THE ROLE OF INTELLECTUAL PROPERTY IN THE DEVELOPMENT OF UNDERUTILISED CROPS

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Abstract

This research is focused upon the availability and suitability of intellectual property protection for developments in underutilized crop species. It has been suggested that intellectual property protection should be a positive tool for addressing food security concerns, by incentivizing innovation and rewarding breeders. Equally, access and benefit sharing mechanisms, which exist to regulate access to genetic material and redistribute the benefits arising from its use, also play a significant role in the development of new crop species. Thus, this research explores the extent to which states are obliged to provide intellectual property protection for plant-based innovations, and whether these are compatible with developments in underutilized crop species. It also considers the overlap between systems of intellectual property protection and access and benefit sharing regimes. This is explored by examining the relevant international norms pertaining to intellectual property protection (the Agreement on Trade Related Aspects of Intellectual Property and the Conventions of the International Union for the Protection of New Varieties of Plants) and the regulation of access to genetic resources (the Convention on Biological Diversity and its Nagoya Protocol, the International Treaty on Plant Genetic Resources for Food and Agriculture). This is developed by exploring how the principles derived from these regimes relate to one another and by drawing upon examples developed in distinct jurisdictions.

The research considers Malaysia not only as a genetically rich state that is reliant upon external inputs to meet national food security, but one that is host to research and development activities involving underutilized crop species. It is focused upon analysing the models of intellectual property protection and access and benefit sharing that have been implemented in Malaysia and evaluating their utility for innovations in underutilized crops by incorporating the perspectives of stakeholders in underutilized crops and comparing the aspects of the Malaysian approach with alternatives. It concludes by analysing whether in this context, intellectual property protection it is likely to be a useful tool for addressing food security concerns.

Abbreviations and Acronyms

ABRBS	Access to Biological Resources and Benefit Sharing Act 2017 (of Malaysia)
ABS	Access and Benefit Sharing
AIPPI	Association Internationale pour la Protection de la Propriété Intellectuelle (International Association for the Protection of Intellectual Property)
APEC	Asia-Pacific Economic Cooperation
ASSINEL	Association Interanationale pour la Protection des Obtentions Vegetales (Association of Plant Breeders for the Protection of Plant Varieties)
BMZ	Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung (Federal Ministry for Economic Cooperation and Development)
CBD	Convention on Biological Diversity
CGIAR	Consultative Group for International Agricultural Research
CIOPORA	Communauté Internationale des Obtenteurs de Plantes Ornamentales et Frutières à Reproduction Asexuée (International Community of Breeders of Asexually Produced Ornamental and Fruit Varieties)
COP	Conference of the Parties
COP-MOP	Conference of the Parties-Meeting of the Parties
DI	Distinct and Identifiable
DSB	Dispute Settlement Body
DSU	Dispute Settlement Understanding
DUS	Distinct, Uniform, Stable
EDV	Essentially Derived Variety
EEC	European Economic Community
EC	European Community
EU	European Union
FAO	Food and Agriculture Organisation
FIS	Fédération Internationale du Commerce des Semences (International Federation of Seed Trade)

GATT	General Agreement on Tariffs and Trades
GFAR	Global Forum for Agricultural Research
GMBSM	Global Multilateral Benefit Sharing Mechanism
IBPGR	International Board of Plant Genetic Resources
ICNP	Intergovernmental Committee for the Nagoya Protocol
ICRISAT	International Crop Research Institute for the Semi-Arid Tropics
IFAD	International Fund for Agricultural Development
IIPA	International Intellectual Property Alliance
IITA	International Institute of Tropical Agriculture
IP	Intellectual Property
IPC	International Planning Committee for Food Sovereignty
IPGRI	International Plant Genetic Resources Institute
IPR	Intellectual Property Rights
IPRA	Indigenous Peoples' Rights Act 1997 (of the Philippines)
IRRI	International Rice Research Institute
ISF	International Seed Federation
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IUPGR	International Undertaking on Plant Genetic Resources
IUCN	International Union for the Conservation of Nature
KATS	Ministry of Land, Water and Natural Resources (of Malaysia)
LMMD	Like Minded Mega Diverse (States)
LM APAC	Like Minded Asia Pacific Countries
MAT	Mutually Agreed Terms
MS	Multilateral System
MOU	Memorandum of Understanding
NCI	National Cancer Institute (of the United States)
NGO	Non-Governmental Organisation
PBR	Plant Breeders’ Rights
PGR	Plant Genetic Resources

PGRFA	Plant Genetic Resources for Food and Agriculture
PIC	Prior Informed Consent
PNVP	Protection of New Varieties of Plants Act (of Malaysia)
PPVFRA	Protection of Plant Varieties and Farmers Rights Act (of India)
PVP	Plant Variety Protection
RAFI	Rural Advancement Foundation International
RFSTE	Research Foundation for Science, Technology and Environment
SBE	Sabah Biodiversity Enactment
SBO	Sarawak Biodiversity Ordinance
SBR	Sarawak Biodiversity Regulations
SBSTTA	Subsidiary Body on Scientific, Technical and Technological Advice
SMTA	Standard Material Transfer Agreement
TK	Traditional Knowledge
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNDRIP	United Nations Declaration on the Rights of Indigenous Peoples
UPOV	Union Internationale pour la protection des obtentions végétales (International Union for the Protection of New Varieties of Plants)
USDA	United States Department of Agriculture
WFP	World Food Programme
WGABS	Ad-Hoc Working Group on Access and Benefit Sharing
WG8J	Working Group on Article 8(j) (traditional knowledge)
WIPO	World Intellectual Property Organisation
WIPO IGC	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
WTO	World Trade Organisation

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Chapter one: Introduction

1.1.1 Background: The challenges of achieving food security

Managing to provide enough nutritious food for continued survival and maintenance of health is the most fundamental challenge to human existence; and historically speaking, one that on a global scale we have consistently fallen short of. The scale of this challenge has only been compounded by an increase of 90% in the global population over the last four decades of approximately 3.3 billion people and is expected to reach 9.1 billion by 2050,[1] the majority of which are expected to be in the developing world.[2] At present, it is estimated that around 795 million people are undernourished globally.[3] Thus, we find ourselves faced with the significant challenge of raising overall food production by 70%, in order to ensure universal food and nutritional security.

The need to address food security concerns has long been recognised by both national governments and supra national organisations. In 1974, in the wake of the large-scale famine in Bangladesh that had taken place over the previous year, and in recognition of previous great famines the United Nations Food and Agriculture Organisation (FAO) held the first World Food Conference in Rome. The 135 states represented adopted the Universal Declaration on the Eradication of Hunger and Malnutrition,[4] which held that:

> 'Every man, woman and child has the inalienable right to be free from hunger and malnutrition in order to develop fully and maintain their physical and mental faculties.'[5]

The Conference recognised that, among other economic, political and environmental factors, the main cause of the famine was a lack of access to sources of food and the affordability of what food was available; thus, in addressing food security

[1] FAO, 'Global Agriculture Towards 2050', available at http://www.fao.org/fileadmin/templates/wsfs/docs/Issues_papers/HLEF2050_Global_Agriculture.pdf (accessed 15th July 2020) at 1
[2] ibid
[3] FAO, IFAD & WFP, *The State of Food Insecurity in the World 2015- Meeting the 2015 International Hunger Targets: Taking Stock of Uneven Progress* (Rome, Food and Agriculture Organisation of the United Nations, 2015) at 8
[4] 16th November 1974, Endorsed by UN General Assembly Resolution 3348 (XXIX) of 17th December 1974
[5] ibid, at 1

concerns, emphasis was to be on food production and supply. The following decades witnessed a dramatic increase in food production, thanks in part to the successful uptake of the technologies made available by the Green Revolution;[6] to the extent to which, food security concerns appeared to fall by the wayside of the global development agenda.[7] Despite this, the numbers of people with adequate access to food supplies and levels of malnutrition failed to improve.

