

TOWARDS A BALANCED 'SUI GENERIS' PLANT VARIETY REGIME:

Guidelines to Establish a National PVP Law and an Understanding of TRIPS-plus Aspects of Plant Rights



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EXECUTIVE SUMMARY

The TRIPS Agreement requires members to provide intellectual property protection to plant varieties. This has potential impacts over farming practices in countries that have long depended on informal exchange of farm-saved seed and knowledge. Farmers in many developing countries save, select and re-use seeds and this practice forms the basis of consecutive harvests, thus ensuring food security for rural communities. This practice is also important for maintaining agricultural biodiversity, particularly *in situ* genetic diversity. Plant variety rights that favor commercial and industrial breeders over traditional farmers can potentially result in the undermining of agricultural biodiversity and the promotion of monocultures. While TRIPS does accord intellectual property protection for plant varieties, it does provide the option for countries to adopt a *'sui generis'* plant variety law. There is no 'one-size-fits-all' approach towards establishing a balanced sui generis PVP regime, given the range of stakeholders involved. In establishing a balanced sui generis regime, countries would benefit from adopting an 'inclusive' process – one that takes into consideration the concerns of various stakeholders and affected groups. Countries must also be cautious about signing away available flexibilities in bilateral and regional free trade agreements and investment treaties which diminish the options available under TRIPS, thus also having dire impacts on farmers' rights and biodiversity.

ACKNOWLEDGEMENTS

This working paper was prepared as part of the work programme of the UNDP Bureau for Development Policy, Poverty Group, Inclusive Globalization Cluster's project on Intellectual Property, Trade and Biodiversity.

Peer review process was held in 2007-2008, experts in the related fields of intellectual property, trade and biodiversity were asked for written comments and inputs on the draft guidelines. This review process benefitted from inputs from Carlos Correa, Biswajit Dhar, Graham Dutfield, Bryn Gay (UNDP), Vanesa Lowenstein, Sisule Musungu, Daniel Robinson, Chee Yokeling and comments from Luisa Bernal (UNDP), Luciana Mermet (UNDP), Diwijen Rangnekar and Sanya Reid Smith.

The author would like to especially thank Kamal Malhotra (UNDP) and Luciana Mermet (UNDP) for their immense support and encouragement. This paper is a working document, if you would like to provide comments or inputs to this paper, please send them to savita.mullapudi@undp.org

ABBREVIATIONS AND ACRONYMS

- ACP African, Caribbean and Pacific countries BIT Bilateral Investment Treaty CAFTA Central American Free Trade Agreement CBD United Nations Convention on Biological Diversity DUS Distinctness, Uniformity and Stability (of plant varieties) EDV **Essentially Derived Varieties** EFTA European Free Trade Agreement EPA Economic Partnership Agreement EU European Union FAO Food and Agriculture Organization FDI Foreign Direct Investment FTA Free Trade Agreement GM Genetically Modified GMO Genetically Modified Organism International Centre for Trade and Sustainable Development, Geneva ICTSD IP Intellectual Property IPR Intellectual Property Right ITPGRFA International Treaty on Plant Genetic Resources for Food and Agriculture IUPGR International Undertaking on Plant Genetic Resources LDC Least Developed country MFN Most Favored Nation NAFTA North American Free Trade Agreement NGO Non-Government Organization PVP Plant Variety Protection **PVPFR** The Plant Variety Protection and Farmers' Rights Act of India R&D **Research and Development** SACU Southern African Customs Union TRIPS Agreement on Trade Related Aspects of Intellectual Property Rights UNCTAD United Nations Conference on Trade and Development UNDP United Nations Development Programme UPOV International Union for the Protection of New Varieties of Plants **US-GAO** United States Government Accountability Office WIPO World Intellectual Property Organization
 - WTO World Trade Organization

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1. INTRODUCTION

The agricultural sector is a crucial source of food, employment and trade, and hence, contributes to overall economic growth and poverty reduction. Plant variety protection (PVP) regimes, which have important impacts on agriculture therefore affect food production, food security and also have important impacts on livelihood, employment, trade and biodiversity. Internationally, there is no 'one size fits all' PVP regime that adequately reflects the diverse needs of different countries. Any successful model put forward must be rooted in the development objectives of the particular country. There are a number of parameters that need to be kept in mind when establishing a PVP regime as part of implementation of the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and other multilateral and bilateral agreements.

First, one has to consider the justification of PVP as a proprietary right on its own and as part of the TRIPS Agreement. In general, PVP laws are justified on the basis that they may contribute positively towards agricultural crop development. However, these regimes, depending on how they are structured, may also have important negative consequences. In this context it is important to understand that technical progress in agriculture in developing countries, in particular, has traditionally occurred through the process of on-farm experimentation, selection and adaptation of domestic varieties and landraces. Another important part of the agricultural structure in developing countries has been the maintenance of biodiversity, particularly plant genetic diversity, since farmers have thrived on informal practices that include exchange of seeds and knowledge. Notwithstanding, the technological progress witnessed in agriculture in recent decades, these practices remain an important part of the agricultural innovation systems in developing countries. How PVP affects this agricultural structure and practices is therefore an important consideration.

Second, there is no doubt that since the implementation of the TRIPS Agreement, an increasing number of developing countries have been adopting PVP legislation. Under Article 27.3 of the agreement, plants, animals and essentially biological processes may be excluded from patentability. However, this provision is made on the condition, in Article 27.3 (b), that Members must provide protection for 'plant varieties' either through patent protection or an effective 'sui generis' system or a combination of the two. A significant number of the countries that have introduced PVP legislation have based them on the International Union for Protection of New Varieties of Plants (UPOV) Convention¹, even though it is not explicitly obliged by the TRIPS Agreement. However, in the context of this document, it is important to note that there are still many developing countries which have not established PVP systems and there are those which have established their own *sui generis* PVP regimes.

Finally, it is important to remember that PVP systems, which establish plant breeder's rights, have only become widespread in the second half of the 20th century. These systems largely reflected the economic structure and circumstances of agriculture prevailing in developed countries, particularly Europe. Considering the short history of PVP even in developed countries there is still much that we do not know about the impacts of PVP. The requirements of Article 27.3 for the protection of plant varieties through a sui generis system, patents or combination of both should therefore be understood with this background in mind.

To put this into practical context, World Bank study (Louwars et al, 2005) of five developing countries (China, Colombia, India, Kenya and Uganda) found no empirical evidence that plant breeders rights would induce new

^{1.} UPOV is based on the French name: L'Union internationale pour la protection des obtentions végétales

research, new varieties or strengthen developing country seed industries, thereby questioning the value of PVP in developing countries. Despite this, in bilateral and regional trade agreements developing countries continue to be pressured to sign the 1991² UPOV Convention or provide patent protection for plant varieties.

Given the various parameters to consider and the implications of PVP, this paper exhorts countries to tread carefully while establishing a PVP regime and while negotiating a bilateral or regional trade agreement that includes PVP provisions. While TRIPS requires that member countries provide PVP, it does give an option of adopting a 'sui generis' system which must be considered a positive flexibility. Importantly, the objective of a PVP law must be more than fulfilling obligations under a multilateral trade agreement. The objective must be to establish a PVP regime that includes and supports the interests of all affected groups including farmers, consumers, indigenous communities and local industries, as the obligations that countries sign into should be of benefit to all. Hence the need to establish a 'balanced' sui generis plant variety regime is paramount towards protection of plant variety rights, consistent with Articles 7 and 8 of TRIPS itself.

Towards this end, the paper examines various approaches to establish PVP regimes, sui generis approaches based on what have been adopted by other countries (India, Thailand, Bangladesh, Organization of African Unity, now the African Union and Malaysia) and available studies and discussions. This paper by no means intends to provide a prescriptive methodology towards establishing a PVP regime, but instead sets out various approaches that should be considered by countries to establish a 'balanced' sui generis PVP regime. The objective of this paper is to provide early guidance towards understanding what a balanced sui generis may entail. In its examination of a 'balanced sui generis' regime, this paper does not discuss the patent system for plant varieties as it is not a sui generis form of protection. This paper also examines in some detail the inadequacies and ineffectiveness of UPOV as a 'balanced' sui generis system of protection.

Instead of adopting UPOV-style systems or allowing patentability of plant varieties, policy makers may consider combining various approaches to create a customized law. Additionally, developing countries should establish and enforce effective seed laws, seed and gene funds where applicable, access and benefit sharing mechanisms (which must include effective regulation, contract law and responsible business practices) all of which combined with a sui generis PVP law shall make a balanced plant variety rights regime. Furthermore, this paper exhorts countries to adopt an 'inclusive' process of engagement with key stakeholders to establish a balanced sui generis plant variety protection law.

The option to adopt an effective sui generis system for plant variety protection is probably the only positive flexibility available for countries under TRIPS for providing PVP in developing and least-developed countries (LDC). This flexibility is being diluted by the onslaught of bilateral and regional trade agreements that are being negotiated outside the WTO. These agreements often include "TRIPS-plus" provisions that go beyond the minimum standards required by TRIPS. Although the full ramifications of these provisions are not yet fully known, it has been widely suggested by experts in the field that the effects will be critical to developing countries access to food, local farming capacities and agricultural biodiversity. The final part of the paper (may be treated as a stand-alone chapter) intends to help countries analyze TRIPS-plus provisions and their effects with regard to plant variety rights. This final section of the paper presents a variety of strategies that countries may adopt to understand and assess the impacts arising from TRIPS obligations and bilateral or regional trade agreements.

^{2.} The balance between 'formal' commercial plant breeders rights and farmers' rights in the 1978 version of the UPOV convention was significantly tilted in the favor of the former by amendments in 1991 by broadening breeders' rights and narrowing farmers' entitlements. Countries that now accede to UPOV must accept UPOV 1991 and no longer have the option to choose UPOV 1978.

2. OBLIGATIONS AND OPTIONS UNDER TRIPS

WTO Member countries, numbering more than 150 of which about two thirds are developing countries,³ are obliged under TRIPS Article 27.3(b) to provide intellectual property protection to plant varieties (See Box1 for relevant provisions). According to these provisions, countries must provide for plant variety protection either by patents or a 'sui generis' system or any combination thereof. While countries would have to follow detailed standards set out in the TRIPS agreement for providing patent rights to plant varieties⁴, the only requirement to establish a sui generis system is that it should be effective⁵. This gives countries the option of determining the scope and contents of the rights to be granted under a sui generis system. Additionally, 27.3 (b) calls for a review of the provision. In addition to this provision, Article 71.1 requires periodic review of TRIPS implementation as a whole.

BOX 1 TRIPS Article 27.

TRIPS Article 27.1

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. 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.

TRIPS Article 27.2

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 in order to avoid serious prejudice to environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

TRIPS Article 27.3

Parties may also exclude from patentability:

- a. diagnostic, therapeutic and surgical methods for treatment of humans and animals.
- 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.

