that DNA engineering will be applied to make the second generation of a seed artificially sterile. Plausibly, any seed might be designed to make it biologically impossible for a farmer to reuse his crop for seed purposes. Such an 'innate plant patent system' could pose enormous social costs in a concentrated industry.

This is now a scientific reality.

Despite the very rich theoretical and empirical tradition exhibited by economists in studying patents, the literature on PBRs tends to be less astute and theoretically underdeveloped. (Kennedy and Godden, 1993)

3.2 Evidence of the Impact of PBRs in Developed Countries[6]

3.2(a) R&D Expenditures

It is often claimed, that at a minimum, IPRs operate as "anticipated" and result in increased investments. (Lesser, 1991, pp3-4) This presumption about the impact of IPRs raises two questions. First, is this increased breeding activity and investment equally distributed across all company? Evidence from the US clearly demonstrates that older companies, i.e. companies that pre-existed the introduction of PBRs, are more R&D-intensive, have a larger scale of operation and breed across a broader crop portfolio. (Butler and Marion, 1985) It appears that older firms have an advantage reflecting their accumulated scientific and technological competencies. However, the evidence also concludes that this advantage is exacerbated by the acquisition of IPRs.

Second, is the increased investment and breeding activity evenly distributed across crops? The only evidence on the distribution of R&D across crops is from the US, where it is self-evident that a few crops (i.e. wheat and soybean) experienced increases in private investment. (Perrin et al., 1983; Butler and Marion, 1985) Unfortunately, there is nothing to suggest that the increases were primarily or entirely on account of the availability of PBRs. With respect to soybean, a range of factors influenced the investment behaviour of private breeders, such as (a) historical trend of increasing acreage under soybean cultivation, (b) fragility of the soybean seed, which disallows farm-seed saving, (c) expanding downstream food processing industry based on soybean, and (d) increasing

[6] The section summarises research reported in Rangnekar (2000), where an extended discussion can be found. As will be evident, much of the evidence is from the US and UK.

international trade. The increase in wheat breeding activity – the other crop to account for sizeable private investments – is explained by the concentrated focus on developing hybrids. (Knudson and Ruttan, 1988)

As such, the R&D impact is considered modest at best. (Butler and Marion, 1985, pp29-35; Kloppenburg, 1988, p141) Though some contributors have claimed a strong incentive effect, (Lesser, 1991) it appears that the modest and uneven impact of PBRs on R&D expenditures has since gained currency. (Fuglie et al., 1996; Ramaswami, 2000; Rangnekar, 2000)

3.2(b) New Varieties Released

Given that PBRs are provided for new varieties, economists have focussed on the release of new varieties as an indicator of the impact of IPRs. A general claim in the literature is that "the availability of PBRs has increased the number of private sector breeders, as well as the number of varieties released and planted". (Lesser, 1990, p60) The claim is (partially) supported by evidence from the US and time series data of UK wheat varieties. Interestingly, even critics accept that the number of varieties released have increased after introduction of PBRs (Mooney, 1983, p153). Recent evidence for the US suggests that the number of varieties released in the 1990s is higher than that in the 1980s. (Fuglie et al., 1996, p36) However, key methodological questions remain in terms of whether the availability of protection *caused* the increase in varietal release and whether this is an economic good. Here we note a statement by ASSINSEL;

> It is not easy to make a direct correlation between the protection of plant varieties and the number of new varieties released. However, it is reasonable to assume that the new incentive given to plant breeders stimulated breeding activity.

Three questions remain before a conclusive statement on the impact of PBRs on varietal release rates can be accepted as an economic good.

First, has there been a change in the historical rates of varietal release in the pre- and post-PBRs period? Naturally, a historical examination of changes in the varietal release rates will also take account of changes in other factors that influence breeding activity. No such study has been conducted. The only effort at partially analysing historical rates of varietal release for select UK crops across 1930-90 reports mixed evidence: while rates of varietal release, following introduction of PBRs, increased in apple, the change in French beans was marginal and it was negligible in strawberry. (da Rocha, 1994)

Second, what are the agro-economic qualities of the new varieties? This is important, since an increase in the availability of varieties is not an economic good in itself, as it might be

that the increase in varieties is on account of cosmetic breeding[7] and/or strategies of planned obsolescence (see below). Further, we must keep in mind that there is no merit test in the process leading to a PBRs grant[8]. It is suggested that "protected varieties will be shown to be good performers"[9] (Lesser, 1997). The claim is based on reports of field trials that aim at disaggregating yield increases amongst different components, which conclude that the 'breeding effort' component is substantial and has increased over time. (Austin et al., 1980; Austin et al., 1989) While there is little doubt that new and contemporary varieties are more productive, it is difficult to disentangle the interactions between the adoption of new varieties and the use of input mixes and crop husbandry practices, since the varieties are themselves selected to respond to the inputs and husbandry practices (Simmonds, 1979, pp61-3). Some commentators are more critical of the methodology adopted in the field trials reported earlier. (Brennan and Godden, 1994)

Third, are changes in varietal release rates part of wider appropriation strategies? At issue here are possible interactions between the process of technical change and the appropriation strategies, which manifest in the entry-exit dynamics of varieties. (Rangnekar, forthcoming) To explain, firms might adopt strategies of planned obsolescence as a means of maintaining market shares, which result in faster rates of varietal turnover and higher varietal release rates. This strategy is underpinned by breeding efforts that focus on incremental productivity improvements (e.g. yield increases) and reduced durability (e.g. narrow disease resistance profiles). Both actively reduce the useful economic life of a variety, and thus warrant adoption of the new vintage by the farmer. Empirical evidence from wheat in the UK reveals that the average age of varieties fell from over 12 years to about 6 years 1960-95.

The three 'questions' place evidence of changes in varietal release rates in a wider context. To sum up, while it might be the case that more varieties are annually released under a regime of PBRs, it is not automatically the case that this is an economic good. In fact, empirical evidence of strategies of cosmetic breeding and planned obsolescence cast doubt on this claim. Finally, there is little doubt that new and contemporary varieties are increasingly productive. However, efforts to claim that this is substantially a result of the 'breeding effort' and not of the wider package (inputs and agronomic practices) are not convincing.

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[7] The breeding of nominally differentiated varieties that are otherwise identical.

[8] Studies on using patent counts as indicators of inventive activity adopt a number of statistical techniques to adjust the absolute number of patents granted to make them more reliable indicators of inventive activity (Acs, 1989; Griliches, 1990). It is surprising that none of the economist studying PBRs have attempted similar exercises.

[9] Ironically, elsewhere Lesser (1991, p36) is cautious about the productivity differences between public and privately bred varieties, accepting that there might be only weak evidence of the superior productivity of private varieties.

3.2(c) Market Concentration

Concerns about market concentration are quite natural in debates on PBRs. But, first some evidence. The distribution of PBRs in wheat in the UK is highly concentrated and the degree of concentration has increased with time: the top five grant holders accounted for 69% of the grants in 1965-74 which increased to 79% in 1986-95. (Rangnekar, 2000, chapter 7) In the case of the US no comparable time series data exists. Evidence of the grants issued between 1971-82 provides the following conclusions (Butler and Marion, 1985):

- In marigold, alfalfa and oats the top 2 grant-holders accounted for more than 70% of the grants.
- In pea, bean, lettuce, watermelon, and barley, the top 3 grantees accounted for more than 50% of the grants, whereas in tobacco they held 100% of the grants.
- The top four grant-holders accounted for between 82-91% of the grants in onion, rice, tomato and cauliflower.

These levels of concentration are high, and it is suggested that seed firms that were established well before the passage of the Plant Variety Protection Act have benefited (Butler and Marion, 1985, pp33-38). More importantly, the adverse crop-level distribution of grants corresponds to seed market concentration (Butler and Marion, 1985; Kloppenburg, 1988). Commenting on the US data, Lesser (1991: 36-7) argues that in the long run, competition pressures will eliminate the negative effects of market concentration. Yet, recent data (c. 1997) on the North American seed market (Hayenga, 1998)indicates the contrary:

- Hybrid corn: the top five companies account for 69% of the market, with the market leader, Pioneer Hi-Bred, alone controlling 42%.
- Soybean: the top five companies account for 51% of the market, with the market leaders, Pioneer Hi-Bred and Monsanto, each controlling 19%.
- Cotton seed: the market leader, Monsanto, alone controls 84% of the market, on account of its purchase of Delta and Pine Land.

Similar evidence is available in the case of wheat in the UK where the market leader, Plant Breeding International[10], has consistently controlled 60-80% of the market through the period 1977-95. (Rangnekar, 2000) Data of the global seed market is notoriously unreliable and difficult to collect. One effort at collating information from company annual reports

[10] Initially a public sector company, Plant Breeding Institute, it was sold to Unilever in 1987. Later in 1998, Monsanto purchased it from Unilever.

indicates that, in 1998, US$30bn of the US$50bn global seed market was accounted for by commercial seed sales – of which, 31% was accounted for by the top 23 companies, with the top 3 accounting for 13%. (ten Kate and Laird, 1999) Another source suggests that the top ten companies account for 30% of global commercial seed sales. (Rural Advancement Foundation International, 1997)

It is the exercise of market power that is of concern, which can be discerned from movements in seed prices. The evidence is not encouraging:

- In the US, expenditures on seeds increased from US$519mn to US$1515 between 1960 and 1980 (constant 1960 dollars). (Perrin et al., 1983) Three-fourths of the increase was on account of seed price rise and the balance on account of increased seed purchases. (Butler and Marion, 1985)

- In the US, over the 1972-92 period, real seed prices increased faster than yields. (Fuglie et al., 1996, p43)

- In the UK, with the removal of controls on royalty rates, farmers are paying more for seeds (Pray, 1996).

The evidence noted above clearly reveals that a high level of market consolidation has developed in the seed industry. More importantly, the evidence of movement in seed prices is *suggestive* of an undue exercise of this market power.

3.2(d) A Cosing Statement

The above review indicates that the introduction of PBRs has differential results across crops. More over, the increasing presence of the private sector in plant breeding is accompanied by appropriation strategies that might have deleterious distributional and allocative impact. For example, increase in the varietal release rate is accompanied by a shortening life-span of varieties. Equally important is the evidence of correspondence between concentration in PBRs grants issued and seed market shares, which manifests has led to increases in seed prices.

3.3 Evidence from developing countries

3.3(a) General Overview/Statements

A wide variety of commentators accept that there is ‘little evidence’ (Lesser, 1991, p37)or ‘mixed and inconclusive evidence’ (UNEP, 1996)about the direct benefits of introducing IPRs in plant varieties in developing countries. Others agree that the costs of stronger intellectual property protection are easily foreseeable, hence the need for identifying and assessing the wider social welfare implications and possible benefits. (Cohen, 1999) Yet,

the enactment of IPRs in developing countries is recommended, as in the following statement;

> If the LDCs do not experiment with strengthened IPRs as a means of bringing more private innovative activity into the effort to capitalise on this new technology, the productivity gap will surely widen (Perrin, 1994: 514).

In contrast, a more cautious approach is also present in the literature. Thus, Barton suggests that it is "doubtful" whether developing countries should enact PBRs because the "tradeoffs are quite different". (Barton, 1982) In this respect, contrast the estimate that by 2000, 75% of US agricultural production would be accounted for by 50,000 large farms, with the estimate that 70% of India's population is dependent on agriculture. (Verma, 1995) Consequently, a detailed empirical analysis of the effects of adopting PBRs is considered a necessary prerequisite before policy formulation/implementation. (Godden, 1984) In this respect, the key questions for policy analysts in developing countries prepared by IPGRI (1999) are useful (cf. section 5 and box 4).