The need to revisit the issue led to the World Food Summit taking place is 1996. The Summit produced the World Declaration on Food Security, which in addition to reaffirming the right to be free of hunger also set out a plan of action to reduce the number of malnourished people in the world by half before 2015. The plan of action included, *inter alia,* a commitment to research into sustainable methods of short and long term food production, with emphasis on improving food security at the national and household level.[8] Nonetheless, improvements in malnutrition levels continued to fall considerably short of the target.[9] The causes have been attributed insufficient access to food, as a result of economic instability and inadequate infrastructure; the loss of harvests to environmental disasters such as drought, flood or major pest outbreak[10] often considered to be a result of climate change and the high cost of commercially developed varieties and their associated inputs, amongst other factors. This suggests that alternative approaches to improved food production and increased access to nutritionally rich food need to be considered. The challenge is not simply to produce enough food, as presently there enough food produced in terms of calorific content to meet the needs of even the current

[6] 'The Green Revolution' refers to the large scale increase in food production that began in the interwar years and rapidly expanded between the 1960s and 1980s. The Revolution was the product of several projects systematically studying crop yields and breeding programmes that resulted in high yield crop varieties (examples include maize in Mexico and rice in Japan, China and Thailand). The uptake of these varieties and farming techniques delivered annual increases in food production; among its successes was the doubling of the global cereal yield between 1960 and 1985. Without the Green Revolution the numbers of hungry people would unquestionably be far greater today. However, the success of these high yield varieties is dependent upon an increased amount of inputs, including fertilizers and pesticides and suitable growing conditions. What is more, the cost associated with purchasing high yield varieties and the various inputs are high. They are also associated with a high environmental cost of cultivation. Consequently, high yield crop varieties are a powerful but limited technology. (see Conway, n11 below, chapter 4 and Conway, n7 below, chapter 3)
[7] Gordon Conway, *One Billion Hungry: Can we feed the World?* (Ithaca NY, Cornell University Press, 2012) at ix
[8] Rome, 1996 at 30
[9] n3 above, at 17
[10] Conway, n7 above, at 97

global population.[11] Rather, it is to engage with an alternative and more accessible means of food production that is adaptable to less than ideal conditions for cultivation.

1.1.2 A brief history of human agriculture and the decline of agrobiodiversity

The emergence of human agriculture approximately 10,000 years ago caused disruption in the natural balance of numerous ecological systems; however due to slow speed of the development and expansion of agriculture, ecological systems were able to adapt and achieve a new equilibrium.[12] During this period, genetic diversity was maintained due to the relatively minimal impact of subsistence agriculture on extant biodiversity and the inclusion of a new portfolio of genetic material from human cultivation and subsequent recombination and development of new varieties. In addition, adaptation to local climate and soil conditions took place so that plants could continue to survive.

In the last five hundred years, the expansion of civilizations led to the development of international trade and the intentional exchange of germplasm. The expansion of agriculture alongside the Industrial Revolution also marks the starting point for the downturn in agrobiodiversity, as higher yielding varieties became more widely cultivated. This process was accelerated by the Green Revolution and the advent of industrial agriculture. The industrialisation of agriculture saw the transformation of the agricultural landscape in many parts of the world from small scale subsistence farming towards commercial farming. The Green Revolution, characterised by the dramatic increase in food production, was reliant upon specifically developed high-yield varieties and intensive technologies, including large-scale irrigation and heavy reliance upon fertilisers and pesticides.[13] As a consequence, many local and regional crop varieties fell out of use. This lead to a rapid decline in agrobiodiversity: of the approximately 1021, crop species that have been cultivated in human history, approximately 7,000 are still in use.[14] It is

[11] Gordon Conway, *The Doubly Green Revolution: Food for all in the 21st century* (London, Penguin Books, 1997) at 1
[12] José Esquinas-Alcázar, 'Protecting crop genetic diversity for food security: political, ethical and technical challenges' (2005) 6 Nature Reviews Genetics 946 at 946-947
[13] Pamela A. Matson, Walter Falcon & Ashley Dean, *Seeds of Sustainability: Lessons from the Birthplace of Green Revolution in Agriculture* (Washington, Island Press, 2012) at 5
[14] Global Forum on Agricultural Research (GFAR), 'The Role of Underutilised plant species in the 21st Century' available at http://www.fao.org/docs/eims/upload/207051/gfar0089.pdf (accessed: 15th July 2020)

estimated that no fewer than 150 crop species are commonly cultivated, with estimates that most people survive on between 12 and 30 crop species. Furthermore, humanity is reliant upon three main crops – rice, maize, and wheat- for up to half of humanities calorific and protein requirements.[15]

The consequence of this is that as a species, we are left vulnerable to food and nutritional insecurity, as widespread homogeneous crop yields are more susceptible to failure as a result of environmental hostility such as pests, drought and poor quality soil. Going forward, we are less able to adapt to climate change, as the loss of agricultural biodiversity equates to a loss of options. What is more, this vulnerability is likely to affect people at the margins the most. On the other hand, the advantages of engaging with the wider agrobiodiversity portfolio are numerous: in addition to their potential for adaptability, denser agrobiodiversity concentrations are better at nutrient cycling and tend to produce higher output per unit land area.[16] It is necessary therefore, to consider alternative, sustainable means of food production, which support agrobiodiversity.

1.1.3 Underutilised crops: An alternative?

In the search for alternative means of food production, underutilised crops are not a new idea. Underutilised and niche crop varieties are essential for the food and nutritional security of up to half of the world's population, and especially that of rural and indigenous communities.[17] The term "underutilised crops" refers to crop species whose potential is not fully realised; this includes indigenous species, local and traditionally cultivated varieties that form part of the wider biodiversity portfolio[18] and may have been neglected for various social or economic reasons.[19][20] These local and farmers' varieties, also known

[15] ibid
[16] Michael Pimbert, *Towards Food Security: Reclaiming Autonomous Food Systems* (London, International Institute for Environment and Development, 2010) at 18
[17] Rosemary J. Coombe, 'The recognition of indigenous peoples' and community traditional knowledge in international law' (2001) 14 St. Thomas Law Review 275 at 277
[18] Stefano Padulosi & Irmgard Hoeschle-Zeledon, 'Underutilized plant species: what are they?' (Liesa, March 2004) at 5
[19] Sean Mayes, 'The potential of underutilised crops to improve security of food production' (2012) 63(3) Journal of Experimental Botany 1075 at 1075
[20] International Plant Genetic Resources Institute (IPGRI), 'Neglected and Underutilised Crop Species: Strategic Action Plan of the International Plant Genetic Resources Institute' (Rome, 2002) at 9-10

as landrace crops or primitive varieties are developed through the selective innovation of farmers over generations; thereby acquiring an equally valuable body of traditional knowledge relating to breeding and cultivation.[21] Thus, it is an umbrella term incorporating a number of ideas.

Underutilised crop species are often situated in diverse farming systems and are cultivated by small scale food producers. The significance of this is enormous, as globally approximately 2.5 billion people live directly from agricultural systems, with smallholder farmers making up 85% of the world's farming population.[22] Many underutilised crop species are nutritionally rich and suited to low input agriculture.[23] They are also often better adapted to local soil and climate conditions, including harsh environments, such as salinification and desertification.[24] Furthermore, many underutilised species are nitrogen fixing in the soil and thus improving the agricultural environment in which they are cultivated and potentially provide opportunities for intercropping with other species. As a result, they are of immense value to local food systems, as they offer a sustainable agricultural model, which in turn benefits long-term food security. Diverse farming practices, including those that in part rely upon traditional agricultural knowledge, traditional farming practices and engage with local exchange practices are increasingly recognised as being essential to the food security of subsistence farmers and rural communities.[25] Furthermore, the role of many underutilised crops is not simply limited to agriculture: many also possess social and cultural significance.

Until recently, underutilised crop varieties and associated traditional knowledge have been largely ignored by commerce and science; however, they have the potential to be commodity crops and provide a valuable resource for the improvement of existing commercial plant varieties.[26] The FAO suggests that the exploitation of these resources is not only necessary but should lead to significant commercial returns. This may be

[21] Valeria Negri, 'Ethical issues in Agrobiodiverity' (2005) 18 Journal of Agricultural and Environmental Ethics 3 at 5
[22] Plimbert, n16 above at 8
[23] GFAR, n14 above, at 2
[24] Plimbert, n16 above, at 18
[25] Coombe, n17 above at 277
[26] GFAR, n14 above at 3

achieved through the mechanism of intellectual property (IP) protection for commercial varieties, which is intended to support further innovation. In contrast to their underutilised counterparts, commercially available varieties have been selectively bred in order to possess desirable and uniform characteristics, thus making them eligible for IP protection and commercial exploitation.

In contrast, many underutilised crops are heterogeneous and therefore genetically and morphologically less uniform, and therefore less likely to meet the requirements for IP protection. However, the Global Forum on Agricultural Research (GFAR) suggests that it is not necessary for underutilised crops to be developed into a global commodity; rather the development and commercialisation of local, national and regional varieties is most likely to provide the best means of supplementing food and nutritional security.[27] To that end, it envisages that adequate research and development into underutilised varieties should secure their position as both commodity and subsistence crops. In the case of commodity crops, both public and private investment in research and development are justified in order to achieve market suitable crops; in the case of subsistence varieties, this is more likely to be limited to the public sector. However, the development of underutilised crop varieties is not limited to institutional research and development: it may also take place as a result of on farm innovation and local seed exchange practices.