The negotiating history of Article 27 reveals that this particular clause was highly contested and controversial⁶. There were three broad positions in this regard, first, the US pressed for Article 27.1; second, the EC proposed

- 3. The updated member list can be found on the WTO website www.wto.org. As of 16th May 2008, 152 countries are members of the WTO.
- 4. This paper does not examine grant of patent rights to plant varieties as the objective of the paper is to analyze and provide some guidance and understanding into establishing a sui generis system for plant varieties. For grant of patents for plant varieties and its ramifications, see Butler L.J. and Marion B.W (1985), The impacts of Patent Protection on the US Seed Industry and Public Plant Breeding, Food Systems Research Group Monograph 16, University of Wisconsin-Madison; Also see Commission on Intellectual Property Rights (CIPR) Integrating IPR and Development Policy, London, September 2002, available at www. iprcommission.org, Also see Jaffe, Adam B and Lerner Josh Innovation and its discontents: How our broken patent system is endangering innovation and Progress and what to do about it?, Princeton University Press (2004).
- 5. Though there has been no general consensus on what 'effective' entails, it is interpreted to mean that the national legislation must provide for the implementation of juridical procedures for right holders to execute their rights.
- 6. See GATT Secretariat Documents, although these are for special distribution and circulation among negotiating members, most trade ministries have access to these documents- UR-90-0178, 0283, also titled under Uruguay Round Negotiation Documents (MTN.GNG/NG11/W/68, 29th March 1990). For a very detailed understanding and analysis of the history of this provision both pre-TRIPS as well as negotiating history, see UNCTAD-ICTSD Resource Book on TRIPS and Development, 2005 pages 390-392.

exclusions similar to that in Article 27.3; and third, 11 developing countries (Argentina, Brazil, Chile, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay) proposed that plant varieties should be excluded.

While the final Article 27.3 (b) is flexible about the form of protection of plant varieties, it forced the introduction of intellectual property protection in an area in which most developing countries had none prior to TRIPS. This obligation has raised serious concerns in many of these countries about the impact of IPR protection on farming practices (particularly the re-use and exchange of seed as well as continuing on-farm plant breeding by farmers), genetic diversity and food security.

Thus, under TRIPS, the obligations with regard to plant variety protection are dual: first, countries must provide for plant variety protection, and second, that Member countries are obliged to review this sub provision⁷.

Under the first obligation of grant of PVP, the options available under TRIPS are thus:

i. Patents for plant varieties

This option offers minimal flexibilities for the drafting of national laws, due to the rigidity of TRIPS patent rules. This would mean that countries have to adhere to regulations and standards already laid down in TRIPS Section 5 for granting of patents to plant varieties⁸. These strict standards for the grant of private monopoly rights are poorly suited to developing country interests and concerns regarding small-scale breeding, traditional farming practices, indigenous peoples collective rights, agricultural biodiversity and food security. For these reasons, there seems little benefit for developing countries to have a combination of both patent provisions on plant varieties and a sui generis law.

ii. An effective 'sui generis' law for protection of plant varieties

This is the most flexible option regarding protection for plant varieties. Sui generis literally means 'of its own kind; unique'⁹. Therefore the purpose of developing a PVP law may be interpreted to mean a customized law that a country establishes according to its biodiversity and agricultural concerns.

^{7.} The issue of review under 27.3(b) of the TRIPS Agreement is discussed and analyzed in detail in section 8 of this paper.

^{8.} As already noted in footnote 2, this paper does not deal with patent rights with regards to plant varieties.

^{9.} According to the Oxford English Dictionary, 10th Edition, 2002.

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3. 'SUI GENERIS'-TRIPS COMPLIANCE

There has been considerable debate over the question of whether plant varieties should be subject to IPRs (though "IPR" has not been defined in TRIPS, it is described in the preamble as "private rights"). Part II of the TRIPS Agreement sets out various types of IPRs but breeders' rights (plant or animal breeders) are not considered a form of IP under the agreement¹⁰. Plant breeder's rights were, legally speaking, the creation of the UPOV convention and its amending Acts. While the TRIPS Agreement has made 'plant varieties' as 'intellectual property', it provides an important flexibility- the type of protection is a matter of national choice. One option is through patents but a sui generis system independent of any of the IPRs under TRIPS is also legally possible. So a country that is not party to UPOV can develop a balanced national PVP law that accords specific privileges to commercial breeders while also providing for the rights of farmers, biodiversity conservation and food security.

In most developing countries, plants and/or plant varieties are encompassed in agricultural and indigenous practices where holders of related knowledge are collective and are not easily categorized into 'private and exclusive rights'. There are inherent dangers in trying to grant exclusive and private rights as PVP in certain contexts. On one hand, it impacts existing farming and agricultural practices where farmers exchange and re-use seeds for consecutive harvests which ensure rural food security. On the other hand, it impacts sovereign rights of indigenous people who are collective custodians of various plant varieties used in their medicinal practices.

A sui generis system could encompass specific types of privileges to reward the generation of plant-based innovations but with essential environmental safeguards and securing farmers livelihoods (even if this means including collective rights). This could be a system of 'liability rules' or a system that does not necessarily provide for exclusive rights that prevent others from use/production of protected matter - the scope of protection could be confined to a specific use of certain objects or processes. Probably the best compromise would be setting out the circumstances and conditions where certain exclusivity may be granted for certain plant varieties – particularly newly bred commercial crop varieties. Additionally there may be provisions for remuneration when a third party engages in activities involving the protected plant variety.

There are certain minimum requirements under TRIPS, wherein a protection system for plant varieties must comply with basic principles of national treatment and most favored nation treatment. The system must also provide for implementation of legal procedures for PVP holders to execute their rights. These minimum requirements however can then be combined with an exhaustive list of safeguards or exceptions. The state may also create specific types of protection for specific types of plants given their characteristics, use and future purpose, all of this while including various stakeholders such as farming bodies, labor groups and key civil society organizations in the process of making and implementing the law.

Finally, reading of Article 27.3(b) seems to suggest that the only requirement of a sui generis system is that it must be effective. 'Effective' in legal parlance may be interpreted as a system that contains implementation of juridical and/or administrative procedures for PVP holders to execute their rights.

^{10.} Correa Carlos, Trade Related Aspects of Intellectual Property Rights: A Commentary of the TRIPS Agreement (2007), Oxford University Press at page 294.

4. INTERPRETATION OF SUI GENERIS SO FAR

S(b) by enacting some form of plant variety protection (PVP) law. While most countries are members of UPOV 1978 or 1991, very few countries have attempted to establish balanced national laws that are customized and take into account interests of various stakeholders such as indigenous peoples, farmers and environmentalists. Generally, the interpretation has been –

- i. Many developing countries have signed the 1991 convention of UPOV¹². As of June 18, 2007, around 39 developing countries are members of UPOV, of which around 21 are party to the UPOV'91 Act (See later section for implications).
- ii. Some developing countries have ratified UPOV1978 (when there was the option to do so) and have also adopted national PVP laws. For example China has two PVP laws, one covering agricultural plants and one covering forest (woody) plants. Among others are Brazil, Chile, Kenya, Panama and South Africa.
- iii. Some developing countries (albeit a few) have adopted PVP laws that are departures from UPOV such as India, Thailand and Malaysia - though some aspects have been modeled on UPOV1978 but these countries are not members of UPOV. These countries have customized their laws, taking into account national interests and involving various stakeholders thereby attempting to establish a 'balanced' sui generis system.

The option of providing PVP via a sui generis system under TRIPS is a flexibility. Furthermore, the only substantive requirement of such a system is that it is effective. If a country member chooses to implement Article 27.3b through UPOV, they still have a positive duty, in case of a dispute to prove effectiveness. Simply being a member of UPOV does not constitute compliance with TRIPS. Additionally, providing plant variety protection similar to that of UPOV may not constitute making full use of the flexibility, as we analyze further whether the UPOV treaty is a 'balanced' sui generis law.

^{11.} Least Developed Countries have a longer time period to implement TRIPS- until 2013. See http://www.ip-watch.org/weblog/index.php?p=157- "Under the 1994 WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), least developed countries (LDCs) were given a transition period to implement the agreement that was due to expire by 1 January 2006. They collectively sought a 15- year extension but met with opposition from developed countries and ultimately agreed to 7.5 years.'

^{12.} A detailed understanding and analysis of UPOV follows in the next part. It is however important to point out that developing countries often seem to be coerced into signing UPOV as the only available sui generis system without taking into consideration their own national environmental and agricultural interests. It might be worth mentioning that UPOV membership does have the benefit of essentially coming with technical assistance from the World Intellectual Property Organization (WIPO) for the development of nationally compliant UPOV systems. While this may be seen as a plus, it comes with some pitfalls due to the narrow focus of UPOV which favors advanced or industrialized breeders and often does not take into consideration local agronomic, environmental, social and cultural conditions of small scale farmers and indigenous communities.

5. IS THE UPOV TREATY A 'BALANCED' SUI GENERIS LAW?

The International Union for protection of New Varieties of Plants (UPOV) is an independent intergovernmental organization having legal personality. Pursuant to an agreement concluded between the World Intellectual Property Organization (WIPO) and UPOV, WIPO provides administrative services to UPOV.

The UPOV Convention was adopted in 1961 to ensure that member states acknowledge the achievements of breeders of new plant varieties by making available to them exclusive property rights for a given period of time. The UPOV Convention took shape when commercial plant breeders in Europe put forth a case for the development of a system that was more adapted to the needs of plant breeders, i.e. continued access to plant varieties for breeding purposes. Therefore it allowed wide exemptions from the property rights for breeders and also some for farmers¹³.

The Convention entered into force in 1968 and has been revised a number of times since then, each time with more restrictive rules for breeders and farmers. Today, most member countries are either member of the 1978 Act or the 1991 Act of UPOV. Pertinently, countries that are currently being coerced into entering UPOV via bilateral or regional trade agreements will have to sign UPOV 1991 since UPOV 1978 is closed for further membership. Countries may use UPOV 1978 as a model to fulfill obligations under Article 27 of TRIPS, however, without accession this does not entitle them membership to UPOV.

5.1: SALIENT FEATURES OF UPOV: (INCLUDING DIFFERENCES IN THE 1978 AND 1991 ACT)¹⁴

a. **Definition of plant variety:** The 1978 Act does not provide any definition of plant varieties, however, the 1991 Act defines plant variety as "a plant grouping within a single botanical taxon of the lowest known rank" and "that the variety must be recognizable by its characteristics, recognizably different from any other variety and remain unchanged through the process of propagation". This moves away from the earlier15 emphasis on phenotypic expression of physiological and morphological characteristics to one based on expression of characteristics arising from genotype. To put it simply, more emphasis is now placed on the genetic make-up of the variety and its protection than on the observable physical or biochemical aspects of the variety. This implicitly renders the UPOV system partial to industrial breeders that engage in plant breeding systems which are not very widespread in developing countries and almost non-existent in UN-defined least-developed countries.

^{13.} Though under the 1978 Act, farmers are implicitly allowed to use their harvested material from a protected variety for any purpose. Under the 1991 UPOV Act, the protection covers not only the propagating material of the protected variety, but also the harvested material (including entire plants and parts of plants), the products made directly from harvested material of the protected variety, and "essentially derived varieties", discussed below.

^{14.} This portion of the section relied heavily on analyses in Lightbourne & Dutfield, Literature Review and Commentary on Legal Regimes and Models for protecting plant varieties, IPDEV Work Package 6; available at www.iprsonline.org.