3.3(b) Research Priorities and the Breeding Effort

At issue here is whether the introduction of IPRs in developing countries will lead to increasing plant breeding activity that meets the agro-economic needs of the country. As with the differential focus on select crops, available evidence of private breeding in developing countries indicates a limited breeding effort that concentrates on few crops that tend to be hybrids and developed for exclusive agro-ecological zones. Evidence in this respect is available in an unpublished USAID study on Argentina and Chile (quoted in Lesser, 1991). The private sector invested only in wheat and soybean.

The only comprehensive study of the impact of PBRs in a developing country setting analyses evidence for five Latin American countries. (van Wijk and Jaffe, 1996) Among the findings, the following is pertinent in terms of the breeding effort: de facto division of labour has evolved with MNCs predominantly operating in hybrid crops and the public sector (and domestic breeding companies) almost entirely focussing on open-pollinated varieties. The MNC-funded breeder lobby group advocated and secured the inclusion of protection of inbred parental line within Argentina's PVP legislation, and consequently, the number of protected inbreds increased to 112 in two years.

Lesser (1991, p38), quoting CGIAR personnel, accepts that agricultural research for developing countries is dedicated to few crops and tends to be suitable for 'post-Green Revolution' areas (viz. the Punjab, Yaqui Valley of Mexico, Central Luzan of the Philippines)[11]. Unfortunately, this type of research focus does not relate to low-input areas

[11] The CGIAR's portfolio of crops has expanded from the initial focus on the cereals that launched the green revolution to include 27 commodities (http://www.cgiar.org/history).

where the diversity and variability of growing conditions cannot be normalised through the purchase of inputs, thus, places a greater premium on breeding for local adaptation (Hardon, 1992; cf. box 1).

Box 1

Resource-poor Farmers and Minor Crops

Resource poor farmers constitute over half of the world's farmers and produce about 15-20% of global food. It is estimated that over 1,400mn people depend on resource-poor farming systems in marginal environments that have not benefited from the dominant agricultural research programme of high-yielding varieties. Much of this population is in the developing world – 100mn in Latin America, 300mn in Africa and 1,000mn in Asia.

At the global level, only 30 crops provide over 95% of dietary energy (i.e. protein), with three cereals (i.e. wheat, rice and corn) accounting for more than one-half. Yet, there are many plant species that are of greater importance to vast populations at sub-national and regional level – all of which have been neglected in conservational programmes and in crop development research. Some 'minor crops' and 'under-utilised species' include the following:

- Staple crops: yam, proso millet, fonio, bambara, groundnut, oca, taro/cocoyam and breadfruit.
- Vegetables, fruits and other species: these include a wide variety of 'wild plants' and 'weeds' that are gathered, and contribute to nutrition and dietary diversification.

During FAO's sub-regional meetings in preparation for the 4th International Technical Conference of 1996, the need for greater attention to these crops and neglected agro-ecological niches was repeatedly mentioned.

Source: FAO (1998)

As such, the likelihood of private breeding meeting the agro-economic needs of the vast majority of farmers is unlikely. This view is reiterated in the following quote:

> The assumption that new varieties are always 'on the shelf', ready to be delivered to farmers, has been disproved by the disappointing experience of many extension programmes meant to deliver supposedly superior varieties that have not been sufficiently tested under farmer conditions. […] The demand for seeds of new varieties, especially in the farming conditions that Chambers (1991) describes as 'complex, diverse, and risk-prone' will depend on the ability of modern plant breeding to adopt strategies that are better able to target these varied environments and to develop appropriate varieties. (Tripp, 1997, p20)

Reflective of the above statement is the difference between the public and private sector in maize breeding in India (Rangnekar, forthcoming). Maize breeding has attracted sizeable private sector investments in India, such that it almost matches the public sector in varietal release rates. (Singh et al., 1995; Morris et al., 1998) However, there are striking differences in the varieties which reveal the agro-economic areas being targeted:

- Hybrids: the private sector exclusively breed hybrids, whereas only 23% of public sector varieties are hybrids

- Varietal Characteristics: private sector hybrids are suitable for full-season and irrigated areas, whereas public sector varieties are hard, flinty grain types that are suitable for small-scale farmers in vulnerable agro-ecological niches

It may be suggested that private sector focus in biotechnology might be relevant. In this respect, rice is an illustrative example with over 160 patent grants issued between 1982 and 1997 (GRAIN, 1998). The research programmes focus on hybrid rice and genetically-modified rice[12], raising question whether predominant production problems confronting developing countries are being addressed. Of interest is a Monsanto presentation at a recent IRRI conference, which emphasised the attraction of the seed market, net present values estimated at US$1-2bn (Teng et al., 2000). In addition, the interest in rice is motivated by the availability of "mechanisms to add value, mechanisms to capture value and mechanisms to preserve value [i.e. intellectual property rights]" (Teng et al., 2000: 155). Clearly, it is the opportunities thrown up by scientific/technological developments, the size of the seed market and appropriation possibilities through IPRs that explain the evidence. Yet, in the absence of patent protection in many Asian developing countries, PVPs could provide some incentive (van Wijk, 2000, p146). As far as global agri-biotech research is generally concerned, there is little focus on the needs of poor farmers. The main crops targeted are soybean, corn, tobacco, cotton and canola together account for over 95% of the acreage (Wright, 2000; Fresco, 2001)[13]. Further, only two traits dominate: insect resistance using Bt and herbicide tolerance. However, herbicide tolerance appears as the preferred trait being pursued, with area under cultivation increasing from 23% in 1996 to 54% in 1997. (James, 1998)

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[12] GM rice breeding aims at introducing specific vitamins and nutrients into rice. Vitamin A rice is one such example that the private sector hopes to market as a 'functional food', while also addressing a global nutritional problem, i.e. vitamin A deficiency amongst over 100mn children in Africa and Asia.

[13] Total area under GM crops has risen from 31mn acres in 1997 to cross 44Mn acres. However, 75% is in the developed world and only 7 developing countries have commercial GM crops under cultivation, though with the exception of Argentina and China, the area is under 100,000 hectares (Fresco, ibid.).

To sum up, existing evidence of the focus of private sector plant breeding is not entirely promising. The range of crops focussed on and the type of agro-ecological niches being targeted do not cater to the wider needs of the majority farming populations in developing countries. It is often suggested that this will change with the availability of IPRs; however, the trend within biotechnology is not promising. On the other hand, it must be reckoned that the vast majority of farmers in developing countries are not a market with purchasing power as a substantial segment of the market is provided by non-commercial transactions or local production. This raises a deeper 'chicken-and-egg' question: is it the absence of effective demand that forestalls the supply of suitable plant varieties; or is the lack of suitable varieties that stunts socio-economic growth in these areas?

3.3(c) Access to Varieties and Germplasm

Another benefit of the availability of IPRs in developing countries is that it will enable access to varieties bred outside the country, as foreign breeders would be more willing to provide access to their varieties when IPRs are available. This appears to be the case for an unpublished USAID study of Argentina and Chile, where access to US and New Zealand fruit varieties improved following the introduction of PBRs (Lesser, 1991, p53). It is similarly argued that Monsanto refused access to Bt-cotton in Brazil, despite extensive crop loss from infestation, because of absence of proprietary protection (Lesser, ibid). Consequently, the claim that the absence of intellectual property protection is a restriction on the access to germplasm. In this respect, the experience of Kenya, where a cut flower industry has flourished, makes interesting reading (cf. box 2). No doubt, Kenya has benefited, to some extent, from the development of a cut-flower industry. However, whether this has improved food security remains a moot point.

Box 2

Kenya: Ornamentals and Food Security
The experience in Kenya – the leader in Africa in terms of production and export of cut flowers – with respect to cut flowers and ornamentals shed interesting insights into questions of intellectual property rights, access to foreign breeding material and the dynamics associated with the presence of MNCs. Agriculture remains central to Kenya – accounting for 26% of the GDP and employing over 70% of the population. The entire industry is export drive, with 98% of the over 40 types of flowers being exported to mainly European countries. Horticulture (of which, 35% is cut flowers) earns Kenya much needed foreign currency and registers 3rd after tea and coffee. MNCs interest in producing cut flowers in Kenya can be linked to climatic conditions and the low cost of multiplying flowers. The industry is largely dominated by a group of 22 large companies – though 80 small-scale producers provide a small amount of the market. Unfortunately, much of the profits leak out via foreign-owned MNCs who dominate the cut flower industry; thus leading to little domestic research-capacity development. Consequently, a public sector breeding programme, in collaboration with domestic seed companies, has been launched to locally develop new

flower varieties.

Despite the presence of foreign breeding companies, Kenya only joined UPOV in 1999, with a ratification of the 1978 Act. Yet, it had a statute on the books in 1972, though the Plant Breeders' Rights Office was only established in 1994. Early evidence of the functioning of PVP system indicates that only one grant was for a 'food crop' – French bean for exports. The balance were all for ornamentals. Further over 90% of the grants were made to foreign nationals.

As such, the availability of PBRs has enabled Kenya to secure a foot-hold in the international cut-flower industry and benefit, to some extent, from access to foreign cut flower varieties. However, the availability of PBRs and the eventual ratification of UPOV78 have done little to generate incentives for plant breeders (domestic or foreign) to develop food crops. Could this be a model to emulate: fostering the development of a cash crop to earn resources that allow the purchase of food? An answer to this question will be based on an examination of changes in land allocation between food production and horticulture and of the use of profits that accrue from the MNC-controlled ornamental export industry.

Source: van Roozendaal (1994); GRAIN (1999) – Plant Variety Protection to feed Africa? Seedling (Dec); Cullet (2001)

There is more to the question of access to breeding material. A five country study in Latin America concludes that access to germplasm was significantly restricted after the implementation of PBRs (Jaffee and van Wijk, 1995) – a result that is consistent with evidence from the US studies reviewed earlier. The transformations that take place are more subtle than apparent. Introduction of PBRs is often followed by dual processes that (a) place pressure on public institutions to behave like 'semiprivate organisations' and (b) motivate closer collaborative research between the public and private sectors. Jaffee and van Wijk (1995: 144) conclude that reduced availability of germplasm was partly because of "joint germplasm improvement programmes" between public and private sectors.

3.4 Impact on Public Plant Breeding

Public plant breeding remains a key component of the agriculture research systems in developing countries. Its importance goes beyond the obvious role of breeding varieties suitable for the diverse local needs and includes the role of providing the scientific background and technological opportunities for private sector developmental activities. However, public agricultural research will have to undergo a radical transformation in an era marked by the increasing presence of the private sector. (Rangnekar, forthcoming) This change is partly a consequence of a deepening resource crunch precipitated by the reluctance of international donors to finance agriculture-based activities. Between the publication of the Brundtland Commission (1988) and the World Food Summit (1996), foreign aid for agriculture-related projects in the South fell by 57% and World Bank loans under the 'agriculture and rural development' category registered a 47% decrease (Paarlberg, 2000). In contrast to these trends is the significant growth in private sector

agricultural research expenditures. Data in Alston et al. (1998) for the decade 1971-91 reveal the following trends:

- Worldwide investments by national governments in public agricultural research nearly doubled in real terms.
- Expenditures of publicly performed agricultural research in developing countries grew at 5.1% pa, whereas in developed countries it grew at 2.3% pa. Yet they totalled US$8bn and US$7.1bn respectively.
- Within OECD countries, the share of private sector agricultural research expenditures has increased since 1981, now accounting for over one-half of the total. The increase has been at 5.1% pa. In contrast, public sector expenditures grew at 1.8%.