Due to the heterogeneity of crops falling within the scope of 'underutilised' and similarly, the disparity in the stakeholders in underutilised crops, it is highly impractical to continue to conceive of them in such broad terms. For this reason, it is pertinent to consider a specific example in order to provide a lens through which we may consider the surrounding issues.

1.1.3.1 Example: The Bambara Groundnut

The Bambara groundnut (*vigna subterranea)* is a grain legume and a highly nutritious underutilised species. It originates from West Africa and is widely cultivated in sub-Saharan Africa and some areas of South East Asia, including Indonesia, Malaysia, the

[27] GFAR, n14 above at 3

Philippines, Thailand and Sri Lanka. Due to its nature as a subsistence crop, virtually no research and development took place up to 2005.[28] It is the third most important legume in Africa, behind the peanut and the cowpea.[29] Although global production of the crop increased by two and a half times between 1961 and 2008, crop yield did not;[30] thus, it is underutilised in the sense that its potential is not fully reached. This section will briefly outline some of the key features of the crop and highlight some examples of its use.

In terms of cultivation, the Bambara groundnut grows underground, and develops into small pods that contain the seeds, which grow to around 8-15mm in diameter. It grows best in dry areas with sandy soil, although it can also be cultivated in humid conditions. It is highly tolerant of low rainfall and poor quality soil and can often produce significant yields in drought conditions. It is one of the crops targeted by the Millennium Seed Bank Global Crop Diversity Trust project 'Adapting Agriculture to Climate Change' which seeks to preserve the wild relatives of key crop foods in order to make them available to breeders for the development of new varieties with greater resistance to the effects of climate change.[31] Due to the nitrogen fixing properties of its roots, it is suitable for intercropping with other species and therefore is capable of support increased food production.

In terms of nutrition, the Bambara groundnut is what is known as a complete food, due to its very high carbohydrate content (approximately 65%), substantial protein content (approximately 20%) and fats (around 6%).[32] The nuts can be eaten fresh or boiled after drying; salted boiled Bambara groundnuts are commonly eaten as a snack in West Africa. Aside from direct consumption, it can be developed into various other food products; for example, it can be used as an alternative source of flour. One traditional use of this type is in cooking dumplings, but it can also be used in cakes and biscuits.[33] A

[28] F. J. Massawe, S. S. Mwale, S. N. Azam-Ali and J. A. Roberts, 'Breeding in Bambara groundnut (*vigna subterranea*(L.) Verdc.): strategic considerations' 2005 4(6) African Journal of Biotechnology 463 at 463
[29] Bioversity, n35 below
[30] ibid
[31] S. Cody, Gwilyn Lewis, '*Vigna subterranea* (Bambara Groundnut)' available at: http://powo.science.kew.org/taxon/urn:lsid:ipni.org:names:525534-1 (accessed: 15th July 2020)
[32] FAO, 'Traditional crops: Bambarra Groundnut' available at http://www.fao.org/traditional-crops/bambaragroundnut/en/ (accessed: 15th July 2020)
[33] ibid

recent project suggests that Bambara flour is an effective supplement to wheat flour in the production of commercial baked goods, with the added advantage of having a higher protein content than the wheat flour it replaces.[34] Thus the advantages of substituting Bambara are twofold: supplementing a mainstream crop and increasing the nutritional content of the end product.

Its uses are not limited to human consumption; however, the leafy offshoots of the crop are themselves nitrogen and potassium rich, which in turn makes them excellent animal feed.[35] Furthermore, it is recognised as having various traditional medicinal uses.

As is the case with many underutilised crops, there are social, cultural, and economic factors prohibitive to its uptake. In the case of Bambara, in some areas it is viewed as a poor person's crop, due to its role in subsistence agriculture. Similarly, in other areas it is largely cultivated by women, which also impedes its cultural status and therefore its uptake. These perception-related issues can be vastly more damaging when they are held by those with the power and influence to increase Bambara uptake (for example, government officials and crop and seed traders).[36]

1.1.4 Development, Innovation, Reward, and the Role of Intellectual Property Protection

Regardless of the intended scale of their use, realising the potential of underutilised crop varieties to address food and nutritional security concerns requires development and innovation. As the GFAR notes, innovations in underutilised crops should be incentivised by providing the innovators with the opportunity for significant returns.[37] The traditional means of according such rewards is an intellectual property right. Such a right should not only serve to reward the innovator for the 'idea' behind their innovation,[38] but investment of time and effort in bringing it to fruition. The solution to promoting the development of

[34] Ferial M. Abu-Salem and Azza A. Abou-Arab, 'Effects of supplementation of Bambara groundnut (*vigna subterranea)* flour on the quality of biscuits' (2011) 5(7) African Journal of Food Science 376
[35] Bioversity International, 'Nutritious and Underutilized Species: Bambara Groundnut (*vigna subterranea*)' available at http://www.bioversityinternational.org/uploads/tx_news/Nutritious_underutilized_species_-_Bambara_groundnut_1683_01.pdf (accessed: 15th July 2020)
[36] ibid
[37] GFAR, n14 above, at 3
[38] P. Torremans, *Holyoak and Torremans' Intellectual Property Law* (Oxford, Oxford University Press, 7th ed., 2013) at 3

underutilised crops then, should be the availability of an intellectual property right for the developer of a new variety.

Since the entry into force of the 1994 Agreement on Trade Related Aspects of Intellectual Property Rights, (TRIPS) member states have been obliged to provide patent protection for inventions in all technological fields, provided that the invention is new, non-obvious and useful. Member states may exclude plants and animals aside from microorganisms and essentially biological processes; however, they are required to provide protection for plant varieties through either patent protection or an alternative *sui generis* system of protection; or a combination of the two. Alternative *sui generis* protection is generally interpreted as Plant Variety Protection or a Plant Breeder's Right, usually those offered by the various enactments of the International Union for the Protection of New Varieties of Plants (UPOV). The recent UPOV Enactments have enjoyed considerable success in the West, where they were conceived as a result of plant breeders' concerns over protecting their innovations.[39]

The arrival of TRIPS obliged a considerable number of states to introduce appropriate legislation offering intellectual property protection for plant varieties where previously no such protection had been available. Many of these states were lower- and middle-income states[40] situated in Asia and Africa. Some elected the option of simply adopting the most recent UPOV enactment as a model for their new Plant Variety Protection laws; others, however, chose to exercise the opportunity to develop alternative models of Plant Variety Protection, in line with national priorities. As a result of this, it is unclear what opportunities exist for underutilised crops in terms of IP protection.

A separate but related issue that arises is that innovation in plant varieties cannot by their very nature be conceived as purely intellectual endeavours: they are dependent

[39] Sean C. Butler, *A guide to UK and EU plant variety rights* (Cambridge, Cambridge University Press, 2005) 3-9

[40] A large volume of the academic discourse pertaining to global intellectual property norms, including the TRIPS Agreement itself, relies upon the nomenclature of 'developed', 'developing' and 'least developed' states. However, this terminology is problematic, as it is laden with imperialist and colonial connotations. To that end, the terminology has been replaced with the terms 'high-', 'middle-' and 'lower- income' as these more directly reflect the economic status of the states being discussed. This is with the exception of where changing the terminology might serve to obfuscate the events being discussed; for example, in the discussion of the background and drafting history of the TRIPS Agreement in chapter 2.2.

upon external inputs, both in the physical form of plant genetic material and in the form of associated agricultural knowledge. The ownership of traditional germplasm and agricultural knowledge is often characterised as one aspect of the broader concept of farmers' rights. Too often however, the transposition of genetic resources and the associated traditional knowledge from the public to the private domain deprives small and local producers and rural communities of the benefits arising from their use.[41] The question is how do we attribute just reward for the individuals and communities that have cultivated local varieties or those whose ownership is a recognised product of traditional resource rights? This issue has been recognised primarily by two international instruments: the Convention on Biological Diversity (CBD) and its associated Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGFRA). Both instruments establish mechanisms intend to facilitate access to germplasm and traditional agricultural knowledge and redistribute the benefits arising out of their use to the recognised originators of the resources. Additionally, the ITPGRFA also explicitly acknowledges the contributions of local communities and farmers to the development of available genetic resources for agriculture.[42]

The theory then, is that the existence of intellectual property rights for newly developed varieties should serve to stimulate innovation by offering a direct reward for innovators, while at the same time the existing access and benefit sharing provisions and the recognition of Farmers' Rights should ensure that the originators of PGRFA and traditional agricultural knowledge are rewarded for their contribution. The development of underutilised crops then, should be adequately supported by innovators engaging with this system.