^{15. &#}x27;Earlier' in this case means the definition of plant varieties under the International Code of Nomenclature for Cultivated Plants, which was relied upon as the 1978 Act did not define plant varieties- please see Footnote 30 in Lightbourne & Dutfield, *Literature Review and Commentary on Legal Regimes and Models for protecting plant varieties*, IPDEV Work Package 6; available at www.iprsonline.org.

- b. Criteria of protection¹⁶ protectable varieties must satisfy following criteria:
 - i. Novelty: at the date of filing of the application, propagating or harvested material of the variety has not been sold or otherwise disposed of to others, by or without consent of the breeder.
 - ii. Distinctness: the variety must bear a characteristic which has no equivalent in other varieties.
 - iii. Uniformity: broad proportion of the seedlings of a sowing must be identical.
 - iv. Stability: the relevant characteristics must remain unchanged after repeated propagation.
- c. **"Farmer's privileges" as opposed to "farmers' rights":** Under the 1991 Act, farmers are only allowed within reasonable limits and safeguarding the legitimate interests of the rights holder to reuse the harvest of protected varieties on their own land holdings without the authorization of the rights holder. They would not be allowed to exchange or sell such material. This in effect places a charge on farm saved seed which then forces farmers to pay a second charge on something they already possess¹⁷. This provision is a far cry from "farmers rights" as envisaged in the FAO International Undertaking under which farmers' rights mean "rights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources, particularly those in the centers of origin/diversity". It may also be argued that this restriction imposed by UPOV conflicts with Article 10 (c) of the CBD¹⁸.
- d. Extensive breeders' rights: Under the 1978 Act, the scope of rights was limited to production for purposes of commercial marketing, offering for sale and marketing of propagating material of a protected variety. The scope of rights has considerably expanded under the 1991 Act. Breeders in addition to rights under UPOV 1978 can now among other things, export, import and stock for the same purposes the protected material. Under the 1978 Act, breeders are free to use a protected variety to develop a new variety, but not if it requires repeated use of that variety. Under the 1991 Act this exemption is restricted while research and breeding is allowed, the resulting essentially derived variety (EDV) cannot be commercialized without the authorization of the owner of the original variety (See Box 2 for a brief analysis of EDV).

BOX 2 Essentially derived varieties (EDV)

There have been concerns raised by the protection of EDV (Essentially Derived Varieties) that has been established in UPOV'91 Act. While it is not clear whether EDV protection will affect the average farmer, there could be implications for small-scale breeders. The provision basically allows¹⁹ the protection of cosmetic modifications on already protected varieties, subject to permission from the breeder of the 'initial variety'. EDVs are somewhat controversial because there is little consensus over the genetic conformity threshold required for the identification of EDVs from initial varieties of crops. Essentially derived variety protection means that breeders and/or biotechnologists will not be able to get away with making a minor modification on an initial variety, protecting and commercializing it, without seeking approval of the original breeder. Indian NGOs have suggested that within EDV provisions under their PVP law, the parent genetic material contributed by rural and tribal peoples be included in the definition of 'initial variety'. However, the protection of general domestic or farmer's varieties from free-riding is not UPOV's intention. Obtaining permission from breeders of the initial variety in this case would be complex — it would be difficult to ascertain which farmer's and breeders would have appropriate authority.

- 16. See Lightbourne and Dutfield ibid at Section 4.
- 17. See ibid and in Rangnekar, Dwijen Access to genetic resources, Gene-based Inventions and Agriculture CIPR Study Paper 3 a, London, 2002. However, an exception may be established as has been under the US law.
- 18. See Leskien and Flitner referenced in Lightbourne and Dutfield; Intellectual Property Rights and Plant genetic resources-Options for a sui generis system in IPGRI no.6, 1997 can also be found on www.grain.org
- 19. The concept of EDV explained in the box is adapted from Daniel Robinson, (2007) Exploring Components and Elements of Sui Generis Systems for Plant Variety Protection and Traditional Knowledge in Asia, available at http://www.iprsonline.org/unctadictsd/docs/Robinson%20Sui%20Generis%20March07.pdf

There has been a significant culmination of analysis and literature²⁰ indicating that UPOV may not serve as the best available option for countries where a significant proportion of the population depends on an informal seed supply system of agriculture for their daily needs and sustenance. While most of the policy ramifications of adopting UPOV provisions remain unclear²¹ as to how exactly they would affect the average farmer, agricultural practices, indigenous knowledge or even biodiversity, some key implications have been documented:

- i. UPOV tends to favor commercial breeders and consequent revisions to the act have leaned towards promoting genetic uniformity in crop varieties, which can have drastic effects on biodiversity. Supporters of UPOV argue that the 1991 revision encourages breeders to conduct research on minor crops and to bring whole new species into commercial cultivation. Opponents point out that even if this were true, small farmers will be worse off if they lose their 'right' to re-sow seeds from their harvested crop, since, in most developing countries a very large proportion of the population depends on agriculture for employment and income, and that many of these farmers are smallholders. For such farmers, seed saving from their harvest for further propagation, sale and exchange is a common practice²².
- ii. UPOV establishes no mechanisms or safeguards against the practice of 'biopiracy'²³. Developing countries that hold many of the genetic resources (and associated traditional knowledge) have concerns over the practice of misappropriation (commonly referred to as 'biopiracy') of their genetic resources for use in inventions patented by researchers that are commonly from companies or institutions based in developed countries. Developing countries have suggested and submitted various proposals²⁴ on the need for an international binding, enforceable disclosure requirement that would oblige patent applicants to disclose source and country of origin of biological resources and traditional knowledge; evidence of prior informed consent and evidence of benefit sharing as established and required under national regimes.
- iii. On the issue of whether intellectual property rights (rights under UPOV or patent rights) encourage crop monocultures and thus cause erosion of biodiversity, experts²⁵ believe that the prevailing policy framework favors 'centralized crop breeding and the creation of uniform environmental conditions and discourages agro-ecological research or local breeding tailored to local conditions'. A parallel may be drawn to expansive patent rights granted in the areas of medicines and pharmaceuticals resulting in distorted priorities in medical research expenditure where lifestyle drugs take precedence over life saving drugs for diseases ravaging developing countries.

The issue of whether UPOV is a balanced sui generis regime is essential for developing countries where heavy concerns lie with respect to farming practices, small scale breeders and food security. As more developing

- 20. See Harbir, Emerging Plant variety legislation and their implications for developing countries: Experiences from India and Africa, Also See Jeroen Van Wijk and Walter Jaffe, Intellectual property rights and Agriculture in developing countries, University of Amsterdam, (1996); GRAIN briefings 10 Reasons not to join UPOV,(1998) available at http://www.grain.org/briefings/?id=1; Rangnekar, Dwijen Intellectual Property Rights and Agriculture: An analysis of the economic impact of plant breeders' rights, Action Aid UK (2000); Kuyek Devlin, Intellectual Property Rights : Ultimate Control of Agricultural R&D in Asia (2001); Srinivasan C.S., Shankar B and Holloway, G. An empirical analysis of the effects of Plant Variety Protection Legislation on Innovation and Transferability available at http://ecsocman.edu.ru/images/pubs/ (2003).
- 21. While evidential ramifications in developing countries are still to be established, several case law document interpretation of UPOV/patent rights over farmers' uses in industrialized nations. See ibid Dutfield and Lightbourne pgs 14-16. UPOV restricts farmers practice of reusing seeds with many farmers facing law suits. See Monsanto Co. v. McFarling, Monsanto v. James Gastel & Monsanto v. Loren David in Spellman, Derek (2008). "Monsanto Co. Suing Jasper Famer," The Joplin Globe, 18 February. If such provisions are extended to developing nations they may result in dramatic repercussions for impoverished farmers who cannot afford the legal expenses or compensation to the companies.
- 22. See FN17 for case laws. For more analysis of UPOV's effects on developing country farming practices, see Tripp, R (1997) New Seed and Old Laws: Regulatory Reform and Diversification of National Seed Systems. Also see Verma, S K (1995) TRIPS and plant Variety Protection in Developing Countries, EIPR, Vol.17. Also see Dhar, Biswajit, Sui Generis Systems for Plant Varieties Protection: Options under TRIPS. QUNO, Geneva (2002). For points raised here, see, Dutfield, G Intellectual Property Rights, Trade and Biodiversity.
- 23. Providing for indigenous communities is not a responsibility under UPOV, since it creates specific individual private rights against plant varieties which are almost impossible to establish under and connect with rights granted under traditional knowledge scenarios where often holders of such knowledge are communities and thus the onus of creating a mechanism falls on the state. However, it is important to mention absence of such a safeguard and expansive rights granted to breeders under UPOV puts indigenous knowledge holders and practices at a disadvantage as well has possible implications over their daily lives. Some biopiracy cases have been documented in Implications of TRIPS on livelihoods of farmers in developing countries, Ruchi Tripathi, available at http:// www.biotech.bioetica.org/docta46.htm. Also see Page 6 of UNDP HDR 2000 with reference to biopiracy and TRIPS as "silent theft of centuries of knowledge from some of the world's poorest communities in developing countries".
- 24. See section 8 of this paper- NOTE on TRIPS review.
- 25. Reid, W V (1992) Genetic Resources and Sustainable Agriculture: Creating Incentives for Local Innovation and Adaption. Biopolicy International, Report No. 2. Reid argues that the only lasting solutions to maintaining the genetic resources base of agriculture are in situ conservation, recognition of local and national ownership of genetic resources and research and investment aimed at informal innovation. Further analysis provided in Graham, ibid.

nations become parties to UPOV, the flexibility of having considerable room to develop an independent and customized 'sui generis' system awarded by TRIPS is undermined and UPOV may become a norm.

In the Uruguay Round negotiations, there were suggestions by the GATT Secretariat that UPOV may be accepted as the framework for PVP²⁶ which suggests that industrialized nations may push for UPOV to be recognized as the only sui generis system by WTO in the context of review of Article 27.3(b). Though this review has been inconclusive thus far²⁷, its eventual outcome may well depend on the existence of different sui generis systems already in place. A large number of developing countries if signatories to UPOV may make it a de facto minimum standard having possible wide range impacts over farmers, women, food security and rural livelihoods in developing countries.

^{26.} Dhar, Biswajit, Sui Generis Systems for Plant Varieties Protection: Options under TRIPS. QUNO, Geneva

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Tweaking existing UPOV provisions²⁸ especially 'criteria protection' has been suggested²⁹ for adoption in national sui generis systems. While substituting 'uniformity' for 'identifiability'³⁰ would possibly make less genetically uniform new varieties eligible for protection, it still does not resolve other impacts on farming practices nor does it provide any safeguard towards biopiracy issues. While it does assist in creating a more balanced 'scope of rights' provision in the national PVP law, it would fall short of creating a sound provision for farmers varieties.

This section of the paper presents the options available for policy makers to create a general scope of rights provision (including scope, term and types of protection, limitations and exceptions to the rights) and then examines various approaches towards protection of farmers' (or also known as domestic/extant) varieties and related farmers' rights and their enforcement. The approaches examined here are not mutually exclusive; policy makers may consider a combination of some or all of them to provide for 'grant of rights' to plant varieties in national PVP laws.