Three closely interconnected issues confront public agriculture research in the future.

First, the growth of private sector research activities has led to reconfiguring the social division of labour between public and private (Kloppenburg, 1988). Here it is crucial to remember that neither one of the two sectors can meet the wide and diverse needs of all users of agricultural research. This is also implies that the research activities conducted by the public and private sectors are not substitutes for each other. In a public welfare sense, the research programmes in the two sectors are non-substitutable. Moreover, as the public sector is increasingly expected to meet the needs of those segments of the agricultural population that lack purchasing power, the possibility of internal revenue generation (or cost recovery) for the public sector is limited. This should place ever greater pressure on international donors to maintain, if not increase, the real funding for public agricultural research.

Second, and closely following the above, there are questions about the emerging relationship between the public and the private sector. Concerns here are warranted by changes in the nature of interactions between the two. Initially fostered by a greater revenue orientation in the US following the Bayh-Dole Act that promoted the transfer of research results from the public sector to the private sector. There remains an uneasy and troubling alliance in these ventures, which are "part of the public research domain but [behave] with the profit motive of a regular firm" (Oehmke et al., 2001, p69). These transformations have been observed within developing countries (Pray, 2001) and even within international agricultural research centres (Binenbaum et al., 2001).

This increased 'networking' between the public and the private sectors raise vital policy questions. To be clear, the issue is not that 'networking' between public and private research centres is to be avoided. Not at all, in fact to the contrary – networking is an important and essential part of the organisation of research that allows the effective exploitation of knowledge spillovers and exploration of a wider technological domain.

Moreover, in today's complementary research environment this might also be considered essential. Rather, issues of concern involve accountability of the public sector institution, transparency, dynamics of the transfer of proprietary research and control over dissemination of research results.

Third, there are considerations about the impact of proprietary control in research tools on the viability and functioning of public agricultural research. This remains an under-researched area; however the following evidence from recent studies needs to be considered:

- Dissemination Problems: Extensive use of proprietary technologies exists in international agricultural research centres (Cohen et al., 1998). While material transfer agreements and licensing of these technologies exist, a sizeable 40% fall within the grey area of 'no user agreement'. Consequently, in 37% of the cases were no dissemination problems foreseen. In 14% of the cases were there clear hurdles to dissemination placed by the right-holder.

- Lack of Clarity: An ISNAR survey of Latin American countries (Brazil, Chile, Colombia, Costa Rica and Mexico), covering 13 different public research centres, identified over 50 distinct end products, of which 74% were expected to be protected by either patents or PBRs (Salazar et al., 2000). Lack of clarity on IPRs meant that in about 30% of the cases dissemination may be a problem.

- Multiple Patents: The possibility of multiple patents in either single technologies or in closely related sets of methods of transformation, selected gene markers, traits and gene expression technologies, raise the cost of research whilst also stalling the pace of progress (Lewontin and Santos, 1997; Pardey et al., 2001). The case of 'vitamin A rice' – otherwise known as 'golden rice' (RAFI, 2000) – might be indicative: use of the variety involves clarifying user licenses for over 70 patents (Pardey et al., ibid.).

These recent examples are reflective of the increasing and complicated burden of conducting research in a world dominated by IPRs. In this respect, a particularly given the paradigmatic feature of plant breeding, the exchange of, and access to, genetic material and enabling technologies is highly constrained. Maybe, at times, this is only a potential problem. Yet, it must be recognised that "modern methods used to develop new crop varieties depend on a wide range of component innovations, the rights to which might be held by many competing parties … if ownership is diffuse and uncertain, it can be difficult or impossible for potential users to successfully negotiate with all of the relevant parties" (Pardey et al., 2001). Typical of an earlier era of agricultural research is CIMMYT's wheat variety VEERY (c. 1977), which involved approximately 3,170 crosses using 51 parental lines. It remains to be seen if this is possible in the future.

Recommendations

4. A substantive review of the functioning of plant breeders' rights, at national and international levels, must be conducted to identify and analyse the impact on agricultural research, agronomic qualities of new varieties released and market concentration. This work can be conducted through relevant international organisations (e.g. UPOV, UNCTAD, and FAO)

5. Developing country governments are recommended to review the evidence from the above-mentioned report as a first-step towards conducting similar national-level study. This study should inform the policy process of making new law to implement article 27.3b.

6. National and international agricultural research centres are recommended to review the impact of intellectual property rights on their conduct of agricultural research (e.g. ISNAR studies) and evaluate their collaborations with the private sector.

7. Donor agencies (e.g. World Bank and developed country departments of international development) are recommended to strengthen their long-term commitment to funding public sector agricultural research.

4. The TRIPs Agreement and Plant Innovations

4.1 Introduction

Before analysing the text of article 27 we draw attention to the guiding principles of the TRIPs Agreement and to general aspects of the obligation facing members. The TRIPs Agreement expresses three broad objectives in its Preambular statement: (a) establishing the minimum standards of protection in terms of the main instruments of intellectual property protection, (b) clarifying the general principles concerning the domestic procedures and remedies for enforcement of IPRs, (c) making disputes between WTO members regarding TRIPs obligations subject to the WTO's dispute settlement procedures. These guiding principles *should* be considered with articles 7 (entitled 'Objectives') and 8 (titled 'Principles'), which some commentators indicate as crucial and important for developing countries. (Reichman, 1995; UNCTAD, 1996) For example, article 7 states the following:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 7 raises questions concerning the sharing of the implementation burden of the TRIPs Agreement between members. However, there is no operational obligation under articles 7 and 8 (Watal, 2001, pp292-94). Developing countries like India have recommended operationalising these principles claiming that "articles 7 and 8.2 are overarching provisions that should qualify other provisions of the Agreement that are meant to protect intellectual property rights" (WTO, 2000, IP/C/W/195). Unfortunately, negotiating history of the Agreement suggests that the inclusion of these articles is essentially hortatorial (Gorlin, 1999)[14]. Yet, they may not be entirely devoid of use as the case of pharmaceutical product patents has recently demonstrated.

The guiding principles and objectives aside, it is well acknowledged that the Agreement endeavours to set minimum standards of intellectual property protection and that there is no obligation to establish identical intellectual property laws across all member countries (WTO, 1995). Consequently, "the mere fact that certain innovations have been granted patent protection in some member states does not imply an obligation for other member states to do the same if the TRIPs Agreement does not require them to do so" (Leskien and Flitner, 1997). Consequently, evidence of 'TRIPs-plus' requirements in a range of bilateral agreements pursued by the US and EC is unfortunate. (GRAIN and (in cooperation with SANFEC), 2001, box 3)

Box 3

Committing Developing Countries to TRIPs-Plus Measures

Countries have historically used treaties as mechanisms to secure their vital economic interests, particularly as these bilateral arrangements avoid the long-drawn and complicated process of negotiations and compliance. However, bilateral agreements, which involve trade, investment, aid, science and technology, can often favour negotiating countries (or trade blocs) that possess greater economic and/or political muscle. This appears to be the case from a recent study of 23 bilateral agreements that affect more than 150 developing countries. Obligations included in these agreements were deemed 'TRIPs-plus' on the following criteria:

- Plants: extensions of standards of protection beyond the obligation under TRIPs, either through a reference to UPOV, reference to vague requirements like 'highest international standard', or removal of possibilities of making exclusions from patentability of life forms.
- Animals: same as above
- Microorganisms: requirements to accede to the Budapest Treaty, which is not referred to in the TRIPs Agreement.

[14] Gorlin (1999) An analysis of the pharmaceutical-related provisions of the WTO TRIPs (intellectual property) agreement, IPI, London; quoted in Watal (2001).

- Biotechnological inventions: requirements to protect 'biotechnological inventions' – a class of inventions which have not been specifically referred to in the TRIPs Agreement.

Examples of treaties that fall within the above criteria include a 2001 EU-Bangladesh trade treaty which obliges Bangladesh to make "best effort" to join UPOV by 2006, or the 1999 Swiss-Vietnam IPRs-treaty that obliges Vietnam to join UPOV by 2002, similarly US bilateral treaties with Jordan, Cambodia, Singapore, Vietnam and Ecuador have obligations to join UPOV. EU treaties with countries like Morocco, Palestinian Authority, Tunisia and South Africa have obligations to either join UPOV or patent biotech inventions.

The study and evidence reported raises an important question: Is the bilateral route still being used as a mechanism to secure harmonisation of global standards and norms of intellectual property protection? If so, does this effectively mean that existing options available for developing countries, in particular the *sui generic* option in article 27.3b, is being closed.

Source: GRAIN, with SANFEC (2001)

The obligation under article 27 of TRIPs is as follows:

> 1. Subject to the provisions of paragraphs 2 and 3, 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[15]. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
>
> 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
>
> 3. Members may also exclude from patentability:
>
> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

[15] For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

A reading of article 27.3b leads to three questions, viz.

- What is the criterion for granting patents?
- What is the scope of, and limits to, the exclusions from patentability in the Agreement?
- What are 'plant varieties' for the purpose of article 27.3b?

The next two sub-sections address the first and third question.

4.2 Patentability of Plant Genetic Resources

At issue concerning the patentability of plant genetic resources are the criterions for granting patents. Any invention applying for patent protection under a TRIPs-compatible system must necessarily fulfil the 'normal tests of novelty, inventiveness and industrial applicability' as given in the Agreement (WTO nd, 'Overview of the Agreement'). These conditions exist "in one or another form" in practically every country which has a patent system (Grubb, 1999, p53). However, none of the concepts – invention, novelty, inventiveness and industrial applicability – are defined in the Agreement. In fact, even the Paris Convention fails to provide a legal concept for 'invention'. Neither is US law particularly helpful. Rather, US law (cf. 35 USCS 101), without providing a legal definition for invention, identifies the subject matter that may be invented as including any useful process, machine, manufacture, or composition of matter or any useful improvement thereof (Leskien and Flitner, 1997; Grubb, 1999). Consequently, much attention is devoted to the procedural requirements of patenting as a means to draw the line between patentable and non-patentable subject matter. In general, the legal concepts can be understood in the following terms:

- Novelty: The invention must constitute new knowledge, i.e. when compared to the state of the art (at the time of priority date of the application); the invention demonstrates an accretion to knowledge.
- Inventive step: The invention must not be 'obvious to a person skilled in the art', i.e. it must demonstrate an extension to the state of knowledge that is beyond mere modifications to known products and processes.

- ❖ Usefulness or industrial application: This is a utility requirement that requires the patent to translate into something with industrial application – a product or process. As such, the test aims at placing a barrier on the patenting of mere ideas, basic scientific concepts and discoveries.

Yet, there are substantive differences between jurisdictions, reflecting differing principles (e.g. the concept of novelty) and subjectivity in the application of the requirements (e.g. inventive step). Also, these differences crop up within jurisdictions at different points in time. (Watal, 2001) There are no clear international standards or practices across different jurisdictions. (UNCTAD, 1996) Add to this public perceptions (and at times misconceptions) associated with the patenting of 'life' and the granting of patents on pre-existing subject matter that might suggest that novelty criterion is non-existent. Further, there are deeper moral, ethical and biosafety issues concerning the inclusion of plant genetic material within the ambit of patent law. These issues that will not be addressed here, instead we focus on technical problems associated with the intellectual property protection of plant genetic resources[16]:

- ➢ Novelty and non-obviousness: The pre-existence of plant genetic material and the fact that 'products of nature' are involved has proved to be a difficult hurdle in differentiating between subject matter that should be deemed novel and what should be considered as common knowledge or state of the art. Patent offices and courts now accept a 'certain level of technical intervention' (see discussion below) as adequate in fulfilling the novelty requirement. Plant variety protection law provides a lower threshold: the variety must be distinct and not previously commercialised. Both these solutions, while pragmatic, are not uniformly applied or well accepted by all stakeholders.