[41] Mary E. Footer, 'A tale of two commons: plant genetic resources and agricultural trade reform' in Han Somsen (ed) *The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents* (Cheltnam, Edward Elgar, 2007) at 174-175
[42] ITPGRFA, art. 9.1

However, the reality appears to be somewhat less clear-cut. Whilst the collection of supranational legal frameworks outlined above might appear *prima facie* to be a cohesive framework, in actuality it represents a system of overlapping obligations; all of which is subject to national interpretation and therefore highly variable in substantive content. Both IP protection and access and benefit sharing systems raise issues as to whether farmers and rural communities are able to engage with and benefit from them: a specific issue created by these frameworks is the transfer of access to germplasm from individuals to the state in question. Of equal concern is the degree of technical and legal expertise required to access intellectual property protection. Additionally, the unique circumstances and heterogeneous nature of many underutilised crops means that they may fall outside of the IP and benefit sharing regimes. Thus, the existence of a concrete legal framework that supports innovations in underutilised crops is in doubt.

1.2 Aim of Research and Research Questions

The aim of this project is to analyse the interface between intellectual property protection and farmers, small scale agricultural producers and stakeholders in the agricultural industry, such as research and development organisations. This in turn, will be used to reflect upon the nature and purpose of intellectual property protection in this novel field.

This project is socio-legal in nature. While there exists a vast body of literature addressing the legal framework for plant genetic resources for food and agriculture[43] and the cultural role of underutilised crops and traditional knowledge in rural communities,[44] very little of that literature seeks to address either the relationship between IP and underutilised crops or the socio-legal interaction between the users of genetic resources and access and benefit sharing systems.

[43] For example, Patricia Lucia Cantuária Marin, *Providing Protection for Plant Genetic Resources: Patents, Sui Generis Systems and Biopartnerships* (London, Kluwer Law International, 2002)
[44] For example, Manuel Ruiz and Ronnie Vernooy, *The Custodians of Biodiversity* (Oxon, Earthscan, 2012)

It is therefore intended to contribute to the field both theoretically and by adding an empirical dimension. In reference to both germplasm and traditional knowledge, the research project will seek to address the following questions:

1) How does intellectual property protection support innovations in underutilised crops? Moreover, concurrently, do IP and Benefit Sharing systems effectively reward those innovations?
2) Is intellectual property protection an appropriate tool for addressing food security concerns?

Within which, there are two central themes: firstly, what practical issues surround the actual usage of intellectual property protection for developments in underutilised crops? This necessarily includes identifying the extent to which intellectual property protection is compatible with innovations in underutilised crops in a particular set of circumstances. Concurrently, there is the issue as to how the mechanisms intended to facilitate access to germplasm and redistribute the benefits arising from its use interact with the intellectual property protection, and whether these mechanisms facilitate research and development. In sum, do intellectual property rights and associated benefit sharing serve to support and promote innovation in underutilised crops?

The second is to consider, at the conceptual level, whether intellectual property protection is an appropriate mechanism for attempting to address food security concerns. As has already been noted, the TRIPS Agreement requires that protection be available for plant varieties, however TRIPS is a trade centred agreement, and as such is not directed at development concerns. Nonetheless, there exists a reasonable consensus that IPRs should be support innovations in underutilised varieties and that this should be useful in addressing food and nutritional security issues.

This then raises the issue as to how we assess the potential impact of intellectual property on food security. The concept of food security in itself is relatively straightforward to understand. Perhaps the simplest definition is that put forward in 1983 by the FAO;

food security is 'ensuring that all people at all times have both physical and economic access to the basic food that they need'. A revised and more comprehensive definition was presented at the World Food Summit in 1996, which states that: 'Food security exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life'. The FAO identifies four key dimensions of food security: availability of food; access to food; utilization of food; and a stable supply of food. Clearly, the notion of food security is complex and multifaceted. Assessing whether there has been an improvement in food security is simply too abstract and complex a task to attempt here. There are too many social, political and economic factors which are difficult to impossible to distinguish and quantify. Furthermore, asserting definitively and empirically the net impact that intellectual property protection has had in any given circumstance is reliant upon comparing the truth against numerous counterfactual situations. It is simply beyond the scope of the present study.

Thus, we need another form of indicator as to whether IP might serve to improve food security. As the other key theme of this research is the relationship between intellectual property protection and underutilised crop species, the measure as to whether the availability of intellectual property protection and/or access and benefit sharing systems support addressing food security concerns will be based upon whether those mechanisms are accessible and useful for end users. This is based upon the premise that the accessibility and usefulness of the mechanisms will be directly linked to whether developers chose to use them, and consequently, whether improved varieties are developed and made available.

Accordingly, the outcome of the first line of inquiry will allow us to pinpoint the legal and extra-legal factors, which affect the level of engagement with IP and Access and Benefit sharing systems; whereas the second line of inquiry will allow us to consider any issues which are a consequence of more systemic concerns resulting from the application of a potentially incompatible legal construct. Identifying which of these factors is the

source of issues affecting the uptake and usage of IP and Access and Benefit sharing will in turn allow us to better propose alternatives/amendments to the current systems.

1.3 Methodology

The socio-legal nature of the research questions necessitates a mixed methods approach. To that end, this study engages with a selection of doctrinal and qualitative methods. This is supported by a Critical Realist epistemological standpoint.[45] This approach has been selected as it allows the observation and critical evaluation of the external reality, both in terms of the legal background and to subsequently propose improvements based upon the outcomes of the research.[46] This is supported by a Realist ontological position.[47]

The selected methods fall broadly within two headings: doctrinal and qualitative. Within the heading of doctrinal methods, a black letter approach is used to synthesise a coherent understanding of the national and supranational legal frameworks pertinent to innovations in underutilised crops. The critique of the normative framework forms the basis for all aspects of the investigation.

A mixture of qualitative methods is used to develop the case study that builds upon and incorporates the doctrinal analysis. The focus of the case study is to investigate aspects of the first research theme. The case study is based around the IP and ABS framework in Malaysia, and primarily upon research and development projects surrounding the development of one crop species, the Bambara Groundnut. The case

[45] As an epistemological approach, critical realism incorporates a spectrum of ideas. The most coherent and systematically developed version of the approach is found in the work of Roy Bhaskar, in his *Realist Theory of Science* and subsequent publications. The central component of realism is that an external world exists, independent of, and often defying our desires of it and attempts to understand and change it. The external world is in principle knowable or discoverable. Critical realism is fallibilist, and open to the possibility of being wrong. From a methodological perspective, what this means is that we are able to use empirical methods to discern reality through observation. We can then in turn build upon these observations to generate theory. Furthermore, critical realism supports the development of proposals for changing observed realities that are unsatisfactory, as a commitment to changing unsatisfactory realities is inherent to the approach. See, Ted Benton and Ian Craib, *Philosophy of Social Science: The Philosophical Foundations of Social Thought* (Basingstoke, Palgrave MacMillan; 2012) at 120-141

[46] ibid, at 121

[47] Realism, as an ontological position, is the belief that there are real existing entities behind universal or general ideas. In the present context, this can be expressed as the standpoint that there is such a thing as intellectual property or intellectual property protection that goes beyond the mere idea. See, Simon Blackburn, *Oxford Dictionary of Philosophy* (Online edition, 2nd revision, 2016), available at: https://www.oxfordreference.com/view/10.1093/acref/9780199541430.001.0001/acref-9780199541430-e-2649?rskey=0pOHOy&result=2649 (accessed: 10 May 2021)

study based approach is necessary for purposes of scale and access. Engaging with research and development projects not only facilitates access to participants and observation of the research and development process, but it is also useful in limiting the framing of the study, both in terms of the huge variety of underutilised crop species and local legal regimes.

The selected qualitative method is an ethnographic approach, although it is not intended to be an ethnography in the traditional, anthropological sense. Rather, the intention is to draw upon the ethnographic methodology of compiling various qualitative observations in order to produce a complete understanding of the crop development process, and how, this in turn reflects upon the legal reality. This is based on the premise that in order to best understand science, you should look at what practitioners do, rather than the results it produces. [48] This aspect of the qualitative inquiry is based on thick description, drawn from observational data and semi-structured interviews. Thus, the purpose of this descriptive data is to document and characterise the crop development process which can then be used to critique the IP and access and benefit sharing framework. Within the ethnographic approach, further qualitative research was undertaken through the medium of semi-structured interviews. The objective of which was to access expert and local knowledge on the process of crop research and development, and opinions and understandings relevant to the IP and Benefit sharing framework. The semi-structured method was based around open ended questions in order to allow participants to include any information that they believe to be relevant and to support the development of unexpected ideas and themes. The questions were open ended, designed to access participants' knowledge, opinions, values and experiences relevant to both cultivating and developing underutilised crops and the pertinent legal framework.