6.1: OPTIONS FOR SUBJECT MATTER AND CRITERIA OF PROTECTION

a. Subject matter of protection

Not all types of plant varieties need to be protected or awarded rights. In fact, UPOV 1978 without defining plant variety, provides that member states are to progressively extend protection to an increasing number of genera or species, beginning with 5 on the date of entry and ending with 24 within 8 years. In addition, member states are free to limit the Act's application within a particular genus or species to varieties with a particular manner of reproduction or multiplication, or a certain end-use.

b. Definition of plant variety

The main aim of a balanced sui generis PVP law must be to create a balance between the interests of commercial breeders – those who develop 'new' varieties – and to uphold practices of local breeders mainly farmers that encourage ongoing cultivation of 'domestic' varieties. It is important to note that farmers may also develop 'new' varieties and that protection must be thus accorded. For this purpose, some sui generis laws define the 'type' of plant variety and accord specific rights to the type.

The Thai PVP act³¹ separates 'new' varieties from 'domestic' and 'wild' and from local varieties so as to give categories for differential protection. The AU model law³² does not define plant variety except to state it as a 'derivative' – a product developed or extracted from a biological resource. A sui generis law would benefit from

^{28.} This especially refers to the provision of 'identifiability' which has been adopted under the Malaysian PVP.

^{29.} Dan Leskin & Michael Flitner, The TRIPS Agreement and Intellectual property Rights for plant varieties (1998); available at www.grain.org. These suggestions of 'identifiability' and relaxing 'uniformity and stability' have been discussed further in this paper.

^{30.} This provision has been made especially available for plant varieties bred by farmers, local and/or indigenous communities under the Malaysian PVP law which is discussed in detail later.

^{31.} The Thailand Plant Varieties Protection Act, B.E. 2542 (1999), for detailed analysis and study of the Act referenced in various sections of this paper, see from Daniel Robinson, Exploring Components and Elements of Sui Generis Systems for Plant Variety Protection and Traditional Knowledge in Asia, available at http://www.iprsonline.org/unctadictsd/docs/Robinson%20Sui%20Generis%20March07.pdf

^{32.} The OAU Model Law- The protection of the Rights of Local Communities, Farmers and Breeders and for the regulation of Access to Biological Resources; available at http://www.grain.org/publications/oau-en.cfm, June 2001.

clear definitions of distinguishable types of plant varieties: new, domestic or wild varieties³³. The definition of 'new' variety is often adopted from the UPOV1991 Act³⁴. The Indian PVP law defines 'extant³⁵' varieties which includes farmers' varieties³⁶.

c. Options for criteria for protection

Most PVP laws so far have adopted DUS (distinctiveness, stability and uniformity) requirements provided in UPOV³⁷ as criteria for protection especially for 'new' varieties. But some PVP laws have either relaxed or modified certain provisions for 'farmers' varieties. The Bangladesh Bill³⁸ awards protection to 'new' plant varieties as long as they meet the criteria of novelty, consistency distinctness and stability. In addition, the varieties must demonstrate 'immediate, direct and substantial benefit to the people of Bangladesh'. The Malaysian law takes probably the simplest route, wherein a breeder's right can be given if the plant variety is new, distinct, uniform and stable. Where a plant variety has been bred, discovered and developed by a farmer, local community or indigenous people, a breeders' right is awarded if the plant variety is new, distinct and identifiable. Hence, in this case, criteria for protection have been distinguished instead of varieties.

In a balanced sui generis law, key attention must be paid to the criteria of protection. Criteria need to be clearly defined and carefully interpreted such that they are advantageous to domestic and local breeders, as well as for the general public interest. Individual countries need to determine how restrictive or relaxed these criteria are, on the basis of a range of in-country agricultural factors. In other words it may be useful to have relaxed criterion, such as an 'identifiability' criterion, in cases where there are many small-scale breeders seeking protection for their varieties. Various available options are analyzed below - note that not all of these options may be advantageous to the adoption of a 'balanced' sui generis regime.

Novelty or 'new'- the plant variety must not have been sold on the market for more than a specified period of years prior to the date of application for protection. UPOV sets different time periods for different types of plants. The Indian law relaxes this requirement for 'extant/farmers' variety.

Distinctiveness UPOV requires that a plant variety must be 'clearly distinguishable in one or more important characteristics from any other variety whose existence in common knowledge at the time when protection is applied for'. The guidelines to the treaty use both qualitative and quantitative plant characteristics including visible attributes such as leaf shape, stem length and color to determine if the difference between varieties is 'clear and consistent'. This criterion may be further constrictive by adding specific requirements in the rules of the law to include evidentiary proof of qualitative, quantitative and physical attributes.

- 35. Extant variety under Indian PVP law Section 2(j) includes farmers' varieties, variety which there is common knowledge and any other variety which is in public domain.
- 36. Farmers' variety under the Indian PVP law Section 2(I) means that which has been traditionally cultivated and evolved by farmers OR is a wild relative or land race or a variety of which the farmers possess common knowledge.
- 37. UPOV here generally means both the 1978 and 1991 Acts, unless specifically mentioned.
- 38. Plant Varieties Act of Bangladesh (in Bill form)- 1998 Draft available on http://www.grain.org/brl/?docid=81984&lawid=1027. According to this law,'plant variety' means a group of plants which has similar or identical genetic and botanical characteristics resulting from a given genotype or combination of geno-types and having specific, stable properties; it can be distinguished from other plant varieties of the same plant species by the expression of at least one of the said characteristics.

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^{33.} Under Section 3 of the Thai PVP Act, there are two categories of domestic varieties- 'local domestic variety' refers to plant variety which only exists in a particular locality within the country and has never been registered as a new plant variety and is registered as a 'local domestic variety'; the other category of domestic variety is 'general domestic variety' means a plant variety originating or existing in the country and commonly exploited and shall include plant variety which is not a new, local domestic or wild variety. Further 'wild' variety means a plant variety which currently exists or used to exist in natural habitat and has not been cultivated.

^{34.} See above Section 5a – UPOV '91 Act defines plant variety as plant grouping within a single botanical taxon of the lowest known rank and that the variety must be recognizable by its characteristics, recognizably different from any other variety and remain unchanged through the process of propagation

Uniformity: under UPOV means that the variety must be 'sufficiently homogenous, having regard to particular features of its sexual reproduction or vegetative propagation'. This was previously the 'homogeneity' requirement (in UPOV 1978) and has been criticized³⁹ as discouraging variability in plant varieties that are often useful for sound agricultural practices and as denying protection to breeders of cultivated landraces that exhibit diversity traits. In other words, by rewarding breeders of 'uniform' plant varieties, plant genetic diversity has been reduced.

Stability: under UPOV1978 requires the applicant to show that the essential characteristics of the variety are homogenous or uniform over time, even after repeated reproduction or propagation; the variety has to show stability between breeding cycles. This criterion has also been criticized⁴⁰ for the same reasons as the 'uniformity' criterion.

Identifiability: Some experts⁴¹ suggest the application of a less strict interpretation of 'uniformity' and 'stability' requirements and/or to replace them with the criterion of identifiability. This would allow the inclusion of plant populations which are more heterogeneous, thus taking into account the interests of local communities. This may prove to be an incentive for breeders to seek out less researched and more genetically diverse germplasm.

Disclosure of source & prior informed consent: Under the Indian PVP law (also known as PVPFR- Plant variety protection and farmers' rights) applicants must include complete passport data relating to the source of the genetic material and information relating to the contribution of farmers, villages or communities in breeding of the variety. They must also make a declaration that the genetic or parental material was obtained through lawful means. It is important to point out⁴² that while such provisions in domestic laws will not prevent extraction of genetic resources to extraterritorial locations, it could restrict deceptive acts domestically.⁴³ Moreover, if all countries follow suit in adopting a disclosure requirement, it may become a norm and easier to adopt into international regimes⁴⁴. Further for this provision to have the ability to combat biopiracy at an international level there would be a need for a uniform standard of novelty and prior art⁴⁵. Though not a 'criteria' in the strict sense of the term, 'compulsory requirement' of disclosure of source and prior informed consent may be construed as such.

d. Options for exceptions to eligibility for protection

Exceptions for eligibility indicate that under 'such' circumstances, the plant variety shall be excluded from protection. The burden of proof must fall on the applicant to establish that his application does not fall under the exceptions list. For example, the plant variety shall not be granted protection under the following circumstances⁴⁶ (these provisions are inclusive and additional ones can be added):

- 42. Graham Dutfield, Intellectual Property Rights, Trade and Biodiversity, 2000.
- 43. Robinson, D. (2007) Ibid.
- 44. See section 8 of this paper NOTE on TRIPS review.
- 45. See Francis Mangneni, Technical Issues on Protecting Plant Varieties by Effective sui generis systems, South Center/CIE, 2000. Also see Savita M Narasimhan Prior Art: Post TRIPS, Background paper for UNDP Asia- Pacific HDR Trade on Human Terms, 2006.
- 46. Some of these adopted from the Malaysian PVP law and the AU Model Law.

^{39.} See L R Helfer, Intellectual Property Rights in Plant Varieties: International Regimes and Policy Options for National Governments (2004).

^{40.} See Helfer, ibid.

^{41.} See analysis of 'identifiability' in Achim Seiler, Sui Generis Systems: Obligations and Options for Developing countries, Biotechnology and Development Monitor, No.34 p.2-5. Also see Carlos Correa, Options for the Implementation of Farmers' Rights over Plant genetic Resources (2000), South Centre Working Paper No.8, Geneva; Also see Leisken and Flitner ibid.

- i. which may affect public order or morality; or
- ii. where there is reasonable ground to believe that the cultivation, reproduction or any other use of that plant variety may produce a negative impact on the environment; or
- iii. where it is potentially harmful to the environment, ecology, health and welfare of the public.
- iv. In addition to all of these exceptions, a PVP law may also provide for explicit exceptions in case of varieties developed under employment contracts, national public research institutions and/or non governmental organizations.

6.2: OPTIONS FOR GRANT OF RIGHTS AND THEIR ENFORCEMENT

Generally, the grant of rights with respect to intellectual property rights refers to the exclusive nature of rights awarded to the PVP holder. However, as discussed earlier, domestic/extant varieties⁴⁷ that include farmers' varieties that have been cultivated by communities are not generally considered to be compatible with 'exclusive' protection. This is due to the difficulties in enforcing such protection since the right would have to be equitably distributed, and that farmers would also be at a disadvantage if expansive exclusivity is granted to these varieties with impacts on existing practices and livelihoods.

Where plant varieties have been distinguished into two main types, 'new' varieties and 'domestic/extant' varieties, it is recommended that while 'new' varieties may be granted exclusive rights, albeit with sufficient amount of limitations and safeguards; domestic/farmers'/local varieties be granted rights that are based upon separate approaches to those of established intellectual property rights systems (exclusive monopolies).

a. Exclusive rights approaches:

This is where the PVP holder may be awarded certain exclusive rights with respect to plant varieties which have satisfied the various criteria of protection. For instance, the rights awarded would allow the right holder to prevent third parties from commercial production, sale or distribution, offer, import or possession of the plant variety with the purpose of cultivating the propagation materials of the protected plant. This approach may be used only for 'new^{48'} plant varieties, and there should be appropriate exceptions and limitations (discussed below). The type and number of exclusive rights may also be limited⁴⁹.

The Indian PVP law confers 'exclusive rights' over extant and farmers varieties, subject to a range of conditions. The approach is to allow equal treatment and allocation of rights to each kind of plant variety-new or extant and to all types of plant breeder: small-scale to advanced. The Indian law states that farmers who have bred or developed a 'new' variety shall be entitled to plant breeders' rights in the same manner as breeders⁵⁰.