- ➢ Technical replication and disclosure: It is difficult for biotechnological inventions and inventions involving plant genetic material to easily fulfil the requirement of sufficient and reproducible disclosures that enable the replication of the invention. For example, replicating breeding steps, which are themselves difficult to adequately describe, may not necessarily result in the production of an identical plant variety. Equally it is difficult to precisely describe microorganisms in a written description. The approach in the case of microorganisms is to require deposit of the stain in a recognised culture collection so as maintain its viability and also allow its availability to the public. Most developed countries now adhere to the Budapest Treaty (1977), which in some instances is included in the 'TRIPs-plus' treaties that either the US or EU is signing with developing countries (cf. box 3). In the case of plant varieties, the approach adopted is to require uniformity and stability as additional requirements for protection, whilst also putting the plant variety through a short field trial system to determine its

[16] The discussion here is based on Rangnekar (2000, chapter 10).

distinguishing characteristics. Breeders are also obliged to maintain the variety 'true to type' throughout the duration of protection (cf. article 22.1 UPOV91).

The solution in the case of biotechnological inventions is mainly a result of advances in the US following favourable court decisions like *Diamond v Chakravarty.* This decision led to gene sequences being considered patentable subject matter when they have been isolated and purified. (Correa, 1994) In this ruling, based on over eight years of legal battle, the US Supreme Court established the principle that 'anything under the sun that is made by man' is patentable. Not long after this decision was the patentability of plants established in the US through the *ex parte Hibberd* ruling. Underlying these decisions is the legal concept of 'product of nature' – the pre-existence of material is not considered an impediment to patenting as long as an act of human intervention, establishing a level of novelty, is demonstrated (Correa, 1994; Leskien and Flitner, 1997; Grubb, 1999). In Europe the Directive on the Legal Protection of Biotechnological Inventions (98/44/EC, 6 July 1998), provides in Article 3.2 that "Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature". Guidelines related to the EPC state that substances have to be isolated from their surroundings, characterised and accepted as 'new' (Leskien and Flitner, 1997). Yet, it is accepted that problems exist as all principles are not well enunciated and adhered to across jurisdictions (Grubb, 1999; Watal, 2001). Some commentators recommend raising the standards of patentability as part of wider reform of the system so as to avoid the patenting of 'normal' scientific and engineering accomplishments. (Barton, 2000)

Following the above discussion the question arises whether legal practices and precedence in developed countries clarify the obligation under TRIPs in terms of the patenting of plant genetic material? As a starting point, there is no explicit obligation to adopt identical/similar practices. In fact, countries are free to reject patents on genetic material that has 'merely been discovered' or where use was already known (Correa, 1994; WTO, 1995). Such demarcations appear in national laws in some developing countries (e.g. Andean Group Decision 344, Argentina and Brazil). However, patents on modified and/or artificial gene sequences would be difficult to reject on the grounds of 'product of nature' doctrine (Leskien and Flitner, 1997; Grubb, 1999). Yet, it is well appreciated that the agreement does not clarify key elements of the obligation, such as 'what are microbiological processes' and how they differ from essentially biological processes and what degree of human intervention is deemed adequate for meeting the patentability requirements? Equally problematic are implications arising from article 28.2, which extend the scope of process patents to 'directly obtained' products, on the rights to be conferred from a patent on a microbiological process. Despite these ambiguities, which require urgent clarification from the TRIPs Council, it is clear that member countries are obliged to provide some intellectual property protection (patents, sui generis or combination thereof) for plant varieties (cf. article 27.3b).

4.3 Defining Plant Varieties

Any instrument of intellectual property protection necessarily requires a definition of the subject matter to be protected, which in the context of article 27.3b is 'plant variety'. Strikingly, despite the fundamental nature of this legal concept, the Agreement provides no definition, nor an agreed interpretation, neither is there a reference to UPOV. Equally problematic is the non-congruence between a scientific/botanical notion and the legal concept of plant variety within UPOV – the primary international convention for the protection of plant varieties (Leskien and Flitner, 1997; Adcock and Llewelyn, 2000). As a result, national implementing legislation has room to manoeuvre in establishing their definition of plant variety.

There is a vast literature on 'defining plant varieties' in terms of UPOV and the EPC[17]. It is fair to say that the founding principles of UPOV reflect a pragmatic approach aimed at achieving a 'working definition' of plant variety that, while corresponding to the activities of the breeder, also provide a legal basis for protection. The resulted in an approach focussing on the identifiability of a plant variety, based on the fixity of distinguishing characteristics, as the means of defining the subject matter of protection[18]. Consequently, the method of identifying plant varieties – the triple requirement of distinctness, uniformity and stability – becomes the legal concept of a plant variety (cf. section 5.3[b]). Inherently, this approach, which has been christened the 'snap-shot' requirement[19] (Bent et al., 1987; Byrne, 1989), conflicts with, among other things, the variability of plant genetic material. The 1978 revision of UPOV resulted in the withdrawal of the definition of plant variety. The 1991 Convention finally proposed a new definition of plant variety in article 1(emphasis added):

> A plant grouping within a single botanical taxon of the lowest rank, which grouping, *irrespective of whether the conditions for the grant of a breeder's right are fully met*, can be
>
> - defined by the expression of the characteristics resulting from a given genotype or combination of genotypes,

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[17] The next couple of paragraphs are based on Rangnekar (2000) and the references therein, unless indicated otherwise.

[18] The demand for fixity of distinguishing characteristics place varying economic burden on the breeder depending on the variety's method of propagation. A higher level of fixity requires increased selection cycles, which act as 'entry barrier' for small breeders and for breeders of open pollinated species. Making fixity requirements vary across the range of protectable species ameliorates the latter.

[19] Article 22.1 (UPOV91) provides grounds for revocation of the grant of protection for varieties that fail to remain uniform and stable.

- distinguished from any other plant grouping by the expression of at least one of the said characteristics and

- considered as a unit with regard to its suitability for being propagated unchanged

Importantly, the above definition aims to widen the legal notion of 'plant variety' to include varieties that might fail to fulfil the DUS test, it also changes the earlier emphasis on phenotypic expression of physiological and morphological characteristics to one based on expression of characteristics arising from the genotype. Yet, some of these 'plant varieties' will fail to secure protection under a UPOV-based system of PVP[20]. Developments at UPOV necessarily interface with developments under the European Patent Convention. In fact, the origins of the EPC reveal a compromise between lobby groups representing patent lawyers (i.e. AIPPI) and plant breeders (i.e. ASSINSEL), wherein a legal distinction was erected to separate the spheres of patents and PBRs in a manner to map the distinction between microbiological and biological, respectively[21]. Patent challenges at the EPO suggest variations and changes in the interpretations of 'plant variety', which with the final passage of the Biotechnology Patent Directive (of 1998) could favour a *narrow* definition of plant variety, thus restricting the legal domain of PVP law.

While there is no TRIPs obligation to adopt the UPOV approach, countries could use the definition of protectable subject matter proposed in article 1 of UPOV91 (Leskien and Flitner, 1997). Alternatively, countries could develop a *sui generis* system that includes 'modern' varieties as well as farmers' varieties, wherein the former fall within a UPOV-like system and the latter within a less stringent system that focuses on 'identifiability'. (Louwaars, 1998; Correa, 2001) Securing and guarding the border between the two domains will be problematic. A solution could be to define protectable subject matter as specifically excluding non-cultivated plant grouping, i.e. wild species (viz., Decision 345 of the Junta del Acuerdo de Cartegena (JUNAC)). Within this law a variety requires some

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[20] A possible implication of the 1991 definition is that all plant grouping are included within the ambit of PVP law, consequently, it might lead patent examiners to hold the view that a variety, which does not fulfil the requirements for protection (i.e. DUS), should not be patented as such. Boringer, D. (1992). Developments in biotechnology and the 1991 Act of the UPOV Convention. Seminar on the Nature of and Rationale for the Protection of Plant Varieties under the UPOV Convention (Tsukuba, Japan, November 12 to 15, 1991). Anon. Geneva, Switzerland, UPOV**:** 61-72.

[21] The Committee of Experts on Patent, established by the Council of Europe, proposed a definition of industrial property that clearly placed 'plant variety' outside the ambit of patent law. It is this definition, with modifications, that becomes article 2 of the Convention on the Unification of Certain Points on Substantive Law on Patents for Invention (1963), i.e. the Strasbourg Convention, which eventually becomes a legal principle through article 53 of the EPC.

active breeding effort to be extended as a condition for inclusion within the subject matter of protection. Similarly, the PBRs legislation in Ecuador prohibits PBRs grants in wild species that have neither been planted nor improved by human intervention. (Ghijsen, 1988)

In establishing a legal definition for plant varieties, policy makers will also need to consider the conditions for grant of protection (cf. section 5.3[b]).

4.4 Possible Disharmony?

The Crucible Group (1994, p53) in its first publication made the following observation on the *sui generis* option;

> The term *sui generis*, however, may offer a wider range of policy choices because it could, presumably, include any arrangement for plant varieties that offers recognition to innovators – with or without monetary benefit or monopoly control.

The statement captures the diversity of views and possible implementation options and positions noted above. Consequently, does this suggest that the implementation of the obligation under article 27.3b will lead to a lack of harmony across member countries? Conceivably, in the absence of any overt/covert coercion, there will be a level of disharmony. This in itself should not be alarming as the Agreement, despite efforts at establishing uniformity in core standards and procedures concerning IPRs, does not seek to achieve a global harmonisation of domestic IP law. More importantly, "even if the exercise of these options [i.e. exclusion clauses and ambiguities in definitions] must remain consistent with the express requirements of the Agreement" a lack of harmony is inevitable (UNCTAD, 1996, p32). A number of commentators agree that available flexibility in the Agreement, in general and also with respect to the *sui generis* option, means that there might be a 'disharmonising effect'. (Correa, 1994; Verma, 1995; Leskien and Flitner, 1997) In fact, WTO officials have acknowledged the 'disharmonising effect' as a fallout of the lack of a definition of 'effective' and the absence of a reference to any existing international Convention. (Otten, 1996)

Further, absence of unanimity on a single implementation model also reflects the differences between different industry lobby groups on this article. (van Wijk, 1998) Thus, in the run-up to the 1999 review of article 27.3b, the following views were expressed:

- International Bioindustry Forum: A forum representing the OECD-based biotechnology industry, it acknowledges different national practices concerning patenting of plant varieties, but expressed a preference for including plant varieties within the ambit of patent law. UPOV91 was considered a second-best option.

- ASSINSEL: This lobby group, which represents seed companies, recommends the patenting of plant genetic components, but oppose the inclusion of plant varieties within patent legislation. As such, the group strongly supports the breeders' exemption available under UPOV91.

- Asia and Pacific Seed Association: A regional seed industry lobby group from the Asia-Pacific region; it supports the implementation of a *sui generis* PVP-type legislation that brings together elements from UPOV78 and UPOV91. In specific, it favours the 1991 Convention's breeders' exemption, but would also like to have the option of including the de facto farmers' privilege of 1978. Finally, it recommends the consideration of limiting the coverage of the legislation to a specified list of species, a provision that exists under UPOV78.