Ethical approval for this study was sought and received the University of Nottingham Ethics Committee in October 2016. A small number of ad hoc scoping

[48] Clifford Geetz, *The Interpretation of Cultures: selected essays* (New York, Basic Books, 1973) at 5

interviews took place between January 2017 and July 2018. The main collection of data took place during January 2019; this was supplemented with written follow up questions until October 2019. Participants were drawn from the following organizations: Bioversity International, Crops for the Future, the International Institute for Tropical Agriculture, the International Islamic University of Malaysia, the Plant Variety Protection Office of Malaysia, the Sabah Biodiversity Centre, and the Sarawak Biodiversity Centre.

In total, there were 23 formal participants in the study, although ad hoc commentary was also provided by additional participants associated with the organizations given above. Although this number does not appear particularly large, it not only represents a high percentage of the experts in the field, but also a substantial spread across the related heads of expertise. It is highly unlikely given the necessary restrictions on the study (the focus on underutilised crop species, specifically the Bambara groundnut) that a considerably wider group of expert participants could have been achieved. Participants included: crop scientists;[49] food product development and quality professionals;[50] experts in the field of intellectual property protection and access and benefit sharing in Malaysia; and officials from the Malaysian Plant Variety Protection Office.

The identities, occupations, and direct quotes of individual interview participants remain confidential. The anonymization of participants' comments was a requirement of access in certain cases. Due to the fact that the participants were drawn from a relatively small pool, anonymity was maintained across the group so as not to affect or caused conflict in participants' relationships with third parties or their employers. The inclusion of the participants' remarks was subject to the informed consent of the participants, on the basis that participants' were free to withdraw at any point until the submission of this work and that any data pertaining to their participation would be destroyed. The interview notes are stored in hard copy with the researcher. Digital recordings of interview audio are stored on the University of Nottingham's research drive, subject to its data retention

[49] The term 'crop scientists' is used as an umbrella term here to encompass various crop related roles, including agronomists, crop geneticists, agricultural management experts, and crop technicians, among others.
[50] The term 'food development product development and quality professionals' refers to individuals whose roles is focused on post-harvest management and products developed from underutilised crops.

policy. Separate copies of the interview audio are stored by the researcher, along with digital copies of interview notes on a purpose specific encrypted data storage device.

1.4 Structure

Chapters two through five will serve to outline the collection of international legal frameworks relating to underutilised crops and traditional knowledge. Chapter two will focus on the TRIPS Agreement. This will begin with an analysis of the substantive content of article 27.3(b) and will include the drafting history of the provision. The implications of articles 7 & 8, concerning the objectives and principles of the TRIPS Agreement for the content of article 27.3(b) will be considered. It will then explore the idea of an 'effective *sui generis* system' and *sui generis* intellectual property rights. Furthermore, it will explore the role of bi and multilateral trade agreements (TRIPS plus) on states' options for implementing article 27.3(b).

Chapter three will consider the various enactments of the International Union for the Protection of New Varieties of Plants (UPOV). It will explore the development of the Enactments to the Convention and the institutional structure of the UPOV regime. It will then review the key concepts under the Convention, such as 'plant varieties' and 'plant breeders' rights', before considering the substantive content and requirements for a plant breeders' right. This will be followed by an analysis of whether the UPOV system of plant variety protection can be considered a tool for addressing food security concerns.

Chapter four will consider the International Treaty on Plant Genetic Resources for Food and Agriculture. It will analyse the Multilateral System of Access and the Benefit Sharing, including the mechanism for accessing genetic resources, the Standard Material Transfer Agreement and the Benefit Sharing Fund. It will explore the concept of Farmers' Rights as presented by the Treaty, in the context of their difficult emergence in international law and their potential as an effective counterweight to private property rights. It will also examine the compatibility between the ITPGRFA and TRIPS, and the ITPGRFA and UPOV.

Chapter five will then move on to discuss the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising out of Their Use. The purpose of this section is to consider the implications of the provisions concerning the sustainable use of the components of biodiversity, access to genetic resources and distribution of the benefits of biotechnology in the context of intellectual property protection for underutilised crops. This will be split into two parts. The first part will consider the Convention on Biological Diversity. It will analyse the framework nature of the Convention and the implications of this, before moving on to discuss the principles of access and benefit sharing it established, as well as the relationship between the principles of the CBD and intellectual property protection. The second part will focus on the Nagoya Protocol, including its elaborated regime for access to genetic resources and traditional knowledge and linked with this, the direct and indirect benefit sharing mechanisms created by the Protocol. It will also examine the various compliance mechanisms established by the protocol. Finally, it will explore the differences and the relationship between the access and benefit sharing regimes under the ITPGRFA and the Nagoya Protocol.

Chapters six and seven will form two halves of the case study, focused upon the development of underutilised crops in Malaysia. The first part, chapter six, will consider the Malaysia and its food security concerns; before critiquing the current system of plant variety protection and the various tiers of the access and benefit sharing framework. This will form the basis for the analysis in chapter seven.

Chapter seven will be based around the empirical aspect of the case study. It will use the qualitative data to synthesise a narrative of the development of the Bambara groundnut in Malaysia and consider how it might be useful in meeting the country's food security objectives, highlighting IP and ABS concerns along the way. It will outline the benefit sharing projects that have been funded in Malaysia. It will then engage in an analysis of the access, IP and benefit sharing concerns that arise out of the development process, incorporating stakeholder concerns. Finally, it will provide an answer to the

question as to whether the current IP framework in Malaysia serves to support developments in underutilised crop species.

Chapter eight will serve to review the outcomes of the previous chapters and as a conclusion.

1.5 Terminology

As has been discussed above, the purpose of this research is to examine whether the certain legal constructs – in this case, intellectual property rights – are a useful and accessible tool for stimulating development and rewarding innovation in the case of underutilised crops; specifically, the Bambara groundnut. Thus, this socio-legal approach necessitates testing the selected legal constructs against the corresponding reality. However, the two legal constructs central to the analysis, plant variety protection and *sui generis* intellectual property protection, do not have a universally held meaning. For this reason, it is necessary to have working definitions of these constructs to provide a point of reference when undertaking the theoretical analysis of IP in chapter two and more importantly, as a guide during both the data collection and analysis phases of the case studies.

1.5.1 Plant Variety Protection, Plant Breeders' Rights and Alternative Plant Variety Protection

Plant variety protection (PVP) and plant breeders' rights (PBR) are the traditional mechanism for according an intellectual property right to the creator of an eligible plant variety. This form of IP protection was the product of negotiations that took place in the 1950s between plant breeders from various states including the USA, Germany, France, the Netherlands and the United Kingdom with the intention of developing a new method of protecting plant varieties from the various methods that had previously been employed as a result of plant innovations not conforming to the technical requirements of patent protection.[51] The result of the negotiations was the 1961 Enactment of the International

[51] Butler, n39 above, 9; see also section 1.1.4 above

Union for the Protection of New Varieties of Plants,[52] which introduced plant variety protection. Whilst the ideas underpinning this new right broadly reflect those underpinning patent protection, its technical requirements have been engineered to suit the specific nature of innovations in plant varieties. UPOV is therefore the bench mark for Plant Variety Protection.

Under the most recent 1991 UPOV enactment, plant variety protection is available to all botanical genera and species that fulfil the criteria of being New, Distinct, Uniform and Stable. These criteria will be considered briefly in turn:

(i) New: A variety is considered new if it has not been offered for sale in the territory of the state of application in the last year, or in another state in the last four years.[53]

(ii) Distinct: a new plant variety is considered distinct if it is clearly identifiable by one or more important characteristics from any other variety in common knowledge (for example, having been entered in an official register of varieties) at the time of application.[54] "Characteristics" may be defined as morphological or physiological characteristics, and must be capable of precise description and recognition. Of special note is the qualification "important": this permits states parties to implement regulation that may prevent the frivolous grant of rights over a new variety with only minimal differences from existing protected varieties; or alternately to determine what characteristics are relevant to distinguishing a new variety dependent upon species.

(iii) Uniform: a new variety should be "sufficiently homogenous", in particular relating to its reproductive or propagative characteristics. [55]

(iv) Stable: a new variety should be stable in its essential characteristics, and remain so after repeated reproduction or propagation. Due to their technical

[52] 'UPOV' is the acronym of the French name of the organisation: Union Internationale por la protection des obtentions végétales
[53] UPOV, art. 6
[54] UPOV, art.7
[55] UPOV, art. 8

nature, complete expansion of the requirements of Uniformity and Stability are addressed on a species basis in the UPOV DUS Test Guidelines.[56]

Thus, a Plant Breeders' Right under the 1991 Act applies in regard to a single plant variety, which is defined as a plant grouping with a single botanical taxon of the lowest known rank which can be defined by the expression of characteristics which result from a genotype or combination thereof and can be distinguished from other varieties on the basis of that expression and can be considered as a unit with regard to its suitability for being propagated and unchanged.