This provision is a significant departure from the way farmers and 'indigenous and local' communities are recognized in the International Undertaking on Plant Genetic Resources (IUPGR) and Convention of Biodiversity (CBD). These agreements recognize farmer innovation within the ambit of the contribution made through their innovations to enhance genetic biodiversity. The Indian law is substantially different from either of these agreements, in that it recognizes the plant breeding efforts of farmers in the same manner as those of breeders engaged in formal research, independent of any program (such as *in situ* conservation) to conserve plant resources.

- 47. See Footnotes 28, 31, 32 for understandings of 'domestic', 'extant' and 'wild' varieties.
- 48. See footnotes 29 and 30 for definitions of 'new' variety.
- 49. Limited exclusive rights as envisaged by UPOV 1978 Act may provide a good base for national laws to apply towards exclusive rights for new varieties; for reasons already analyzed, a PVP law may want to avoid expanding on these exclusive rights, especially those envisaged in UPOV'91.
- 50. Shaila Seshia, Plant Variety Protection and Farmer's rights in India: Law Making and the Cultivation of varietal control.

The exclusive rights approach has faced some criticisms, namely regarding the practicality of DUS requirements for farmers' varieties⁵¹, and the argument⁵² that property rights on extant varieties could ironically cause an 'anticommons tragedy' whereby too many parties independently possess the right to exclude others from utilizing the resource. This could lead to disputes among farmers with counter-claims on the same variety by other farmers⁵³. The Indian law does accord rights to communities to receive compensation if the community is found to have made a significant contribution to the evolution of the protected variety.

To combat this first criticism, the Malaysian PVP law provides protection for plant varieties that have been bred, discovered or developed by a farmer, local community or indigenous people as long as the plant variety is new, distinct and identifiable.

On enforcement and implementation⁵⁴, the Indian PVP law establishes the PVP authority under the central government which consists of a chairperson and fifteen members (from various departments) which oversee the general administration of farmers' varieties and a separate registry for management of new varieties. The authority recently established a Task Force for the development of guidelines and formulation of benefit sharing.

The Indian PVPFR rules and regulations established various committees including the Extant Variety Recommendation committee to determine DUS criteria for different species and varieties. Application forms include detailed provisions and requirements regarding geographical source, origin and details of farmer, village, community, institution and/or organization. While these details may be burdensome, they could assist in reducing disputes and misappropriations of plant varieties in the long term. The form also requires information regarding recognition and benefit sharing arrangements with communities where these groups have conserved the genetic resource that has contributed towards development of the variety seeking protection.

The Malaysian PVP law requires an application to specify the method by which the variety was developed, documents and information relating to the characteristics of the plant variety which distinguish the plant variety from others, including:

- information relating to the source of the genetic material or the immediate parental lines of the plant variety;
- documents relating to the compliance with any law regulating access to genetic or biological resources;
- documents relating to the compliance with any law regulating activities involving genetically modified organisms in cases where the development of the plant variety involves genetic modification; and
- prior informed consent in cases where the plant variety was developed from traditional varieties.

Pre-grant opposition procedures are also available under the Malaysian PVP law and grounds for opposing are the same as for exclusion of registration. Under the Malaysian law, a Plant Varieties Board is set up to approve registration with around 11 members on the Board which includes various representatives from the Agricultural, Trade, Science and Technology Ministries. An important safeguard adopted by the Malaysian law, is that

^{51.} Seshia, ibid. points out in FN8- the extent of which this provision will be meaningful in practice is however, open to debate. To obtain protection farmers varieties must still conform to UPOV criteria of DUS. Given that breeding efforts of farmers typically occur in situ, and that farmers (unlike breeders in formal programs) cannot entirely control the agro-ecological conditions in which varieties are bred, it is questionable to what extent varieties claimed by farmers will meet DUS criteria.

^{52.} Ramanna A & Smale M, Rights and Access to Plant Genetic Resources Under India's New Law, Development Policy Review, 2004.

^{53.} Shalini Bhutani, Seed laws need resowing available at http://www.thehindubusinessline.com/2007/02/06/stories/2007020600760900.htm

^{54.} The Indian Ministry of Agriculture passed the PVPFR Regulations in December 2006, http://plantauthority.gov.in. Also see Robinsin ibid. and A. Ravishankar and othrs, NCAP Policy Brief 11, available at www.grain.org. The details from the Malaysian PVP law presented here are adapted from a background note by Chee Yoke Ling, Third World Network.

on grant of right, the applicant shall deposit samples of the seed or any other propagating material of the plant variety in the quantity specified by the Board and the holder should ensure that the registered plant variety is available in reasonable quantities at reasonable price as may be determined by the Board. These are safeguards to protect Malaysia's genetic resources.

b. Liability rules and compensation approaches⁵⁵

A liability rules/rights approach entails a regulatory system that allows "users" to access materials without necessarily gaining prior permission, provided that they provide some compensation to those that are the "providers" of, in this case, a plant variety that has been developed or improved in some way⁵⁶. It is essentially a "use now, pay later" approach suggested for particularly incremental "sub-patentable" innovation. The liability rules approach is envisioned as being particularly useful where the know-how or innovation is already in wide circulation.

The benefits of a liability regime approach include the recognition of traditional knowledge, innovations and development of plant varieties in cases where it is considered to be in the public domain. The compensation paid could be disseminated through funds operated by a government agency or by private organisations. This approach may be criticised for essentially commodifying knowledge that may be linked to customary norms, ritual and local beliefs. In other cases, local communities may feel a sense of distrust over the distribution of compensation funds that are administered by the government or private bodies. Last, local people may want to control access to their knowledge and innovations, particularly where it is not widely distributed. In this sense a "use now, pay later" approach could be inappropriate given that the "public domain" is a concept that is relatively alien to many indigenous and local peoples. In these cases, prior informed consent and respect of customary protocols may be the preferred outcomes for indigenous and local communities.

The Thai Plant Varieties Protection Act (PVP Act, 1999) provides different kinds of protection for general domestic and wild varieties, as well as local plant varieties. It was an objective of those that developed the law that all plant varieties within Thailand are subject to state sovereignty, and can be protected under one of the specific categories (new or local varieties) or under one of the general categories (domestic or wild varieties). Rather than attempting to formalise exclusive protection for all varieties, Thailand has sought to provide other forms of incentives to breeders of domestic and farmers' varieties (i.e. the general domestic and wild variety components of the law are closer to a liability regime than a property rights regime).

For general domestic and wild varieties, the Thai PVP Act (Ch.5) essentially details access and benefit sharing rules but does not allocate exclusive protection like those available in the Indian PVPFR Act. Therefore it resembles a liability rights approach with some exceptions: a range of stipulations must be made, including the intentions of those seeking access with regards to IP rights. Government officials have noted that local farmers are exempt from Section 52 thus allowing the continued and free use of the variety by farmers, and seeking to provide them with benefits via a PVP Fund if the germplasm is commercialized. Currently the law requires permission to be granted by government officials for collection, use, development and research for *commercial interest* (see Box 3), but countries who utilise this sort of approach could consider extending it to include the consent of farmer groups.⁵⁷

CHAPTER 6

^{55.} Analysis presented under this approach has been reproduced from a background paper presented by Dr. Daniel Robinson. Large portions of this background paper were subsequently published in the 2008 article "Sui generis plant variety protection systems: liability rules and non-UPOV systems of protection" Journal of Intellectual Property Law & Practice.3(10): 659-665.

^{56.} J. H. Reichman Of green tulips and legal kudzu: Repackaging rights in subpatentable innovation, Vanderbuilt Law Review 53(6); Graham Dutfield, Protecting Traditional Knowledge: Pathways to the future, ICTSD, Geneva, 2006.

^{57.} Box 3 detail based on a translation of the Thai PVP Act (1999), see D. Robinson (2008), ibid.

The Thai PVP Act does give more specific and exclusive protection rights for new varieties (similar to UPOV 1978 rules) and registered local community varieties that only exist in a relatively small geographic area (Ch.4). For the local community protections, the community would then receive exclusive rights to conserve, use, research, sell, and commercialize their local variety if so desired, in a similar manner to a new plant variety right.

BOX 3 Section 52 of the Thailand PVP Act

A person who collects, procures or gathers general domestic plant varieties, wild plant varieties or any part of such plant varieties for the purposes of variety development, education, experiment or research for commercial interest shall obtain permission from the competent official and make a profit-sharing agreement under which the income accruing therefrom shall be remitted to the Plant Varieties Protection Fund in accordance with the rules, procedure and conditions prescribed in the Ministerial Regulation.

The profit-sharing agreement shall at least have the following particulars:

- 1. the purposes of the collection and gathering of the plant variety;
- 2. the amount or quantity of samples of the intended plant variety;
- 3. the obligations of the person to whom permission is granted;
- 4. the stipulation as to intellectual property rights in the products which result from the development, study, experiment or research of or into the plant variety and which are derived from the use of the plant variety under the agreement;
- 5. the stipulation as to the amount or rate of, or the term for, the profit-sharing under the profit-sharing agreement in respect of products derived from the use of the plant variety thereunder;
- 6. the term of the agreement;
- 7. the revocation of the agreement;
- 8. the stipulation as to the dispute settlement procedure;
- 9. other items of particulars as prescribed in the Ministerial Regulation.

The Act indicates that those seeking to conduct a study, experiment or research on a general domestic plant variety or a wild plant variety or any part thereof for a non-commercial purpose shall comply with the Regulation prescribed by the Commission (S53). In other words, the contract and profit sharing arrangement is required only when activities are conducted for commercial interests, and non-commercial activities only have to comply with the Regulations. However, these detailed PVP Regulations have not yet been fully developed and passed through the Council of State of Thailand.

The Act establishes a PVP Fund which accrues income from the collection, use, research or commercialisation of general domestic or wild varieties, registration fees, and other sources (Ch. 6). The Fund is intended to be used to assist in the conservation and development of domestic and wild relatives of plant varieties by communities, as well as to cover other administrative expenses

On enforcement and implementation, whilst New Plant Variety Protection Regulations have been developed by the Thai Ministry of Agriculture, regulations on general domestic, wild and local plant varieties have been held up by a number of definitional issues and due to conflicting agendas over the scope of these protections. Plant Variety Protection Division officials of the Thai Department of Agriculture have blamed the delays on concerns over the definition of "general domestic plant varieties" for the delay. The PVP Act (S.3) uses the definition:

"general domestic plant variety" means a plant variety originating or existing in the country and commonly exploited and shall include a plant variety which is not a new plant variety, a local domestic plant variety or a wild plant variety" The term "existing" is most contentious, with departmental officials debating the merits of allowing protection for varieties that "exist" in the country (i.e. that may have been introduced in the past). Other organisations, academics and NGOs have been blaming government stalling tactics on the delays suggesting favouritism towards industry through the passing of the PVP Regulations for new varieties shortly after the Act was passed.

While it may take some time for the government of Thailand to establish implementation measures regarding rules and regulations for domestic varieties, liability rules compensation approaches based on access and benefit sharing systems must be considered while establishing a sui generis PVP law. There are several national benefit-sharing systems currently under development implementing liability rules as well as regulatory controls such as prior informed consent mechanisms and the respect of customary protocols or laws⁵⁸.