The next section discusses key components of an IP system for plant varieties and also draws attention to the ambiguities in the Agreement (cf. box 5).

Recommendations

8. Developing countries should take full opportunity to exercise their national sovereignty in developing and implementing national intellectual property right legislation. In this respect, the TRIPs Council should review the use of bilateral treaties as mechanisms to secure 'TRIPs-plus' standards in developing countries.

9. A clear agreed interpretation of the obligation with respect to the patentability of plant genetic resources should be developed at the TRIPs Council, wherein the non-patentability of naturally occurring plant genetic resources (including gene sequences and genes) should be established. Countries should be free in opting to disallow patents on plants.

10. Member countries of the WTO should direct the TRIPs Council to take cognition of the different, and at times conflicting, views on the patentability of plant genetic resources and the difficulties facing developing countries in implementing their obligation under art. 27.3b of the Agreement. Appropriate extension periods for compliance to the Agreement should be made available.

5. Implementing Article 27.3b – The Case of Plant Varieties

5.1 Introduction

Article 27.3b has given rise to a growing literature on model implementing legislations. In many instances this literature recommends going beyond the exclusive focus on 'plant varieties' and using the (as yet) undefined and ambiguous elements of the TRIPs obligation

to provide rights to presently disenfranchised segments of society, viz. indigenous peoples and farming communities. (Mugabe et al., 1997; Biodiversity and Development Monitor, 1998; Biothai/GRAIN, 1998) There is nothing in the TRIPs Agreement that prevents the inclusion within the system fulfilling article 27.3(b) of other subject matter (i.e. traditional knowledge) or combining the same with other instruments of protection (i.e. farmers' rights).

Intellectual property legislation can play an important role in the socio-economic development of a country through the effective utilisation of various checks and balances that provide incentives to inventors whilst simultaneously ensure the wider social diffusion of useful inventions. In developing domestic legislation, policy makers must have a clear understanding of national priorities with respect to agriculture (cf. box 4).

Box 4

National Interest and PVP Legislation

The following are questions that require close analysis before the drafting and implementation of PVP law:

- The domestic seed industry: the state and capacity of the public breeding sector, the national seed supply system, present and near future breeding activities.
- The farming community: the extent of farm-saved seed used, the extent of use of inputs in agriculture,
- National agri-economy: production needs of the country, aims for strategic alliances in terms of agriculture.
- Biotechnology: current capacity and application of biotechnology, present and future strategic needs and alliances with respect to biotechnology.

Source: Based on IPGRI (1999)

In this respect, the issue is to maintain a fair level of access: (a) access to genetic material to enable the continuation of plant breeding activities and (b) access to varieties to enable the diffusion of useful and productive genetic material within farming communities. Of relevance in policy deliberations aimed at achieving access will be evidence in terms of the actual functioning of IP-systems, which might differ from the intent of the legislation.

The discussion in this section is directed at discussing key elements of a sui generis system for developing countries.

5.2 Implementation Options: The Basics

The obligation under art. 27.3b is for an IPR consistent with the meaning of art. 1(2)[22], i.e. provide for a legally enforceable right that would either exclude others from unauthorised use of the protected variety or allow the obtaining of remuneration for its use. (Leskien and Flitner, 1997; IPGRI, 1999) Consequently, the following three components of a TRIPs-compliant sui generis system for plant varieties are essential and necessary:

- National treatment: Article 3(1) establishes that national treatment applies to all categories of intellectual property that are the subject of sections 1 through 7 of Part II. Importantly, UPOV member countries do not automatically meet this requirement as the Convention is grounded on 'international reciprocity' rather than 'national treatment'.

- Most favoured nation: Privileges granted to nationals of any other member country are automatically extended to nationals of all other member countries. Despite the rather innocuous looking obligation, bilateral deals might lead to discrimination that secures particular concessions for a specific country's nationals (Correa, 1994).

- Effective enforcement: Enforcement of rights is a core objective of the TRIPs Agreement that also finds mention in the preambular statement of the Agreement. This may be taken as an obligation to provide mechanisms for juridical remedy (IPGRI, 1999). However, 'effective' remains an explicit but undefined requirement for the intellectual property system for plant varieties. Many commentators agree that 'effectiveness' cannot easily be defined in a global sense[23]. More importantly, it is also suggested that "effectiveness does not, however, depend on its requirement for or on the level of protection" (Leskien and Flitner, 1997). Lack of unanimity persists in terms of the link between 'effectiveness' and the scope of protection (see section 5.3[c]).

Despite the widely accepted interpretation of the three *basic* requirements for a TRIPs-compliant sui generis system, there are some who suggest that the obligation under art. 27.3b is exempt from national treatment and most-favoured nation. (Tansey, 1999) However, four implementation scenarios are identifiable (Leskien and Flitner, 1997; IPGRI, 1999):

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[22] Article 1(2) refers to IPRs to all categories of intellectual property that are the subject of sections 1 through 7; the requirement to protect plant varieties is in section 5. The obligation for an IPR is also inferred from art. 68 which refers to the sui generis option as IPR (Leskien and Flitner, 1997).

[23] A recent *South Centre* publication recommends a paradigm shift in the debate concerning 'effective' so as to include concerns about national development, other articles in TRIPs (e.g. articles 7 and 8) and the CBD (Mangeni, 2000).

- ❖ Exclude plants (including plant varieties) from patentability, thus establishing a *sui generis* system for the protection of plant varieties, either under patent law or set up an independent system.

- ❖ Not exclude plants (including plant varieties) from patentability, hence applying normal patent requirements to plant varieties. Consequently, there is no need to develop a *sui generis* system for the protection of plant varieties.

- ❖ Not exclude plants from patentability, while simultaneously allowing for the protection of plants/plant varieties by two forms of protection, i.e. *sui generis* system and patent law. This is the approach adopted by the US.

- ❖ Exclude only plant varieties from patentability, thus develop and provide for the protection of plant varieties through a *sui generis* system. This reflects the current situation under the European Patent Convention – no doubt, there remain complicated questions about the scope of the exclusion.

Given concerns of 'national interest' (cf. box 4), particularly those related to access to plant genetic resources (as raw material and as finished product), it is strongly felt that developing countries might find the option of introducing a sui generis system for the protection of plant varieties as the preferred route. This recommendation raises an important question:

- ❖ Should developing countries join UPOV?

This question deserves close scrutiny for a variety of reasons, not least because it is the only international convention dedicated to plant variety protection: (a) WTO-based commentators have indicated that the UPOV system, in particular the 1978 Convention, should be considered 'effective' in a TRIPs-sense; (Sutherland, 1994, see box 6) (b) strong negotiating countries, like the US, have clearly indicated their preference for UPOV91 being considered a minimum bench-mark for art. 27.3b (cf. US Submission at WTO, 3 Nov. 1998 WT/GC/W/107); and (c) UPOV itself has made great accommodation for letting developing countries accede to the 1978 Convention by repeatedly extending the deadline – most recently to allow for the accession of three developing countries, viz. India, Nicaragua and Zimbabwe (see fn33). Even while UPOV is a constructive alternative to patents, it must be recognised that joining UPOV opens the possibility of regulatory progression to stronger levels of protection; (Crucible Group, 1994, pp63-65) though, on the other hand there are benefits in adopting a 'ready-made' template that is relatively easy to implement (Ghijsen, 1998). Alternatively, the benefits of a UPOV-based model can be gained without joining the Convention.

5.3 Components of a *Sui Generis* System

The analysis now focuses on specific components of a sui generis system. Here, we keep in mind the empirical evidence reported elsewhere in the paper (cf. section 3) and the fact that the Agreement does not define core elements of the sui generis system (cf. box 5). Some of these have been examined in section 4, earlier.

Box 5

Undefined in the TRIPs Agreement
With respect to the specific obligation in article 27.3b, the following remain undefined in the Agreement: ❖ a plant variety ❖ the requirements for protection, such as novelty, distinctness, uniformity and stability ❖ the scope of protection, i.e. whether a right should extend to vegetative, reproductive and harvested material, or to the export of the protected material ❖ the duration of the right ❖ the relationship between a *sui generis* right and other IPR such as patents. *Source:* IPGRI (1999)

Of particular importance, even when countries adopt the sui generis option, is the need to balance the impact of providing intellectual property protection in plant genetic material. In this respect, the FAO's Technical Mission to Malaysia (Bombin and Silva-Repetto, 1997, p46)makes useful reading,

> The system of protection should provide incentives for the technological advancement necessary for economic growth and development, facilitate technology transfer and access to foreign varieties, stimulate investment, including that of foreign firms, and encourage local breeders.
>
> At the same time, the system should avoid, as far as possible, the disadvantages that often go together with the present systems of plant variety protection, such as limitations on the flow of varieties in the local seed system (e.g. prohibition against small farmers using and exchanging farm-saved seed), direct and indirect loss of biological diversity through the global expansion of today's uniform varieties, loss of local landraces and farmer's varieties, limitations of protection to the efforts and investments of the modern breeder while disregarding the efforts and investments of past generations.

It is with this balanced approach that analysis of components of a sui generis system is undertaken. Here we focus on the coverage of the legislation, the conditions for protection, and the scope of protection.

5.3(a) Coverage of the Law

The first issue to consider is the 'coverage of the law', i.e. for which plant species and botanical genera will intellectual property protection is available. An answer to this question has grave implication on a wide range of issues that includes the cost of running the system and concerns about biodiversity loss.

Like many other central components of a sui generis system, the Agreement does not provide any explicit indication of the required coverage. More importantly, the Agreement does not suggest that the provision should be limited to a specific range of botanical genera and species – consequently, implying that all genera and species be included within the ambit of the law. (Bombin and Silva-Repetto, 1997; Leskien and Flitner, 1997) Here note the following explanation,

> … it seems clear that member states have to provide for the protection of plant varieties of all species and botanical genera. Any other interpretation of art. 27.3b TRIPs would have to indicate for how many species or for which type of species member states have to grant *sui generis* protection and there is no such provision in the TRIPs Agreement (Leskien and Flitner, 1997).

In contrast to the *implicit* TRIPs obligation to make available intellectual property protection for plant varieties of all botanical genera and species, UPOV has maintained a more gradual expansion of legal coverage, viz.

- The 1978 Act: Under art. 4, members *may* apply the provisions to all botanical genera and species and are obliged to adopt measures for the progressive expansion of coverage. The explicit and binding obligation is to provide protection to at least five genera or species upon entry into force of the Convention and expand coverage to twenty-four genera or species within eight years (cf. art. 4.3).

- The 1991 Act: Here a dual track programme of expanded coverage is provided based on whether the member is new or old. For old members the provisions of the 1991 Convention must be immediately applied to genera or species that were covered by previous sui generis protection and coverage be extended to all botanical genera and species within five years of entry into force of the 1991 provisions (cf. art. 3.1). New members can also avail of a gradual expansion of coverage, wherein fifteen genera or species are protected at the time of entry into force of the Convention and protection extended to all genera or species within ten years (cf. art. 3.2).