A breeder may be an individual, their employer or legal person. Under the 1991 Act, a successful applicant for plant variety protection will have monopoly over the production and reproduction,[57] conditioning for the purpose of propagation,[58] offering for sale,[59] selling or marketing,[60] import,[61] export[62] and stocking for any of these purposes.[63] This monopoly applies to the vegetative and propagating material of the registered variety, including whole plants[64] and extends to harvested material or products derived thereof obtained through unauthorised use of propagating material from protected varieties, unless the breeder has had sufficient opportunity to exercise their rights.[65]

The concept of Alternative Plant Variety Protection is more difficult to address. If UPOV style plant variety protection is generally taken to be the standard form of plant variety protection, then Alternative PVP is necessarily what falls outside of the UPOV paradigm. Aside from this somewhat obvious observation, it is not strictly possible to define the characteristics of Alternative PVP, as there exists a broad spectrum of approaches. Some examples include: the adoption of alternative criteria to the DUS requirement;[66] protection

[56] UPOV, art. 9
[57] UPOV, art. 14(1)(a)(i)
[58] UPOV, art. 14(1)(a)(ii)
[59] UPOV, art. 14(1)(a)(iii)
[60] UPOV, art. 14(1)(a)(iv)
[61] UPOV, art. 14(1)(a)(v)
[62] UPOV, art. 14(1)(a)(vi)
[63] UPOV, art. 14(1)(a)(vii)
[64] UPOV, art. 14(2)
[65] UPOV, art. 14(3)
[66] Malaysia; Protection of Plant Varieties Act 2004, art. 14(2)

for extant and farmers' varieties;[67] protection for local and domestic varieties;[68] protection of general domestic plant varieties and wild plant varieties.[69] Some alternative approaches better reflect a registration and licensing regime rather than an intellectual property right in the traditional sense. A number of these examples will be considered it greater depth. Thus, the term escapes precise definition.

For the purpose of this work:

- Plant Variety Protection and Plant Breeders' Rights are taken to mean an intellectual property right for an eligible plant variety that conforms with UPOV standards. It is not necessary for a given state to be a contracting party to any UPOV enactment, as a number of states have adopted UPOV style protection without acceding to the convention. These may be referred to as 'traditional Plant Variety Protection' or 'traditional Plant Breeders' Rights' for purposes of clarity.
- Alternative Plant Variety protection refers to a unique, *sui generis* intellectual property right or one that is distinctly different from traditional Plant Variety Protection that arises out of national legislation

1.5.2 *sui generis*, *sui generis* rights, *sui generis* systems

In the discourse on intellectual property protection for innovations in plant varieties, the term *'sui generis'* is frequently encountered. The TRIPS Agreement introduces the idea of an effective *sui generis* system of protection for inventions concerning plant varieties. The term *'sui generis'* is Latin for 'of its own kind'.[70] In other words, *'sui generis'* refers to a unique form of intellectual property protection. There is no reference in the text nor the drafting history[71] of the TRIPS Agreement as to what should constitute an effective *sui generis* system. It is the view of a number of states parties that *'sui generis'* should be taken that the protection provided by the UPOV system, and in

[67] India: Protection of Plant Varieties and Farmers Rights Act 2001, s.15(2), s. 41
[68] Thailand: Plant Varieties Protection Act 1999, s.11(3)
[69] ibid, s.43, s.11
[70] 'sui generis' *OED Online,* (Oxford, Oxford University Press, June 2016) available at http://www.oed.com/view/Entry/193700?redirectedFrom=sui+generis#eid (accessed: 15th July 2020)
[71] Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4th ed., London, Sweet & Maxwell, 2012) at 420-428

particular its 1991 enactment, is the effective system to which the provision is referring.[72] This view is particularly prominent among the industrialised nations that promoted the creation and expansion of the UPOV system. Many have adopted this approach in order to comply with the TRIPS Agreement or have introduced similar legislation into national law without acceding to the Union. However, there is no requirement for states to accede to the Convention or adopt a similar approach.

The alternative view is that the UPOV system is but one example of an effective *sui generis* system, and that art. 27.3(b) leaves member states the freedom to select or develop a system that meets their national needs and priorities.[73] This view is consistent with the Objectives and Principles outlined in arts. 7 and 8 of the TRIPS Agreement, which asserts that member states should adopt measures 'in a manner conductive to social and economic welfare, and to a balance of rights and obligations'. Furthermore, member states are permitted to 'adopt measures necessary to promote public health and nutrition, and to promote the public interest in sectors of vital importance to their social and economic development' in the formulation of their national laws.

Thus, there is some disagreement as to the scope and substance of a *sui generis* system for protecting innovations in plant varieties. What is more, it is clear that there are two distinct concepts referred to by the term *sui generis*: an intellectual property right and a broader system, which includes the interests of various stakeholders. By process of reduction, the only characteristics that can be attributed to a *sui generis* IPR are the same as other rights mandated by the TRIPS Agreement: that they are private rights and in relation to certain acts covered by an IPR, confer no further exclusive right other than equitable remuneration for the rights holder.

However, as a result of the diverse range of interests in developments in plant varieties, particularly in developing and biodiversity rich parts of the world, *sui generis* intellectual property protection for crop varieties sits on the nexus between intellectual property protection, conservation regimes and traditional rights (including farmers'

[72] ibid, at 456
[73] Gervais, n71 above, at 456

rights). Consequently, it is arguable that a *sui generis* system is composed not only of a *sui generis* IPR but a collection of overlapping voluntary and non-voluntary obligations.[74] In fact, some states have modelled their approach to protection for plant varieties around this idea, by building IP protection for plant varieties, benefits for resource holders and biodiversity into the same legislative framework.[75] Even where this is not the case, for analytical purposes it is possible to theoretically construct such a system by identifying the various components.

A further point to clarify is the confusion that surrounds the term '*sui generis* system'. Whilst the lack of a concrete definition has already been established, the precise meaning of the term is further clouded by the broad range of subject matter to which various authors have applied it. For example, the term is often used to refer to farmers' rights.

Thus, for the purposes of this research:

- the term '*sui generis* right' will be taken to mean an intellectual property right in a plant variety, other than those explicitly referred to in the text of the TRIPS Agreement. This will include both traditional UPOV style plant variety protection and alternative forms of plant variety protection.
- the term '*sui generis* system' will be used more broadly to refer to frameworks containing *inter alia*, *sui generis* intellectual property rights, farmers' rights and access and benefit sharing provisions.

[74] Philippe Cullet 'Revision of the TRIPS Agreement concerning the Protection of Plant Varieties: Lessons From India Concerning the Development of a *Sui Generis* System' (1999) 2(4) Journal of World Intellectual Property 617 at 626

[75] The most prominent example of this is India's Protection of Plant Varieties and Farmers' Rights Act 2001, No. 53 of 2001

Chapter 2: The 1994 Agreement on Trade Related Aspects of Intellectual Property

2.1 Introduction

At the very centre of the present analysis, is the fact that states parties are required to make available intellectual property protection for plant-based innovations. As discussed in the previous chapter, this near universal[76] obligation stems from the 1994 Agreement on Trade Related Aspects of Intellectual Property (TRIPS, TRIPS Agreement). It is therefore the objective of the chapter to develop an understanding of that obligation in context, and how it intersects with food security concerns and the consequences of this obligation for the development of underutilised crop varieties.

To recall from the previous chapter, we are considering whether intellectual property protection is useful device in the development of underutilised crops and whether it might aid in addressing food security concerns. As a trade focused agreement, with a subject matter of IP protection, TRIPS does not directly address developmental concerns such as food security *per se*. However, as a result of requiring states to make IP protection available for plant-based innovations, it inevitably intersects with food security concerns. The purpose of this chapter is to consider the content of the TRIPS Agreement in the context of those concerns.

This chapter will first briefly consider the history of the TRIPS Agreement, both prior to and during its negotiation; it will examine the linkage between IP and trade and how has this shaped the outcome of the TRIPS Agreement. It will then include an examination of the notion of *sui generis* IP protection, in order to answer the question: what is *sui generis* intellectual property protection as envisaged by the TRIPS Agreement? This will form the basis for the case study analysis in chapters six and seven. It will then consider the relevance of bilateral and multilateral trade agreements, or so called 'TRIPS Plus' agreements, on member states ability to develop and implement suitable IP rights for plant-based innovations. Finally, it will consider the dispute settlement and compliance

[76] 193 member states to the WTO (only excludes the Holy See and the State of Palestine)

mechanisms incorporated into TRIPS, and their relevance for member states in implementing article 27.3(b).