6.3: OPTIONS FOR LIMITATIONS AND EXCEPTIONS TO RIGHTS 59

The national PVP law must set aside conditions under which rights over plant varieties cannot be exercised and/or situations under which protection granted shall be receded.

In case of limitations to rights, the rights have already been granted with some conditions. In other words, a third party can commit all the 'exclusive' rights without the authorization of the rights owner under such circumstances. Examples of some such conditions/cases under which the rights granted will not apply are as follows:

a. Private, non commercial exploitation: any act for personal benefit with no commercial purposes in cases of 'new' varieties, therefore permitting subsistence farmers to use seeds and other propagating material for their own consumption.

Notwithstanding the existence of breeders' rights, any person or farmers' community may sell plants or propagating material of that variety as food or for another use that does not involve the growing of the plants or the propagation of that variety (from the AU Model).

- b. Any act to study, discover, experiment or research to improve, develop or innovate on a new plant variety or any act for other scientific pursuit.
- c. Innocent infringement: infringement by a farmer who at the time of such infringement was not aware of the existence of such a right.
- d. Compulsory licensing and restriction of rights: Where the government considers it necessary, in the public interest, the rights in respect of a 'new variety' shall be subject to conditions restricting the realization of those rights (adapted from the AU Model law), including:
 - i. anti-competitive practices;
 - ii. where food security or nutritional or health needs are adversely affected;
 - iii. where a high proportion of the plant variety offered for sale is imported;
 - iv. where the requirements of the farming community for propagating material of a particular variety are not met;
 - v. where it is considered to promote public interest for socio-economic reasons and for developing indigenous and other technologies;
 - vi. any other reason that the Government deems necessary in the public interest, in situations of emergency or to alleviate poverty.

^{58.} One of the ways to develop a system for farmers and domestic varieties with ABS rules is to establish these systems in related laws such as biodiversity and communities laws and then harmonize the national PVP law accordingly. In other words, award protection for 'new' varieties under the national PVP law and create liability rules and compensation mechanisms in related laws while requiring PIC and proof of ABS for new varieties under the national PVP law. For an overview of various national approaches to regulation of biological resources see Robinson, D. (2008) ibid.

^{59.} Most of the options presented here are adopted from the AU Model law, the Bangladesh Bill and in some cases the Thailand PVP Act.

e. Implementation of compulsory licenses⁶⁰: In any of the above cases the government can issue a compulsory license or government use license to undertake production, distribution and sale of the seed or other propagating material of that variety. Additionally, after the expiry of three years from date of issue of the certificate of registration, any person can make an application for grant of a compulsory license on any of, but not limited to, the above grounds.

Where such restrictions are imposed:

- i. a public notice shall be given;
- ii. the grantee shall be given a copy of the instrument setting out the conditions of the restriction;
- iii. The compensation shall be awarded and specified;
- iv. The rights-holder may appeal against the compensation award, however this appeal shall not suspend the execution of the license.

The development and implementation of various approaches towards establishing a sui generis PVP law is still in its infancy in many countries. Though on paper, a balance can be sought by establishing 'exclusive' rights over 'new' varieties and 'nonexclusive' approaches over 'farmers' varieties, there are several implementation and enforcement hurdles in practice. Moreover, in many countries, the control of access to plant varieties and biological resources, as well as subsequent benefit-sharing, has caused controversy between local farmers and/ or communities for cultural as well as economic reasons⁶¹.

There is a tendency for many policy-makers to assume, through "entitlement theory", instrumentalist, utilitarian and moral rights ideological frameworks, that local plant breeders from indigenous communities and developing countries want compensation and/or rights of protection⁶². But these are generally Euro-American, not universal, ideological frameworks that may not be compatible with the varied traditional laws, customary protocols and social norms of the diverse local communities that innovate on and develop plant varieties. In the development of national and international frameworks for plant variety innovations, benefit-sharing and traditional knowledge protection, policy-makers need to be mindful of the diverse perspectives that surround the use and breeding of plants⁶³.

Given the complexities and complications attached to implementation of PVP laws as envisaged under the Indian and/or Thai PVP laws, countries may benefit from adopting a 'less is more' approach wherein plant varieties are granted protection as long as they fit established in-country criteria of 'new', independent of the type of variety. Strict criteria may be adopted wherein options such as strong novelty requirements, constrictive distinctiveness requirements and others, are applied to particular plant varieties. In other words, plant varieties are not distinguished into farmers or extant varieties but are distinguished according to criteria for protection. If a plant variety is sufficiently new, distinctive, stable and uniform *or* identifiable, the variety may be protected given that all other conditions with respect to application procedures are met. The type of protection awarded may then be either through exclusive rights or a compensatory liability system, or a system where certain privileges are granted all of which are subject to a blanket of safeguards.

^{60.} As provided in the AU model law.

^{61.} D. Robinson (2008), ibid. Also see Shalini Bhutani ibid- 'A PVP law, no matter how "good" it appears, only privatises planting material. Traditional farming knowledge needs to be protected from IPRs and not by IPRs'

^{62.} For an example of such assumptions, see Chen, J. (2005) 'There's no such thing as biopiracy... And it's a good thing too.' McGeorge Law Review. 36: 1-35

^{63.} This paragraph has been presented as conclusions in D. Robinson Sui Generis PVP Systems: Liability Rules and Alternate systems of protection; UNDP Background paper, 2008.

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7. FINAL RECOMMENDATIONS: WORKING THROUGH AN 'INCLUSIVE' PROCESS

There is no 'one-size-fits-all' approach towards establishing a balanced sui generis PVP regime, given the range of stakeholders involved. In addition to creating a PVP law, policy-makers should establish and enforce effective seed laws, gene funds where applicable, access and benefit sharing mechanisms (which must include effective contract law and responsible business practices) all of which combined and harmonized with a sui generis PVP law should make for a balanced plant variety rights regime. This would mean taking into consideration the concerns of various stakeholders to create a customized national law. In order to establish a balanced sui generis PVP regime, countries may benefit from what can be described as an 'inclusive' process towards establishing the law instead of adapting an established 'model' law into national PVP regimes.

Suggestions or elements of what that 'inclusive' process entails are detailed below:

- a. Analysis of the objectives of PVP law: The objective of a PVP law must be more than fulfilling obligations under a multilateral trade agreement. The objective must be to establish a PVP regime that includes and supports the interests of all affected groups including farmers, consumers, indigenous communities and local industries, as the obligations that countries sign into should be of benefit to all. For example⁶⁴ in order to help countries devise an appropriate sui generis system, the International Plant Genetic Resources Institute (IPGRI) came up with a list of key questions that policy makers may take into account. They are:
 - What kind of domestic seed industry exists?
 - What kind of public breeding sector exists?
 - What kind of seed supply system is in place?
 - To what extent is farm-saved seed used in the country?
 - What is the current capacity of breeders?
 - What do local breeders want to do in the next 5-10 years?
 - Are external inputs to agriculture low or high?
 - What is the country's biotechnology capacity?
 - What are the goals and realistic expectations of the biotechnology sector?
 - What kinds of strategic alliances will the country want to enter into the next 5-10 years and how involved will other countries be?

In addition to trying to identify the commercial potential of local breeders and biotechnology companies, policy-makers must also consider questions that address food security concerns as well as identifying the level of preparedness of the country's institutions to implement and manage specific elements of the PVP regime.

b. **Involvement of all relevant ministries:** To be able to establish a truly balanced regime, it is important that all relevant ministries of agriculture (for issues of food security and farmers' rights), environment (for issues pertaining to biodiversity), trade (for issues regarding market capacities and relevant intellectual property obligations) and law (for assisting in drafting and understanding of implementation and enforcement procedures) be part of the process. Recommendations from all of these ministries must then also refer to international obligations as administered by the appropriate ministry of foreign affairs (or equivalent).

^{64.} Reproduced from Lightbourne and Dutfield ibid. The list of key questions can be found on the IPGRI (now Biodiversity International) website: www.bioversityinternational.org.

- c. Assessment of obligations under all relevant treaties: Countries must assess all relevant provisions in various treaties they are party to. The PVP legislation must fulfill all obligations equally, including those under the CBD⁶⁵, FAO⁶⁶ and other bilateral and regional arrangements. This is especially relevant for establishing corresponding rights for farmers' varieties and creating national ABS systems⁶⁷. Policy-makers must also take into consideration other regional and bilateral agreements and whether negotiations undertaken in those agreements have resulted in reduced flexibilities⁶⁸.
- d. Interface with seed laws: Intellectual property protection and plant breeders' rights shall lead to significant changes in the areas of both plant breeding as well as seed production. It is therefore essential for any PVP law to be established keeping this in mind. Implementation of a PVP law must be harmonized with procedures set by existing national seed laws and vice versa. Importantly, the objectives behind the establishment of both laws must be the same.
- e. **Establishing a network of affected groups:** Governments should establish and/or engage a national network of affected groups such as farmers unions, non-governmental organizations that work in relevant areas, indigenous community groups, and others. This is to facilitate their involvement in the process in various ways such as eliciting viewpoints, commissioning relevant studies, providing presentations and consultations in the drafting of the PVP law and in turn providing assistance in bringing awareness of the policy implications to all relevant grass-roots stakeholders.

- 65. See Helfer (2004)- The CBD contains numerous provisions relating to IPRs. In particular Article 16 recognizes that IPRs 'may have an influence on the implementation' of the CBD and obliges member states to cooperate in order to ensure that IPRs are 'supportive of and do not run counter to' the treaty's objective. Over time, the biodiversity regime's approach to Intellectual property protection has evolved beyond the text of the CBD. In fact, in April 2002, it adopted the 'Bonn Guidelines on the Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of their Utilization'- among the recommendations the most important one encourages applicants for IPRs such as patents or plant breeders rights to disclose the country of origin of the genetic resources or the traditional knowledge upon which those IPRs are based. It is this aspect of CBD that has been pushed by developing country members at TRIPS review.
- 66. Also see Helfer (2004) ibid- The International Treaty on Plant Genetic resources for Food and Agriculture (ITPGR) in force since 2004, 57 governments have ratified the ITPGRFA administered by FAO. The treaty's principle aim is to facilitate the exchange of seeds and other germplasm to be used by research, breeding and crop development. It promotes this exchange by establishing a multilateral system to which member states and their nationals will be granted 'facilitated access'. In essence, the multilateral system is a communal seed treasury composed of 35 food and 29 feed crops now held by governments – covers ex situ in national seed banks and ex situ collections in gene banks of the International Agricultural Research Centers of CGIAR. The recipient cannot claim intellectual property rights that may limit the facilitated access to the materials or their components. While there is some debate on what this means in terms of the inconsistencies with ABS and IPR, the expansive interpretation is that this provision permits 'breeders to take exchanged germplasm, extract commercial genes, insert them into other plant varieties, and claim protection either on the new variety or on the extracted genes as adapted to the new varieties. According to this, the original plant material, including its genetic components, would remain within the multilateral system free for others to use and exploit.
- 67. In 2002, The World Summit on Sustainable Development in its Plan of Implementation called for action to negotiate within the framework of CBD an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of utilization of genetic resources. Work on the international regime was taken pursuant to the 7th meeting of the Conference of Parties (COP) to the CBD in 2004. There has been further progress and a decision to finalize the regime by 2010.
- 68. This aspect is examined in more detail in the next section/chapter. In fact, some of the policy options discussed in the strategic approach in the final part of the chapter would also apply here.