UPOV's Model Law recommends a gradualist approach that is similar to the provisions available in art. 3.2 of UPOV91. (UPOV, 1996, art. 2)

In light of this more gradualist approach of expansion, it is appears unreasonable that the TRIPs obligation is interpreted as requiring immediate and maximum coverage. There is a point to consider here, which suggests that the 'standards of protection' of UPOV78 are consistent with TRIPs. (Sutherland, 1994, see box 6) The rationalisation suggests that as UPOV91 was being negotiated in parallel to TRIPs and leaves open till 1995 for new members (i.e. developing countries) to accede to UPOV78, "it would not be reasonable to interpret the international community as having, at the same time, left open this opportunity [i.e. UPOV78] under UPOV and foreclosed it under TRIPs" (Sutherland, 1994). This argument, in various permutations and combinations, is often made to suggest that provisions under UPOV78, in particular the de facto farmers' privilege, is consistent with TRIPs. Hence, this writer's question: are other components of the UPOV78 standards of protection also compatible with TRIPs? To be precise, is the explanation presented by Sutherland legitimate:

- If the assurance about farmers' rights is valid; can the same rationalisation be extended to the question of coverage?
- If not, what should developing countries make about the assurances about farmers' rights?

To close this discussion, the question of coverage remains a grey area, which might only be resolved either through a decision at the WTO's Dispute Settlement Board or an agreed interpretation at the TRIPs Council.

5.3(b) The Conditions for Protection

The conditions for grant of protection within a sui generis system are also undefined in the TRIPs Agreement. Consequently, much of the available literature and the legislative effort in implementing countries take the UPOV system as a reference point, which under the 1991 Convention are the following three conditions:

- *Distinctness:* Art. 7 require that the variety must be "clearly distinguishable from any other variety whose existence is a matter of common knowledge" at the time when protection is applied for[24]. This requirement ensures inter-varietal identification.

[24] UPOV78 had other qualifiers to this simple requirement of distinctness, wherein the distinguishing characteristic was to be an "important characteristic" (art. 6.1a). Various UPOV members (e.g. France and Czechoslovakia) have this in their national laws. However, UPOV clarifies that the procedural work interpreted this requirement as 'important for distinguishing

- *Uniformity:* Art. 8 place the condition that the variety must be sufficiently uniform in its distinguishing characteristics, such that different individuals of the same variety are reasonably similar. This requirement ensures intra-varietal uniformity.

- *Stability:* Art. 9 states that a variety must be stable in its distinguishing characteristics, i.e. it remains "unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle". This requirement addresses varietal identification across time.

Finally, the plant variety must be novel in that the propagating material or harvested material has not been offered for sale by/with the consent of the breeder, either earlier than one year in the jurisdiction of application or four years in jurisdictions of contracting members (UPOV91, art. 6). This requirement has been criticised for being strikingly liberal compared to patents and setting a very low threshold (Byrne, 1989)and for exclusively focussing on commercial novelty. (Rangnekar, 2000)

The literature on the UPOV conditions for grant of protection is extensive; we thus focus on only a few key themes[25]. First, the demands for uniformity have been recognised as a legal requirement that places excessive burden on the breeder, while having little agronomic value. (Simmonds, 1979) Others note the adverse impact on on-field biodiversity. (Fowler and Mooney, 1990) In fact, the increasing diffusion of genetically uniform varieties is one of the primary factors contributing to increased genetic vulnerability of modern agriculture. (FAO, 1998) Even the OECD secretariat acknowledges that the manner in which uniformity requirements for PVP are administered create "perverse incentives" for the breeding of uniform varieties. (OECD, 1996) This growing criticism of the uniformity requirement in PVP has also filtered into the portals of the WTO, where the Commission on Trade and Environment recognised that "the uniformisation [sic] of productive varieties/races" might be a result of the patenting of genetic resources. (World Trade Organization - Committee on Trade and Environment, 1996) Second, the exclusive focus on distinctness places a low threshold for a test that is said to parallel the patentability requirement of inventive step. Moreover, there is no test for *merit* within the PVP system[26]. Because of the low threshold, it is argued, breeders are able to secure protection for cosmetically differentiated varieties [Kloppenburg, 1988 #85;

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characteristics' and should not be confused with an assessment of the value conferred by the variety (UPOV, 1996, p26).

[25] Some of these problems are intertwined with complementary seed market regulations, such as the seed certification system. In some instances, particularly in terms of uniformity and stability, seed market regulations have higher standards.

[26] The absence of a merit test or a stronger requirement for inventiveness reflects a political compromise wherein the latter were left to be determined by the market and later through separate regulation (i.e. National Listing in Europe) (Rangnekar, 2000).

Fowler, 1990 #82]. Consequently, breeding companies are able to flood the market with near-identical varieties, thereby adopting strategies of product differentiation and planned obsolescence. (Rangnekar, forthcoming) In this respect, the statement of a Pioneer Hi-Bred breeder is instructive: "… USA farmers have many more soybean varieties available to them today … unfortunately, many of these commercial soybean varieties are very close relatives, if not essentially identical …" (Donald Duvick)[27].

Third, there are problems associated with the demand for stability. Of particular importance for developing countries are the economic consequences of high standards of stability and the increased time and costs this places in making available new varieties. Interestingly, this issue confronted European breeders in the 1950s during the debate surrounding seed market regulations and PVP, where some countries (e.g. Sweden) preferred lower standards for quicker access and diffusion of new varieties amongst seedsmen and farmers. (Akerman and Tedin, 1955) On the other hand, lower standards of stability can also lead to increased varietal variability and diminished reliability.

Quite apart from the points raised above, it is useful to also consider the implications of a DUS-type standard on the inclusion of other subject matter within the scope of a sui generis system. For example, how would traditional varieties and/or farmer varieties fare in a DUS-based PVP system, given the inherently variable and heterogeneous. (Brush, 1994) Naturally, questions like these have to be addressed along side considerations on the subject matter included within the ambit of the proposed legislation.

What than should developing countries do when formulating their sui generis system? Should a UPOV-based system be replicated? Or, should modifications be considered? Equally, are there any other conditions for grant of protection that should be introduced? Given the criticisms noted above and the empirical evidence reported in section 3, it is clear that a re-examination of the UPOV-based conditions for grant of protection is warranted. While the literature on appropriate model laws for developing countries is still formative, here we highlight some useful points:

- Amending Distinctness: Concerns about the low threshold for demarcating new and protectable subject matter, a result of the focus on distinctness of a variety, has led commentators to recommend re-examination of the phrase in UPOV78 – 'clearly distinguishable by one or more important characteristics' – that UPOV91 deleted (e.g. Leskien and Flitner, 1997; IPGRI, 1999). While clarification presented by UPOV is useful (see fn24), developing countries should be informed of useful precedents in enhancing the test for distinctness. In this respect, the 1989 Czechoslovakian law and the 1970 French law are instructive in incorporating a requirement for distinguishing characteristic to be 'important' (Leskien and Flitner,

[27] Quoted in Pray and Knudson (1994).

1997). Consequently, IPGRI (1999, p14) recommends that "truly important characteristics, i.e. traits of agronomic or nutritional value" be the basis for establishing the distinctness of varieties. The inclusion of additional criteria to raise the threshold for distinctness could provide the necessary incentives to direct breeding towards developing useful new varieties. In this respect, developing countries could consider the National List system in Europe where tests for a range of agronomic attributes acts a basis for marketing of the variety. Consequently, a marrying of the conditions for grant of protection and tests for marketing a variety is worthy of consideration. However, any such development will definitely need to consider that additional criterion will make the availability of protection more costly and complicated. In as much as some of these tests for agronomic qualities are nationally conducted, it would seem that linking the two is not problematic. Yet, as UPOV notes, tests for distinctness as they currently exist are easy to administer and not too costly (UPOV, 1996, p26)and adding other criterion will raise the issue of setting up new standards.

- Amending Uniformity: Two main concerns have been expressed with respect to the requirements for uniformity and stability, viz. loss of biodiversity[28] and difficulty in providing protection to farmer-varieties. Existing literature suggest a close review of the possibility of using 'identifiability' – emphasising the legal need to identify the protected subject matter through a combination of a few characteristics – as an alternative (Leskien and Flitner, 1997; Louwaars, 1998; IPGRI, 1999). There are notable benefits of 'identifiability' as an alternative – lowering the adverse biodiversity impact of IPP in plant varieties and possibility of protecting less uniform/more heterogeneous varieties (i.e. farmer varieties)[29]. Given the instability and variability of farmer varieties, it would seem that a lower threshold of uniformity of characteristics would allow their inclusion within the ambit of the law. Yet there are hurdles in easily adopting this alternative. For example, lower standards of uniformity/stability could very well lead to overlapping between protected varieties as the subject matter changes and evolves through the period of protection (Louwaars, 1998). In addition, there is no long-term study on the biodiversity implications of replacing 'uniformity' with 'identifiability' (IPGRI, 1999).

- Other Requirements: A variety of contributors explore the sui generis option as a means of introducing provisions available in the CBD as a mechanism to recognise

[28] A range of factors, of which the conditions for grant of protection is one, contribute to the loss of on-farm biodiversity. The conditions for grant of protection (along with the Test Guidelines) and the practices of national PVP authorities provide the incentives to breed uniform varieties.

[29] See Louwaars (1998) and Brush (1994) for a discussion.

and reward the contribution of indigenous peoples. Of particular importance are the possible inclusion of requirements like declaration of geographical origin of the relevant genetic material and submission of certificates of prior informed consent. These provisions can be useful steps in curtailing the misappropriation of genetic material and associated knowledge, which also occurs in the case of plant variety protection as has been documented in the grants made by the Australian Plant Variety Rights Office, some of which have been since revoked. (Rural Advancement Foundation International and Heritage Seed Curators Australia, 1998) In this respect, UPOV's Model Law (1996) makes interesting reading in that it clearly recommends that "grant of a breeder's right shall not be made subject to any further or different conditions provided that the applicant complies with the formalities established by this Law and pays the required fees" (art. 5.2). In terms of the principles underpinning these additional requirements – stalling the misappropriation of genetic material and associated knowledge – it is useful to examine the appropriateness of including these as conditions for grant of protection. An alternative might be to have them as binding administrative requirements. Other requirements that are worthy of consideration include environmental impact assessment and risk assessment for genetically modified organisms. This could be a route through which TRIPs art. 27.2 – the only explicit reference to the environment – can be operationalised.

To close this discussion, considerations on alternatives to the UPOV template is still developing. There is a growing expression of the need to modify the focus on distinctness and uniformity while also including other requirements that enable the protection of the rights of indigenous peoples. However, as IPGRI (1999) notes, wide variations in the sui generis system across developing countries might raise greater problems from a lack of harmony. Further, the biodiversity implications of these alternatives require further scrutiny.

5.3(c) The Scope of Protection

The scope of protection refers to the rights that accrue from a grant of protection, which ultimately define the technological and economic control available to the right-holder (Rangnekar 1999). It is here that public policy comes to bear in its effort at balancing diverse socio-economic and political interests, which can be broadly and somewhat crudely be delineated between 'incentives for the investors' and 'measures to ensure wide access/diffusion'.

The obligation under the art. 27.3b makes no specific statement with respect to the scope of protection, nor is there any reference to the pre-existing template, UPOV. Yet, some commentators suggest that 'effective sui generis system' should be understood in a dual sense of (a) having necessary 'checks and balances' and (b) being TRIPs-compliant in terms of the available scope of protection. (Lesser, 2000, for example) Unfortunately, this

exposition confuses two separate issues, viz. (a) the legal obligation to provide a TRIPs-compliant legislation and (b) the *effectiveness* of the legislation in meeting national priorities. No doubt, these two issues are intertwined; however, there is no a priori reason to assume that a TRIPs-compliant sui generis system will simultaneously fulfil national priorities or vice versa! To be fair, the confusion surrounding the term 'effective' owes its origins to the negotiating history of the article and the absence of any explicit definition or reference to UPOV. (Watal, 2001) Equally, WTO-based commentators have also conflated the two by statements on what an 'effective sui generis system' might be and on 'acceptable' exceptions to the scope of protection (cf. box 6).