2.2 Background

The relationship between international trade and intellectual property rights began to develop in the 1970s. During this period, there was a gradual realisation among high and middle income states that counterfeit goods were negatively affecting trade revenues.[77] This lead to a draft anti-counterfeiting agreement between the US and the European Economic Community in 1979.[78] Its sole focus was to address trade in falsely trademarked goods. [79] While the draft agreement between the US and the EEC was not adopted, it stimulated discussion on the position of IP protection within the arena of the General Agreement on Tariffs and Trade (GATT).

During the early to mid-1980s, the US government experienced persistent lobbying from industry concerns about the impact of counterfeit products and copyright piracy prompted significant upon trade returns and investment, estimated to be causing losses of tens of billions of dollars;[80] who consequently argued that there existed a need for global minimum standards for IP protection.[81] At the same time, the International Intellectual Property Alliance (IIPA)[82] produced a study indicating that ineffective copyright laws in larger and more advanced developing economies was directly responsible for large scale losses by US industries.[83]

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[77] Michael Blakeney, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPS Agreement*, (London, Sweet & Maxwell, 1996) at 1
[78] 'Agreement on Measures to discourage the Importation of Counterfeit Goods' (L/4817, 31 July 1979)
[79] Charles Clift, 'Why IPR issues were brought to GATT: a historical perspective on the origins of TRIPS' in Carlos M. Correa (ed), *Research Handbook on the Protection of Intellectual Property under the WTO Rules: Intellectual Property in the WTO Volume I* (Cheltenham, Edward Elgar, 2010) at 5
[80] Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4th ed; London, Sweet & Maxwell, 2008) at 12
[81] Clift, n79 above, at 6-7
[82] Formed in 1984, the IIPA is a coalition of seven trade associations representing US copyright based industries. See, https://www.iipa.org/about/ (accessed; 15th July 2020)
[83] IIPA, *Piracy of US Counterfeited Works in Ten Selected Countries* (1985) at 7; cited in Michael Blakeney, *Intellectual Property Law and Enforcement: A Commentary on the Anti-Counterfeiting Trade Agreement* (Cheltenham, Edward Elgar, 2012) at 32

The revisions of the Paris[84] and the Berne Conventions[85] taking place in the World Intellectual Property Organisation (WIPO) during this period failed to manifest the stronger IP standards desired by developed states.[8687] The US proposed that the Uruguay round of the GATT consider all aspects of intellectual property rights, asserting its belief that the GATT was an appropriate forum for the enforcement of IPRs.[88] This was met with mixed responses; the EEC remained ambivalent as to the appropriateness of GATT as a forum, however many lower and middle income states, including Brazil and India, were hostile to the development.[89] Ultimately, a mandate for the negotiation of an agreement concerning the 'trade-related' aspects of intellectual property rights was included in the Punta del Este Declaration during the Uruguay round of the GATT.[90]

The rationale for its inclusion was to reduce distortions or impediments to trade and to prevent the enforcement of IPRs becoming a barrier to trade. The declaration also gave the scope to 'elaborate as appropriate new rules and disciplines'; thus opening the door to the obligatory provision of IPRs in the field of biotechnology. The link between IP protection and trade was therefore firmly cemented before the negotiation of the Agreement began.

Negotiation of the Agreement began in 1987. The first challenge was defining the scope of the Agreement, as the mandate had not established what exactly the 'trade-related' aspects of intellectual property were. Initially, there was little progress as a number of lower and middle income states, most prominently Brazil and India, continued

[84] Paris Convention for the Protection of Industrial Property 1883: the seventh revision of the Convention failed to yield a significant outcome, as a result of the polarisation of standpoints between developed and developing states. See, Wei Zhuang, *Intellectual Property Rights and Climate Change: Interpreting the TRIPS Agreement for Environmentally Sound Technologies* (Cambridge, Cambridge University Press, 2017) at 53-54
[85] Berne Convention for the Protection of Artistic and Literary Works. The alternations made by the 1971 revision process may even be considered a step backwards by developed states, as they included an appendix containing 'Special Provisions Regarding Developing Countries' which allowed developing states to grant licenses to its nationals over foreign copyrighted works for educational or research purposes. See, Norja Maija Tocups, 'The Development of Special Provisions in Copyright Law for the Benefit of Developing Countries' (1982) 29 Journal of the Copyright Society of the USA 402
[86] Gervais suggests that the two major flaws that the Paris and Berne Conventions share are a) a lack of detailed rules on the enforcement of rights before national authorities and b) the absence of a binding and effective dispute settlement mechanism. See Gervais, n80 above, at 11
[87] Abdulqawi A. Yusuf, 'TRIPS: Background, Principles and General Provisions' in Carlos M. Correa & Abdulqawi A. Yusuf (eds), *Intellectual Property and International Trade: The TRIPS Agreement* (2nd ed; Netherlands, Kluwer Law International 2008) at 5
[88] Blakeney, n77 above, at 3
[89] Clift, n79 above, at 9
[90] GATT, 'Ministerial Declaration on the Uruguay Round' (20 September 1986) available at https://www.wto.org/gatt_docs/English/SULPDF/91240152.pdf (accessed: 15th July 2020) at 7

to question the relevance of GATT as a forum for an agreement on intellectual property and maintained that the scope of the agreement should be interpreted restrictively.[91] One of the main reasons for the resistance of many lower and middle income states in Asia, Africa and the Pacific against a comprehensive agreement on IP was that many had only recently liberated themselves from colonially imposed IP regimes and in some cases, had deliberately scaled back the available IP protection in order to support their development aims.[92]

During the Mid-Term Review from 1988-1989, a framework for the agreement emerged. This included, *inter alia,* the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights; the provision of effective means of enforcement of IPRs; and an effective means of dispute settlement between governments.[93] Thus, the content of domestic IP regimes was now firmly established as an arm of the international trading regime.

The drafting process came to a head in March 1990 when the European Community proposed a text entitled 'Draft Agreement on Trade Related Aspects of Intellectual Property Rights' which concerned all aspects of IP protection, its enforcement and relevant principles.[94] This was followed by proposed texts from the United States,[95] Switzerland[96] and Japan.[97] This was met by increased participation from a number of lower and middle income states, including submissions of a detailed proposal on measures the availability, scope and use of IPRs in addition to draft rules on counterfeit goods[98] by a group of 14 developing countries.[99]

The developed states' texts were compiled into a 'composite draft text' which is often referred to as the 'A' text; and the developing countries' counterproposals were

[91] Blakeney, n77 above, at 4
[92] Carolyn Deere-Birkbeck, 'Developing countries in the global IP system before TRIPS: the political context for the TRIPS negotiations' in Correa (ed) 2010, n79 above, at 22-28
[93] MTN.TNC/11 (April 21, 1989) at 21
[94] MTN.GNG/NG11/W/68 (March 29, 1990)
[95] MTN.GNG/NG11/W/70 (May 11, 1990)
[96] 'Draft Amendment to the General Agreement on Tariffs and Trade on the Protection of Trade Related Intellectual Property Rights' MTN/GNG/NG11/W/73 (May 14, 1990)
[97] 'Main Elements of a Legal Text for TRIPS' MTN.GNG/NG11/w/74 (May 14, 1990)
[98] Yusuf, n87 above, at 13
[99] The initial proposal was tabled by Argentina, Brazil, Chile, China, Columbia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay; Pakistan and Zimbabwe later joined the group. MTN.GNG/NG/NG11/W/72 (May 14, 1990)

branded as the 'B' text. The two approaches differed in both substance and structure. The B text was eventually abandoned by developing countries who instead pursued flexibilities in the A text.[100] Elements of the B text were incorporated into the A text; most notably articles 7 and 8 of the TRIPS Agreement, concerning its objectives and principles, although its influence can also be found elsewhere.[101] Negotiations over the details of the text continued until December 1991, when the so-called 'Dunkel draft' of the Agreement was produced, which broadly mirrors the final draft.[102]

The TRIPS Agreement was adopted at Marrakesh on April 15 1994 as Annex 1C of the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations and entered into force for developed members on January 1st 1996; for developing country members on January 1st 2000, with the option to delay protection in certain areas for five years; and for least developed states on January 1st 2006.[103]

As is clear from the text of the TRIPS, most, if not all aspects of IP are considered to be trade-related and are thus within the scope of the Agreement. In the sphere of biotechnology and plant-based innovations, it has been necessary for many lower- and middle- income states to implement measures in order to meet their obligations under art. 27.3(b) TRIPS. The Agreement provides for minimum universal standards in all fields of intellectual property protection[104] and as such, leaves the implementation of the substance of the Agreement to individual member states. This in theory, should allow sufficient flexibility for states to introduce solutions which support their development and food security aims. However, this flexibility is still relative to the stronger IP standards desired by high income states and is subject to implementation and enforcement mechanisms which are considered below.