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8. NOTE ON REVIEW OF TRIPS ARTICLE 27.3 (CBD-TRIPS ALIGNMENT)

he TRIPS Agreement requires a review of Article 27.3(b) which deals with patentability or non-patentability of plant and animal inventions, and the protection of plant varieties. Paragraph 19 of the 2001 Doha Declaration has broadened the discussion⁶⁹. It indicates that the TRIPS Council should also look at the relationship between the TRIPS Agreement and the UN CBD, the protection of traditional knowledge and folklore and other relevant new developments that Member governments raise in the review of the TRIPS Agreement. It adds that the TRIPS Council's work on these topics is to be guided by the TRIPS Agreement's objectives (Article 7) and principles (Article 8), and must take development issues fully into account.

The relationship between TRIPS and CBD (The Convention on Biological Diversity) has been subject to heated discussions and calls for requirements to disclose the origin of genetic resources in patent applications figured high at the Hong Kong WTO Ministerial (December 2005). At the TRIPS Council Meeting in October 2007, member countries continued to be divided on the biodiversity issue, even though 32 LDC members of the WTO announced support for the biodiversity-related TRIPS proposed amendment⁷⁰. While most developing countries proposed 'disclosure' requirements as an obligation under TRIPS, developed nations largely wanted these requirements to stay outside the purview of TRIPS with Switzerland proposing the WIPO Patent Cooperation Treaty, the EU proposing enforcement issues 'outside patent law' and the US proposing use of national legislation, including contracts rather than a disclosure obligation.

The disagreement over TRIPS issues has continued into the recent Mini-Ministerial talks (July 2008)⁷¹. The TRIPS council did announce further support for the proposed amendment to the TRIPS Agreement that would require disclosure of origin on genetic resources and traditional knowledge. With formal support from the Dominican Republic and the African, Caribbean and Pacific (ACP) countries, the total number of amendment supporters totals nearly 80 members out of the total WTO membership of 15272.

As far as TRIPS is concerned, the result of the Mini-Ministerial leaves matters more or less at the state they entered⁷³. While on one hand, an increasing number of developing countries support the amendment, developed countries have showed few or no concessions on their part. The trade-related-IP agendas of several of the most industrially advanced nations (the US, Japan and EU) have been re-routed into bilateral and regional trade negotiations and agreements, due to the perception of slow progress in multilateral negotiations. By entering into these bilateral and regional agreements, developing nations are giving away important flexibilities available under TRIPS that will not only impact upon their development objectives but also undermine the hard work and support they have garnered at the multilateral level.

^{69.} Under the reviews Article 27.3(b) or the whole of the TRIPS Agreement under Article 71.1- see http://www.wto.org/english/tratop_e/trips_e/art27_3b_ background_e.htm.

^{70.} See http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm for proposals and relevant documents circulated during the ministerial process.

^{71.} Differences over TRIPS were not responsible for the infamous 'collapse' of the recent round.

^{72.} Kaitlin Mara and William New TRIPS Council: Half of WTO membership Backs Biodiversity Amendment; available at http://www.ip-watch.org/weblog/index. php?p=961

^{73.} Fredrick M, Abbot, Post-mortem for the Geneva Mini-Ministerial: Where does TRIPS go from here? Information Note Number 7, August 2008, ICTSD. The Note presents the current negotiating status and possible future negotiating strategy on the two issues under TRIPS review- Disclosure requirements for patents and extended GIs protection.

UNDERSTANDING TRIPS-PLUS PROVISIONS IN RELATION TO PLANT VARIETY PROTECTION

UNDERSTANDING TRIPS-PLUS PROVISIONS IN RELATION TO PLANT VARIETY PROTECTION⁷⁴

As countries attempt to understand their obligations under TRIPS with respect to plant variety rights, there are asimultaneous pressures to sign away the available flexibilities in bilateral and regional trade agreements.

The TRIPS Agreement provides the flexibility to member countries to design sui generis laws for protecting plant varieties. Although, intellectual property provisions of a sui generis system may have to comply with some minimum requirements, this paper has highlighted that countries have policy space and a range of options available to shape sui generis systems in compliance with TRIPS stipulations as well as their own developmental and ecological demands.

This policy space is threatened by the onslaught of bilateral and regional trade agreements that are negotiated outside the WTO. These free trade agreements (FTAs), typically between the US, EU, Japan and developing countries often include provisions that go beyond TRIPS (TRIPS–plus). Increasingly, countries are being pressured to adopt patent laws or UPOV 1991 (implications of which have already been discussed earlier) diluting the flexibility under TRIPS which provides an alternative for countries to develop a tailored protection system for plant variety right⁷⁵.

The TRIPS-plus provisions outlined in this chapter have particular implications for human development and policy space to protect plant varieties in developing countries. TRIPS-plus standards are continually pushed by the most industrially advanced countries for protections in new areas, such as genetically modified organisms, agri-tech related microchips and nanotechnologies, digitized genetic information and bioresearch processes. Yet biodiversity-rich developing countries too often end up transferring royalty streams to R&D-equipped developed countries/foreign research institutes on these patented technologies. Monopoly power over how these technologies are shared creates impeded access for countries which cannot afford the high mark-up prices, meaning that technology transfer is inhibited rather than supported.

TRIPS-plus provisions feature in free trade agreements, bilateral investment treaties, scientific and research cooperation agreements, development or technical assistance agreements and multifaceted 'partnership' agreements. Of these bilateral/regional arrangements, the ones that are likely to have the greatest impacts are free trade agreements that have stringent dispute settlement provisions. Non-compliance with the commitments taken under these FTAs can lead to retaliations that authorize increases in tariffs on goods. A further area of concern for developing countries is that some of the FTAs or economic cooperation agreements include an investment protection agreement with intellectual property being considered as one of the forms of investment. TRIPS-plus provisions with regard to plant protection as present in some of these agreements are analyzed below.

^{74.} This part of the paper may be treated as a stand alone chapter and has benefited greatly from inputs and discussions with Sanya Reid Smith, Third World Network and a background paper by Bryn Gay, APTII, UNDP Regional Center Colombo.

^{75.} Of more than 130 or so FTAs being negotiated (in various stages- under preparation, in force, talks underway, planned, signed etc); 60-80 or so are signed or in force and all of them contain TRIPS-plus provisions with respect to plant varieties. For instance almost all call for the developing nation to join UPOV 1991 or call for recognition of patent protection for plant protection and biotechnological inventions. Source: www.grain.org; www.bilaterals.org.

The following table presents TRIPS-plus provisions pertaining to plant variety protection (present in the Intellectual Property chapters of the agreements⁷⁶):

TRIPS- PLUS PROVISIONS	SOME EXAMPLES OF FTAS AND EPAS	THE GENERAL WORDING OF THE PROVISION IN THE AGREEMENT
PATENTS ON PLANTS TRIPS allows members to exclude plants (and animals) from patentability. (Patents on plants automati- cally bring in other related TRIPS-plus provisions such as data exclusivity in case of agrochemicals, restrictions on compulsory licensing and limitations on parallel importations- for implications see box)	US - Republic of Korea; US - Sri Lanka; US - Nicaragua; Cotonou; CAFTA; NOTE A recently released US- GAO report states that with respect to two FTAs negotiated with Colombia and Peru, 'patents on plants and animals' is negotiable;	 'country name' must provide patents on plants and animals; '' may not exclude plants or animals from patent law No exclusions for plants and animals from patent law permitted '' must make all reasonable efforts to provide patents on plants, once it does, cannot reverse its policy' (This provision usually follows a provision that requires the country to join UPOV).
Accession to UPOV: (UPOV 1991 only) TRIPS does not make any reference to UPOV (Acts of 1978 or 1991), instead allows countries to adopt customized systems for plant variety protection.	EFTA-Jordan; EU-Algeria; EU-Egypt Japan-Indonesia; EU-Carib- bean; US-Panama; US-Colom- bia; US-Peru; NAFTA	'' must join UPOV within five years (some EU FTAs state the year, in case of US FTAs, upon the time the FTA enters into force)of the agreement's entry into force.
HIGHEST STANDARDS Many texts call for implemen- tation of IPRs with the highest international standards. These are not defined and usually the trade benefits awarded to the developing country are gauged on the extent to which the standards are 'greater than' what TRIPS provides.	EU-South Africa; EU-Syria; African Growth and Oppor- tunities Act (w/US); EU-Sri Lanka Cooperation Agree- ment; Caribbean Basin Trade Partnership Act (w/US)	 '' must implement the highest international standards of IPR protection 'and undertake to go beyond TRIPS standards of IPR protection ''shall follow highest standards including, not limited to, the TRIPS Agreement.

^{76.} The FTAs and economic partnership agreements (EPAs) in this chapter include agreements at various stages of negotiations and there may have been some changes since the first drafts or discussions. For e.g. The Cotonou agreement does not require patents on plants and the Pacific opted out of sub-stantive IP obligations for the EPA. For a detailed analysis of TRIPS plus provisions in EPAs, see Sisule F. Musungu at http://www.iprsonline.org/ictsd/docs/Musungu%20Pacific%20EPA.pdf

BOX 4 Patent Related TRIPS-Plus Demands

Restricting flexibilities

Often countries sign off flexibilities, (US-Sri Lanka BTA of 1991, which limits use of compulsory licensing, and TIFAs with Afghanistan, Indonesia and Mongolia) such as using compulsory licenses or permitting parallel importing, in order to solidify an investment agreement or BTA with IP chapters. There is the possibility that the use of compulsory licenses (if used in the form of a competition regulation) can be perceived as indirectly expropriating an investment. Signatories are obliged to ensure that the use of the compulsory license is TRIPS-consistent and pays remuneration as compensation to the patent-holder. However, if compulsory licenses (and terms for remuneration) are not clearly defined in the investment agreement, users may find difficulties at investment tribunals, in terms of how this exception to exclusive rights is viewed. Countries that sign investment agreements with IP chapters do have the ability to negotiate for full inclusion of rights afforded to them under TRIPS, as well as for the inclusion of a general exception clause, which refer to exceptions in cases that protect the public interest, human health and life, and potentially the natural environment.

Data Exclusivity: (Note that data exclusivity does not directly relate to plant rights, however it has impacts over agrichemicals and thus indirect impact over farmers' livelihoods). The extension of patent duration (over 20 years) under FTAs is another feature that goes beyond what is required under TRIPS. Along with extended patent life TRIPS-plus agreements generally include longer protection periods for data of the protected innovation. This 'data exclusivity' means monopoly over the data and test trials that led to the successful innovation; such protection excludes other researchers from creating generic versions, e.g. generics of agricultural pesticides. Without generic competition agricultural input costs remain high, leaving little choice for impoverished farmers to lift themselves from subsistence levels. Abiding by data exclusivity provisions could create unfair competition. Smith (forthcoming) suggests that FTAs could further reduce or eliminate tariffs on certain imported technologies and facilitate an influx of monopolistically priced seeds and other farming inputs. To enable fair competition countries' *sui generis* systems could omit data exclusivity provisions and opt for policies that would enable the 'reverse engineering' of technologies, or the ability to produce, using a different method, a similar technology with same function. Furthermore, a research exception (as backed by TRIPS Article 30) would allow researchers to continue research on a patented innovation. Over a dozen countries in the Asia-Pacific include some form of an experimental exception in which patent rights do not extend over acts related to experimental purposes These actions would encompass principles of accessing data and sharing knowledge.