Box 6

Peter Sutherland on Article 27.3b
Protest in opposition to 'patents on seeds' were widespread in India throughout the negotiation of the Uruguay Round. It is in this context that two key articles authored by Peter Sutherland - former Director General of GATT - in one of the most widely circulated English dailies, *The Times of India*, make remarkable reading. Relevant excerpts from each of the articles are reproduced below. **Times of India, 15 March 1994** "… while the TRIPs provision on plant variety protection do not refer to any international convention, it is clear that, if the standards of protection of UPOV 1978 were to be followed, it would be reasonable to claim that an effective *sui generis* protection had been provided". **Times of India, 12 March 1993**[1] "There are worries that the farmer will lose access to seeds as the price goes up, that he will not be able to save his seeds for the next crop, or exchange seeds across the fence with his neighbour, as he has being doing for ages, and that generally he will be in a state of dependency on the plant breeder. These concerns are largely unfounded".
[1]Quoted in van Wijk (1998)

However, a closer reading of these statements suggests that the reference was only to the 'standards of protection' and cannot be construed to imply that UPOV78-type scope of protection would be accepted as 'effective' (Leskien and Flitner, 1997)[30]. However, there is little comfort in these pronouncements and explanations as the Agreement does not

[30] Mangeni (2000) in a recent *South Centre* paper makes a case for widening the notion of 'effective *sui generis* system' by including concerns about national development, other articles in TRIPs (e.g. articles 7 and 8) and the CBD.

make a reference to UPOV. Speculating on this noticeable absence, with some personal insight, Watal (2001, p140, emphasis added) makes a pertinent point,

> Unlike the other subjects under TRIPs, there is no mention of adherence to the pre-existing international convention, UPOV. One possible reason was that UPOV 1991 had not yet entered into force; *a reference to UPOV 1978 was considered inadequate*, while a reference to UPOV 1991 was considered premature. Another reason for this brevity of this provision is that there was no agreement among industrialised countries as to the details of an effective sui generis system of protection for plant varieties.

Watal (1999: 140) than proceeds to conclude that "countries are free to construct their own individual regime for such protection, provided it meets the undefined standard of 'effectiveness'". Yet, there is no clear suggestion that the scope of protection is the measure for effectiveness. Rather, 'effective' might be interpreted in a narrow sense to require the provision of a right that either excludes others from certain acts in relation to the protected variety and/or allows a remuneration to be earned in respect of certain acts involving the protected variety (Leskien and Flitner, 1997). This interpretation, and for that matter many others, of art. 27.3b will ultimately be tested at the WTO's Dispute Settlement Body or clarified through some agreed interpretation at the TRIPs Council. Here, we identify and discuss five key elements concerning the scope of protection.

- Should there be a uniform scope of protection across all plant species and botanical genera?

It is useful to consider variations in the scope of protection based on the plant species, which would take into consideration the economic use of the variety, or its mode of propagation, or the agro-economic interests of stakeholders. For example, countries with mixed agricultural economies might find it useful to meet diverse interests by having different scopes of protection. In particular, it could be the case that patent-like protection could be made available in ornamentals and high-value, export crops, while weaker protection exists for other species (Ghijsen, 1998; IPGRI, 1999: 17). Ghijsen (ibid.) makes a telling point by recommending that developing countries should consider a weaker scope of protection for open pollinated food crops, which would allow farmers to freely trade, exchange and save seeds. These practices are of crucial importance in countries with informal seed systems as they foster quick dissemination of useful varieties (cf. section 2)

- How far should the scope of protection extend in terms of the reproductive material, non-reproductive material and harvested material of the protected variety?

The limits to the scope of protection depend on whether transactions involving any of the following require the explicit authorisation of the right holder, viz. (a) reproductive

material, (b) non-reproductive material, and (c) products derived from harvested material[31]. The subject matter of protection under PVP is the physical embodiment of the variety, which has led to the scope of protection (under UPOV61 and UPOV78) being limited to (commercial) transactions involving the reproductive material[32]. This is often characterised as the basic/fundamental right, because provisions exists to expand the scope of protection to the marketed product – a provision that has been applied in the case of ornamentals. UPOV91 expands the basic/fundamental right to include commercial transactions involving the harvested material and/or parts of the plants (art. 14.2, 14.3). It is this basic right that is recommended in UPOV's Model Law (art. 13). Interestingly, there exist provisions for further expansion of the scope of protection (art. 14.4, UPOV91). Based on these legal templates, countries could very well adopt a system that provides a hierarchy of scopes depending on an established set of criterion. An alternative starting point to define the basic fundamental right could be the PVP Seal, a system that is the historical source for modern day PVP systems (Leskien and Flitner, 1997; IPGRI, 1999). Under this system the scope of protection offered to the right holder is exclusive use of the 'seal' which certifies that the variety conforms to the regulations laid down by the relevant national authority when the protected variety is sold, offered for sale, or exchanged. The 'seal' provides competitive advantage to the breeder – who may price the seeds accordingly – while it also allows pre-existing seed-related practices to continue without being deemed infringing acts.

There is clearly no 'best' option; developing countries would be best served by mixing-and-matching elements from the different models based on their best assessment of meeting national priorities (IPGRI, 1999, pp17-21). It could be assumed that developing countries with a flourishing breeding industry and an active industrialised agricultural sector would probably opt for a *sui generis* model akin to UPOV91. In contrast, a developing country dominated by a less resource-intensive (low input) agricultural sector would benefit from adopting a PVP seal model.

- What should the duration of protection be, and should this vary between different plant species and botanical genera?

Some economists assume that changes in duration of protection can be traded for variations in the scope of protection. This is a fundamentally erroneous conceptualisation that fails to acknowledge the dynamic and sequential nature of the innovation process. (Merges and Nelson, 1990) The actual impact of changes in the duration and/or scope of protection are sectorally different and varies with the techno-economic characteristics of

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[31] Issues concerning breeders' exemption and farmers' exemption are examined separately.

[32] Consequently, the *de facto* right to reuse harvested grain as seed in subsequent planting. The rationale being that replanting saved seeds was an act involving reproduction for the purpose of further production of *grain* and not production for the marketing/sale of *seed*.

the relevant sector, such as the effective economic life of an invention (i.e. new variety) and the relationship between innovation and appropriation. Empirical evidence from UK wheat breeders reveals that the economic life of a variety has exhibited secular decreases over the 1965-95 period and that only one wheat variety remained protected for the full duration available. (Rangnekar, forthcoming) This may prompt policy analysts to adopt short durations within their legislations. However, this is not entirely advisable as more evidence is required.

As far as the Agreement is concerned there is no indication on the required duration nor a clear statement that the twenty-year period required for patents in other 'fields of technology' also applies to the *sui generis* option. UPOV91 obliges members to have a minimum period of 20 years (25 years for trees and vines) (art. 19.2), which has accordingly been increased from 15 and 18 years respectively in UPOV78 (cf. art. 8). The 1991 provisions are recommended in UPOV's Model Law (art. 17). Developing countries will need to consider the different options and assess their national priorities before making a decision. In this assessment, it is important to keep in mind the significance and role of 'seeds' as carriers of genetic information that enable technical change (see section 2). Longer durations will necessarily allow the right holder to control the use of the protected variety (and its embedded genetic information) by others (seed merchants, competing breeders and farmers). On the other hand, shorter durations will enable faster access and as Merges and Nelson (1990) conclude place competitive pressures for a faster pace of innovation. In this respect, India's experience with pharma patents, where a seven year duration was introduced in the 1970 Amendment is illustrative of the possible benefits of legally enabling quick access to innovations by local industry.

- What right, with respect to the protected variety, should farmers possess?

Most PVP laws tend to implicitly allow for the non-commercial production of the propagating material based on the rationale that the intent is further production of *grain*, and not reproduction for sale of *seed* – hence the de facto exemption from the breeders' right in UPOV78. Allowing this exemption is a pertinent question that cuts across political, socio-economic and ethical issues, particularly as the issue concerns IP claims that extend beyond existing subject matter and onto the progenies:

> Opposition to IP on ethical grounds arises largely from the concept of ownership over living products and life processes including the regeneration of life. These opponents note a fundamental difference from the transfer of ownership of seeds or specific animal breeds without any claims on their progeny. This involves owning biomass only, and is a practice as old as commerce itself. The retention of rights over the regenerative capacity of organisms, while selling their biomass, is entirely new and extends ownership beyond society's accepted limits. (Crucible Group, 1994, p56)

This sentiment was even articulated by the Committee on Transactions in Seeds – the consultative body that recommended the introduction of plant breeders' rights in the UK in the 1960s – who state that a charge on farm-saved seeds would effectively force the farmer to pay a second charge for something they already possess. (Committee on Transactions in Seeds, 1960) In part, the fact that a *second charge* could be placed on farmers raise deeper political and socio-economic tensions. Yet, we must recognise that these tensions are not unique to resource-poor farmers in the developing world. Both, Europe and the US have experienced resistance to this expansion of the breeders' right to include the progeny; hence the more gradual and piecemeal expansion of the scope of protection. Here, an extract from a UPOV background document dealing with the protection of biotechnology is revealing:

> As far as the minimum scope of protection [of PBRs] is concerned, it may be noted that this is less than the protection offered under the patent system, ... there is nothing to prevent a farmer or horticulturalist from saving part of the crop of the protected variety in order to sow it or plant it on his land in the following growing period. (An exception exists in respect of the use of material for producing cut flowers or ornamental plants.) The possibility of "saving seed" is of great importance for agriculture and it is doubtful whether it would be *politically feasible* at present to restrict this right in all countries. The assertion of the right to prohibit under general patent law would probably lead to serious political difficulties. (UPOV, 1986, emphasis added)

In the US, the extension of the scope of protection to include the regenerative capacity of the variety has occurred, predictably, through the courts in decisions like the *Asgrow v.Winterboer*. (Seay, 1993; Smith, 1996)

Three separable elements constitute the exemption with respect to farmers: (a) provisions for reusing harvested grain of a protected variety as seed for the next planting – the plant-back option, (b) 'over-the-fence' exchange of seed saved of a protected variety, and (c) sale of limited quantities of (saved) seed of a protected variety – the brown-bagging option. In UPOV91 the farmers' exemption reads as follows:

> [*optional exception*] Notwithstanding Article 14, each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety covered by Article 15(5)*(a)*(i) or (ii).

This optional exception effectively allows within reasonable limits the farmer to plantback on their own field saved-seeds of a harvest from their own field. Clearly, other

components, such as 'over the fence' exchange of saved-seeds, will be considered infringing acts. In developing a provision for this exception to the breeders' right, policy makers need to take into consideration the specific characteristics of the seed system, viz. (a) existence of informal seed exchange systems, (b) size of the non-commercial seed sector, and (c) the importance of diverse seed diffusion mechanisms (see section 2). Equally pertinent are political questions concerning the rights of farmers in terms of plant genetic resources. Also worthy of consideration are economic issues in terms of the incentives to breeders. Ironically, despite the politics surrounding this issue, there is little economic analysis of the impact of this exception on investments in plant breeding. Evidence from the US reported in Lesser (2000) indicates that there is negligible profit loss from allowing this exception to farmers. More important is the fact that cash flow considerations (i.e. seed prices) plays a decisive role in determining the seed purchasing behaviour of farmers.