For more detailed understanding of these issues See Correa, Carlos (2007). "Human Development Implications of IPR Protection and TRIPS-plus provisions in Asia-Pacific," Paper presented at UNDP RCC/UNDP Malaysia/Third World Network workshop, *Doha and Beyond: Incorporating Human Development into Trade Negotiations*, Penang, 17-18 December 2007 also see Smith FN5.

In addition to the Intellectual Property chapter in FTAs, countries must consider their commitments under Investment chapters of FTAs as well as bilateral investment treaties.

INVESTMENT⁷⁷ TREATIES

By including TRIPS-plus requirements in investment treaties the stronger protection is more far-reaching and could reduce maneuvering room for countries to make use of flexibilities granted under TRIPS. On one hand, proponents of TRIPS-plus regulations to be included in bilateral investment treaties or investment chapters assert that it will increase foreign direct investment (FDI) and technology transfer to the signatories. In some ways, this investment could be targeted to developing plant and TMK (traditional medicinal knowledge)-related industries⁷⁸, which could encourage the growth of small and medium enterprises (SMEs) and gain market access for small-scale producers. The rights of the knowledge holders would need to be clearly defined; for instance, if investment and R&D goes towards developing medicinal properties of a plant, the original purveyors of this knowledge would need to have opportunities to fully participate in the R&D and gain from the potential derived benefits (e.g. in the form of IPRs).

On the other hand, there is the likelihood that the investment treaties do not translate into affordable technology transfer for developing countries⁷⁹. Developing countries rely on importing the monopoly-priced technologies, which could further prevent the building of capacity for innovation and new technologies. FDI does not rely solely on high levels of IP protection; rather concomitant macroeconomic conditions and human capital are said to be determinants for driving FDI (UN 1993, as cited in Smith forthcoming). Developing countries may very well find themselves indebted in cases whereby investors deem that their IPRs have been infringed (e.g. facilitating seed sharing, unauthorized use of GM varieties). These countries, or even individual farmers, may have to pay enormous sums as compensation. There are clear human development implications for countries that continually pay out large sums to, often foreign, patent holders; these payments ('tantamount to nationalization or expropriation' clauses) could detract from state revenue that is crucial for providing essential services. A cut in essential services may have distinct gendered consequences; user fees may increase. As gender norms shape how women and men access these services, increased fees or limited availability of health, water, sanitation, etc services would contribute to a drop in women as consumers⁸⁰. It is important to note that if the investment treaty defines property rights as covered under investments and the country has provided plant variety developers expansive exclusive property rights -sui generis or otherwise - probably all provisions of the investment treaty would apply to such rights unless specific caveats have been made.

Some of the TRIPS-plus provisions that affect plant variety protection as present in investment chapters of trade agreements (and bilateral investment treaties) are analyzed below:

Definition of Investment

The term investment is so broadly defined (*any other tangible and intangible movable and immovable property, and any related property rights*- Chile-US FTA) that it most often includes IPRs, potential IPRs, any other tangible property and contracts etc, so much so that biological materials may be considered 'property' of foreign

^{77.} For other definitions of investment, see Ermias Tekeste Biadgleng (2006). "IP Rights Under Investment Agreements: The TRIPS-plus Implications for Enforcement and Protection of Public Interest," Research Papers 8. Geneva: The South Centre, August.

^{78.} China has developed new varieties of tomatoes, chillies, aubergines, and disease-resistant wheat; further, it exports about 75 percent of its traditional medicinal herbs, amounting in hundreds of billions of RMB as trade revenue.

⁷⁹ See Biadgleng and Smith, Sanya Reid (forthcoming). "Intellectual Property in Free Trade Agreements," Paper presented at UNDP RCC/UNDP Malaysia/Third World Network workshop, Doha and Beyond: Incorporating Human Development into Trade Negotiations, Penang, 17-18 December 2007

^{80.} For example, the government of Tanzania relies on fee-dependent healthcare; after the introduction of the user fees there was a decline in the numbers or women seeking treatment, preferring to send other members of the household instead (Hussein and Mujinja 1997 Impact of User Charges on Government Health Facilities in Tanzania," East African Medical Journal 74(12): 751-7; Nanda, Priya (2006). "I Would Pay, If I Could Pay in Maize: Trade Liberalization, User Fees in Health and Women's Health Seeking in Tanzania," in Grown, Caren, Elissa Braunstein and Anju Malhotra (eds.) Trading Women's Health and Rights? Trade Liberalization and Reproductive Health in Developing Economies. London, New York: Zed Books.

collector who may claim rights over them as investor. This provision often has a non-exhaustive list of possible things that could constitute investments (*investment means every kind of asset ...including...*), often explicitly includes intellectual property rights and this includes new plant varieties (See Japan-Malaysia Economic Partnership Agreement)

Most Favored Nation Status⁸¹ (MFN)

Under MFN, any advantage, favor, privilege or immunity granted to investors/investments from another country must be granted to the party of the agreement. This has critical implications given the broad definition of investment and all it entails. For example, if a developing country has given more favorable treatment in any form to investors/investments from another country, this protection must also be given to the country with whom an FTA/BIT with and MFN provision has been signed. Thus, if it is found that the broad/strong investor protection that has been given to a country has had detrimental effects, this 'mistake' may spread to investors from other countries via the MFN clause. Countries may negotiate the clause to include a list of exceptions to the MFN clause.

The provision is worded something like 'Each party shall accord to investors/investment of another Party treatment no less favorable than that it accords, in like circumstances, to investors/investments of any non-Party.' (See for e.g. Japan-Malaysia EPA, CAFTA, Switzerland-India BIT).

Expropriation

Under most FTAs (See for e.g. Japan-Malaysia EPA, NAFTA, Nicaragua-US BIT) any act that results in reduction of the value of the investment could be considered to be expropriation and require compensation. What can constitute an expropriating measure is also usually not defined. This means, the investor could claim a reduction in value simply by the effects of a judicial case decision or a change in government policy.

The wording of this provision is something like 'No party may directly or indirectly nationalize or expropriate an investment of an investor of another Party in its territory or take a measure tantamount to nationalization or expropriation of such an investment except for a public purpose; on a non-discriminatory basis and on payment of compensation'

The compensation is usually required to 'be equivalent of the fair market value of the expropriated investment immediately before the expropriatory action was taken' and include interest often at a 'commercially reasonable' rate.

Dispute Settlement

Under the multilateral trade system (WTO), a government can use the mechanism only against another Member government. However, under the investment chapter of many FTAs as well as a bilateral investment treaties, investors can sue the host state directly, reducing the 'diplomatic window' available in case of state versus state disputes. The investor can sue the state at an international tribunal whereas the state does not enjoy this privilege. If the government does not comply with the decision, under FTA provisions, the investor's government can apply tariffs on the host country's exports.

The provision can be very detailed (for example in most US FTAs, the provision goes on for 12 pages), but essentially they allow the foreign company to sue⁸² the host country at ICSID or another international tribunal and often set out the procedures that must be allowed. For example, See Japan-Thailand EPA, Morocco-US FTA, US-Cameroon BIT.

^{81.} Though Prima facie, it may appear that the MFN aspect may be no different than one under WTO Agreement, in case of investment however, as explained, the implications are far reaching and more critical.

^{82.} Most patented plant varieties are owned by foreign companies in the North with the access to legal expertise and finances to support lawsuits – which puts developing countries at a massive disadvantage. In this case, developing countries which sign FTAs but which are not WTO or UPOV members to begin with, may sign away flexibilities – thinking that stringent IP protection will lead to increased FDI flows, yet in another light, they may be subject to more litigation if they rely on their bio-resources and practices of seed sharing.

STRATEGIC APPROACHES TOWARDS BILATERAL/REGIONAL TRADE & INVESTMENT NEGOTIATIONS

It is clear that bilateral and regional trade agreements and other arrangements such as bilateral investment treaties diminish flexibilities (which are limited in the first place) contained in WTO and TRIPS. This is usually the result of inequitable and often untransparent, undemocratic and confidential trade negotiations. To combat this, developing countries who wish to be parties to such agreements must equip themselves with a strategic approach towards bilateral and regional trade (and other) agreement negotiations.

- 1. Interministerial Committees: In order to develop a better understanding of the various implications that a trade agreement shall have over agriculture and environment, it is essential that these ministries realize how intellectual property rights affects their portfolios. Interministerial committees can be established with officials from trade, law, agriculture and environment. This committee may be responsible for trade and investment agreement analysis, negotiations and creating awareness of such agreements to the public.
- 2. 'Trade Monitor' units within ministries: In addition to an interministerial committee, the state may also set up 'trade monitor' units within their relevant ministries to better understand implications over local industries, farmers and human development. For example, upon realizing that international trade rules (including intellectual property rights) have a significant impact on public health, the Malaysian Ministry of Health dedicated resources to monitor, consider and provide inputs from a health perspective on the Government's decisions on international trade agreements.
- 3. Stakeholder involvement: Involving all stakeholders is crucial to ensure trade and other bilateral and regional arrangements contain balanced provisions and safeguards vis-à-vis plant variety rights and farmers' rights while maintaining a fair and equitable trading environment. This means more dissemination of information to stakeholders, consultation of groups from various backgrounds to prepare and uphold national positions. Inclusion of various stakeholders would also be helpful in building sound technical, policy and coordination capacity at international negotiations. For safeguarding plant variety rights the stakeholders would include (but not limited to) indigenous peoples associations, environmentalists, agriculturalists, farming bodies, law associations, local businesses, health advocates, grass roots organizations, civil society, academicians and non governmental organizations.
- 4. Alternative Agreements: Trade agreements and investment treaties often have serious implications in case of non compliance. Following an internal needs assessment, a country may choose to look into alternative arrangements that have less serious repercussions. Most often, these may be in form of scientific and research cooperation agreements or development and technical assistance agreements.
- 5. National Experts Commission: The state can set up a national expert commission that sets up a roster of international and national consultants to work with on trade negotiations. It may also set up a strategic substantive and operational procedure for trade negotiations. For example, drafts of the agreement may be reviewed by the commission along with inputs from international experts in the field, and trade negotiators may include national/regional experts in trade negotiations.
- 6. **South-South Cooperation:** There are two types of south-south cooperation: regional coordination and cross regional collaboration. Regional coordination helps to establish better bargaining power, pooling of technical resources to create a sound negotiation bloc and in the case of plant varieties, regional stake-holder associations. Regional coordination (regionalism) is already taking place in several regional free trade agreements, where there have been some successes, for example, the far-reaching intellectual property provisions of the US-SACU FTA have been one reason why the talks broke down. The US is now considering offering SACU a Trade and Investment Cooperation Agreement instead of an FTA. Cross Regional

Collaboration can take place outside the geographical regional realm, where countries with similar socio-economic structures share and benefit from best practice exchange. This type of cooperation may assist in helping countries build better national systems that balance country's trade priorities and national interests while meeting global development goals.

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