A possible text for this exception is the one contained in India's Protection of Plant Varieties and Farmers' Rights Act (1999) that was recently passed by Parliament. Art. 39.1(iv) allows the farmer to "save, use, sow, re-sow, exchange, share or sell his farm produce including seed of a variety protected … in the same manner as he was entitled to before the coming into force of this legislation". This right is subject to the non-use of the brand name of the protected variety. This clause, in particular how it will be operationalised, will be an important test of the flexibility actually available in implementing the sui generis option. Moreover, since UPOV has specially kept the 1978 Act open for accession to India[33], it is to be seen if this clause will be considered acceptable and in conformity.

- What right in terms of the protected variety should competing breeders retain?

This is another key access related question where policy makers have to decide how to balance the incentives/control granted to breeders with the rights and needs of other users, which in this instance are competing breeders. Considerations here relate centrally to the key characteristics of the activity of plant breeding and the basis of developing new varieties – new varieties are developed through the recombination of characteristics in pre-existing genetic material. It is this access to genetic material that enables breeders to continue their activity and continuously produce new varieties. Empirical evidence clearly demonstrates that breeders are overwhelmingly dependent on advanced genetic material – well characterised and stabilised genetic material. A CIMMYT study of the use of wheat

[33] In 1997, UPOV decided to allow accession to the 1978 Act, despite it being closed, to those countries who had sought its advice on conformity prior to the entry into force of the 1991 Act. This special provision was open till 24 April 1999. However, at its 33rd Ordinary Session in October 1999, it decided to make further special provisions for allowing accession to the 1978 Act for India, Nicaragua and Zimbabwe. While it is not clear whether any final date for accession has been set by UPOV, the 2000 Annual Report states that accession talks are on-going.

genetic resources covering 52 countries revealed that over 68% of all genetic material in breeding blocks was advanced genetic material, composed of own advanced lines (39.7%), nationally released varieties (17.4%) and advanced lines from other countries (11.0%). (Rejesus et al., 1996) This use pattern is explained by the fact that advanced breeding materials possess the preferred traits that dominate the market and tend to be well documented and easily adapted to the target markets. (Poehlman and Sleper, 1995) It is a reflection of this central feature of the activity of plant breeding that UPOV maintains an exception to the exclusive right of the breeder – an exception that is remarkable in comparison to the scope of protection available under patents:

- UPOV78: Art. 5.3 allows other breeders to use the protected variety as a source of initial variation and market any derived variety without requiring prior authorisation of the breeder. The only limit to this free access arises when the "repeated use of the [initial] variety is necessary for the commercial production" of the derived variety, i.e. in the case of F1-hybrids.

- UPOV91: Art. 15.1 allows for the use of a protected variety as a source of initial variation for the production of new varieties. However, art. 14.5 narrows this exception by introducing the concept of 'essentially derived varieties', which then remain within the legitimate scope of the breeders' right.

The 1991 revision is an attempt to curtail the activity of cosmetic breeding – the breeding of nominally differentiated varieties that are otherwise identical – whilst simultaneously strengthening the borders of already protected varieties by widening the genetic distance between varieties. A less ambiguous demarcation of the borders of a variety requires a notion of 'genetic conformity', which must necessarily correspond to breeding methods and the variety's method of propagation. (Lange, 1993)

Developing countries must carefully consider the different options available in drafting this exception to the breeders' right. On the one hand, having a loose exception, such as UPOV78, will allow wider access to protected genetic material for the breeding of new varieties. However, this will also raise problems like that of cosmetic breeding. On the other hand, introducing a UPOV91 like exception will necessarily act as a stronger incentive to breeders and control access, which could result in reduced competition in the market. More importantly, defining and regulating essentially derived varieties is not an easy task (IPGRI, 1999).

Recommendations

11. The option to fulfil the obligation under article 27.3b by implementing an effective sui generis system for plant variety protection should be retained without modifications aimed at establishing a possible benchmark (e.g. UPOV).

12. Developing countries are recommended to undertake an extensive review of policies on agricultural development as a first step towards formulating and implementing an effective sui generis system for plant variety protection. This review exercise should be conducted in a participatory manner with the full and active involvement of all segments of society that are impacted by transformations in agriculture.

13. It is recommended that developing countries should reiterate their demand for the TRIPs Council to complete its substantive review of article 27.3b, which should also bring on board evidence of the impact (actual and/or potential) of IPRs in genetic resources and survey the issue of capacity-building as pre-requisite to effective implementation.

14. Developing countries are strongly recommended to examine key components of a sui generis system (e.g. the coverage of the legislation, the scope of, and conditions for, protection) to assess what might be appropriate and in the national interest.

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Appendix One: UPOV and Patents – A Comparison

PROVISIONS	UPOV 1961/1978	UPOV 1991	PATENT LAW
COVERAGE OF LEGISLATION	. Plant varieties of nationally specified schedule of species. . Coverage expanding gradually to encompass a finite list of species or genera.	. Plant varieties of all genera or species. . Coverage expanding within a specified duration to include all genera and species.	. Inventions in any field of technology. . Certain exemptions exist, such as `ordre public and animal and plant varieties (TRIPs art. 27; EPC art. 53).
CONDITIONS FOR GRANT OF PROTECTION	. Distinctness . Uniformity . Stability . Commercial novelty	. Distinctness . Uniformity . Stability . Commercial novelty . Not essentially derived if using protected variety as source of variation	. Novelty . Inventive step (i.e. non-obviousness) . Industrial applicability (i.e. utility) . Enabling and complete disclosure
PERIOD OF PROTECTION	Minimum 15 years, varying according to species.	Minimum 20 years, varying according to species.	Ranging between 17-20 years in OECD countries.

PROVISIONS	UPOV 1961/1978	UPOV 1991	PATENT LAW
SCOPE OF PROTECTION	. Basic scope restricted to commercial use of the reproductive material of variety. . Countries may expand the scope under special provisions.	. The basic scope includes all commercial acts related to all parts of the protected variety, including stocking, selling, importing, exporting and trading of the variety. . Countries may expand the scope to include acts related to the harvested material of the protected variety.	. If a product, then any commercial act related to the product, such as making, using, offering for sale, stocking, selling. . If a process, then using the process, and any of the above acts involving the product obtained directly from the process.
BREEDERS EXEMPTION - RESEARCH EXEMPTION CLAUSE	. Yes. . However, if production of the derived variety repeatedly requires the use of the protected variety, then explicit authorization is required, prior to commercialisation of dependent variety; this applies to breeding processes like F1-hybrids.	. Yes. . Apart from the contingency of UPOV 1978, essentially derived varieties cannot be commercialised without permission of the breeder of the initial variety.	. No.
FARMERS EXEMPTION	. De facto, yes. . Some countries, like the US, permitted the sale of a portion of harvested grain of a protected	. Dependent on national implementing law. . Some countries have restricted use of farm-saved seeds to sowing	. No.

PROVISIONS	UPOV 1961/1978	UPOV 1991	PATENT LAW
	variety as seed by farmers, as long as the variety name was not used.	the next crop, following payment of administratively fixed royalty rates.	
POSSIBILITY OF DUAL PROTECTION	. No, any species eligible for PBRs may not be protected by patents. . However, countries may provide patents and/or PBRs for the same species or genera, if the provisions existed prior to 31 October 1978.	. In principle, no. . However, the explicit ban on dual protection is revoked; members are obliged to grant and protect breeders rights. As such, distinction between PBRs and patents has been removed.	---

Appendix Two: PVP Legislations in the South

Prior to the TRIPs Agreement very few developing countries provided for intellectual property protection of plant genetic material (Verma, 1995). In fact a 1988 WIPO study reported the following:

- 44 countries explicitly excluded plant varieties from patenting
- 45 countries excluded animal varieties from patenting
- 42 excluded biological processes for the production of animal and/or plant varieties

It is in this setting that developing and least developed countries face the obligation under article 27.3b The deadline for implementation of the obligation under article 27.3b is 1 January 2000. The state of progress on implementation is alarmingly slow: only 21 developing countries have a PVP legislation in place (cf. table 3). Thus, 47 developing countries have failed to fulfil their obligation.

Table 3

WTO Developing Country Members with *Sui Generis* Legislation, as on 1 Jan. 2000		
Africa and Middle East	**Asia-Pacific**	**Latin America & Caribbean**
Kenya*, Morocco, South Africa*, Zimbabwe	Hong Kong, Korea, Thailand	Argentina*, Bolivia*, Brazil*, Chile*, Colombia*, Ecuador*, Mexico, Nicaragua, Panama*, Paraguay*, Peru*, Trinidad & Tobago*, Uruguay*, Venezuela*
*Member of the Union for the Protection of New Varieties of Plants (UPOV, Geneva), 1978 Act *Source:* GRAIN (2000)		

Early evidence of the impact of the PVP legislation is not encouraging (see main report). It is in this respect that a substantive review of article 27.3b, which did not occur under the mandate built-in agenda of TRIPs, should take place. A number of developing country proposals on plant genetic resources, traditional knowledge, and *sui generis* legislation exist (cf. table 4). These could form the basis of a substantive review of the Agreement.

Table 4

Developing Country Proposals for the TRIPs review (1999)		
Country/Group	**Patenting of Life Forms and Biological Processes**	***Sui Generis* Rights**
Kenya	- Need five-year extension of transition period - Harmonise TRIPS with CBD	Need five-year extension of transition period Increase scope of 27.3(b) to include protection of indigenous knowledge and farmers' rights Harmonise TRIPS with CBD
Venezuela	In 2000, introduce mandatory system of IPR protection for traditional knowledge of indigenous and local communities, based on the need to recognise collective rights	
Africa Group	- Review should be extended + additional five year transition after that - Review should clarify that plants, animals, microorganisms, their parts and natural processes cannot be patented	Review should be extended + additional five year transition after that *Sui generis* laws should allow for protection of community rights, continuation of farmers' practices and prevention of anti-competitive practices which threaten food sovereignty Harmonise TRIPS with CBD and FAO
LDC Group	There should be a formal clarification that naturally occurring plants and animals, as well as their parts (gene sequences), plus essentially biological processes, are not patentable. Incorporate provision that patents must not be granted without prior informed consent of country of origin Patents inconsistent with CBD Art 15 (access) should not be granted	- *Sui generis* provisions must be flexible enough to suit each country's seed supply system - Need for extended transition period

	Need for extended transition period	
Jamaica, Sri Lanka, Tanzania, Uganda, Zambia	No patenting plants without prior informed consent of government and communities in country of origin	
SAARC	No patenting plants without prior informed consent of government and communities in country of origin	
SADC	- The transitional period for implementation of 27.3(b) should be extended and the 2000 review should be delayed. - The review of 27.3(b) should harmonise TRIPS with CBD. - The exclusion of essentially biological processes from patentability should extend to microbiological processes.	- The transitional period for implementation of 27.3(b) should be extended and the 2000 review should be delayed. - The review of 27.3(b) should retain the *sui generis* option.
G77	Future negotiations must make operational the provisions relating to the transfer of technology, to the mutual advantage of producers and users of technological knowledge and seek mechanisms for a balanced protection of biological resources and disciplines to protect traditional knowledge	
Bolivia, Colombia, Ecuador, Nicaragua, and Peru	The Seattle Ministerial Conference should adopt a mandate to: (a) carry out studies in order to make recommendations on the most appropriate means of recognizing and protecting traditional knowledge (TK) as the subject matter of IPR; (b) initiate negotiations with a view to establishing a multilateral legal framework that will grant effective protection to the expressions and manifestations of TK; (c) complete the legal framework envisaged in paragraph (b) above in time for it to be included as part of the results of the new round of trade negotiations.	

Source: The entire table is reproduced from GRAIN (2000).