[100] Gervais, n80 above, 23
[101] See, Gervais, n80 above, at 27
[102] Antony Taubman, Hannu Wager & Jayashree Watal (eds) *A Handbook on the TRIPS Agreement* (Cambridge, Cambridge University Press, 2012) at 8
[103] TRIPS, art. 65
[104] TRIPS art. 1.1 provides that 'Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is provided by this Agreement, provided such protection does not contravene the provisions of this Agreement.'

2.3 TRIPS and plant-based innovations

Plant-based innovations are addressed by article 27 of TRIPS, which concerns patentable subject matter. It provides that:

'patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application'.[105]

However, states are permitted to exclude plant and animals (other than micro-organisms) from patentability provided that IP protection is available for plant varieties either in the form of plant specific patents, an alternative 'effective *sui generis'* form of IP protection, or a combination thereof.[106] Thus, the provision for protecting innovations in plant varieties exists as an exception to patentability.

Prima facie, article 27.3(b) appears to be flexible in its applicability. This apparent flexibility is a product of the particularly contentious provision in the drafting of the Agreement which was the subject of a number of north-north and north-south divides.[107] Among high income states, debate was centred upon the extent of application of IP protection to the field of biotechnology.[108] Lower and middle income states raised numerous concerns, including the moral issues surrounding the 'patenting of life', and in particular, concerns of bio piracy and the exploitation of the resources of the genetically wealthy south by the technologically advanced north.[109] These concerns are not explicitly reflected in the text of article 27.3(b). However, they can be viewed more broadly as an aspect of member states option to develop their own solution for implementing article 27.3(b), appropriate to their needs and concerns, which may include the conservation of biological diversity and safeguarding food security concerns.

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[105] TRIPS, art. 27.1
[106] TRIPS, art. 27.3(b)
[107] Gervais, n80 above, at 428
[108] The optional exclusion in the final text of the TRIPS came from the Draft Agreement produced by the European Community. The US had been opposed to any form of exclusion, but ultimately accepted an optional one that it could chose to ignore. Andreas Heinemann, 'Trade-Related Aspects of Intellectual Property Rights: Report on the 9th Ringberg Symposium from July 6-8, 1995' in Friederich-Karl Beier & Gerhard Schricker (eds.) *From GATT to TRIPS: The Agreement on Trade Related Aspects of Intellectual Property Rights* (Munich, Max Planck Institute for Foreign and International Patent, Copyright and Competition Law, 1996) at 181
[109] Gervais, n80 above, at 428.

In common with its other substantial provisions, the interpretation of the extent of obligations arising out of article 27.3(b) TRIPS can be supplemented by other relevant components of the TRIPS Agreement. The preamble recognises both 'the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives;' and 'the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations'. Equally, article 7 on the objectives of the Agreement states that: 'The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation ... in a manner conducive to social and economic welfare, and to a balance of rights and obligations'. In the same vein, article 8.1 permits member states to adopt measures necessary to protect public health and nutrition.

This then raises the question as to whether these provisions permit member states additional flexibility in their implementation of article 27.3(b)? According to article 31.1 of the Vienna Convention on the Law of Treaties,[110] the term of a treaty are to be interpreted in good faith, in accordance with the ordinary meaning to the terms of the treaty in the light of its objective and purpose. Thus, the designation of articles 7 and 8 as the objectives and principles is a strong indication that they are relevant for assessing the objective and purpose of the TRIPS Agreement, as they are structural provisions which overarch the substantive provisions of the Agreement.[111] To that end, the values expressed in articles 7 and 8.1 should be factored into any implementation of TRIPS obligations. This reflects the basic mission of the WTO, to promote trade and economic development; it might therefore be suggested that the function of the objectives and principles of TRIPS is to provide a balance between the holders and users of knowledge.[112]

However, assigning any concrete significance to these provisions in its interpretation of TRIPS obligations has been largely avoided by the Dispute Settlement

[110] 1969
[111] Alison Slade, 'The "Objectives" and "Principles" of the WTO TRIPS Agreement: A detailed anatomy' (2016) 53(3) Osgoode Hall Law Journal 948 at 950
[112] Peter K. Yu, 'The objectives and principles of the TRIPS Agreement' (2009) 46(4) Houston Law Review 979

Body (DSB).[113] It is therefore difficult to attribute any particular relevance to the provisions. The best possible argument that might be made is that they provide a degree of flexibility for balancing the implementation of IPRs against other obligations, but it is questionable whether this provides any more flexibility than already exists in the wording of article 27.3(b). Thus, on paper at least, it appears that there is sufficient elasticity built into TRIPS obligation to allow member states to implement article 27.3(b) in line with their needs and priorities obligations, provided that it is still consistent with their other obligations arising out of the TRIPS Agreement.

2.3.1 The review of art. 27.3(b)

Art. 27.3(b) contained a built-in provision for review after five years, which was scheduled to take place in 1999. This was before many lower and middle income states were required to have implemented the substantive provisions of the TRIPS Agreement. At the time, many lower and middle income states hoped that the review might serve to clarify the scope of their obligations and that it might present the opportunity to revise the substance of the article to better accommodate their development needs.[114] The process of the review began in December 1998, but did not reach a conclusive outcome, nor did it provide developing states with answers in the time frame they had anticipated.

The review process began on uneven ground when the agenda was defined by developed countries as being restricted to the implementation of the provision, rather than its substance as was argued for by many developing states.[115] The scope of the review was further limited by the fact that only developed countries were obliged to have implemented the provision by this point. The initial review on implementation took the format of a relatively short questionnaire to which some 30 states responded.[116]

[113] For example *Canada: Patent Protection of Pharmaceutical Products – Report of the Panel* (17 March 2000) WT/DS114/R; *European Communities: Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs* (15 March 2005) WT/DS174 & 290/R (*EC – TMs & GIs)*.
[114] GRAIN, 'For a Full Review of TRIPS 27.3(b): An update on where developing countries stand with the push to patent life at WTO' (March 2000) available at https://www.grain.org/article/entries/39-for-a-full-review-of-trips-27-3-b (accessed: 15th July 2020) at 2
[115] Ibid, at 3
[116] TRIPS Council, 'Review of the Provisions of Article 27.3(b)-Illustrative List of Questions' IP/C/W/122 (December 1998)

Discussion of the substance of the provision did take place in the latter half of 1999, when India presented its analysis of the issues faced by developing states regarding art. 27.3(b). Its submission raised questions on the ethics of patenting life; the incompatibility of industrial property with traditional knowledge sharing systems and the need to reconcile the provision with the Convention on Biological Diversity.[117] With particular regard to *sui generis* systems of IP protection, it is interesting to note that India considered the provision to contain sufficient latitude for member states to develop an effective means for providing protection for plant varieties which was flexible enough to incorporate development and policy objectives, as well as meeting obligations from other international agreements.[118] It concluded that assessing the scope of an effective *sui generis* system was perhaps best left to individual member states.

In the debate that took place in the following months, nearly 100 lower and middle income states submitted nine distinct proposals concerning the reform of art. 27.3(b).[119] These positions were rejected by high income states, although there was a spread of opinion among high income states as to the strictness of the provision.

Thus, at the end of the review the TRIPS Council decided to leave the matter for future meetings and noted the "non-outcome" of the review process.[120] Issues raised that remained unaddressed included the scope of the exceptions to patentability; ethical exceptions to patentability; applicability of patent protection to plant varieties; the applicability of patent protection to plant varieties; the availability of plant variety protection; the elements of 'effective *sui generis*' protection; the relationship between TRIPS and UPOV; provisions concerning transfer of technology; and the relationship between TRIPS and traditional knowledge and farmers' rights.[121] Essentially, the review produced little by way of results and failed to meet expectations.

[117] TRIPS Council, 'Review of the Provisions of Article 27.3(b)-Communication from India' IP/C/W/161 (November 1999) at 2
[118] Ibid, at 3
[119] See, GRAIN, n114 above, 'Official developing country proposals for the review and renegotiation of TRIPS as regards biodiversity and associated knowledge' in Annex
[120] Gervais, n80 above, at 40
[121] Gervais, n80 above at 454-457

The issue of art. 27.3(b) arose again in the context of the Doha Development Round of the WTO, beginning in 2001. Paragraph 19 of the Doha Ministerial Declaration instructs the TRIPS Council to continue its review of art. 27.3(b) and the relationship between TRIPS and the Convention on Biological Diversity, with particular emphasis on the interests of developing countries in this regard.[122] Despite the fact that numerous rounds of discussions have taken place since then, no significant progress has been made. Thus, while the review cannot be considered a total failure, because at the very least it has managed to keep the discussion concerning the uncertainties of art. 27.3(b) alive; it does not appear to have achieved any notable success. From the perspective of developing states seeking to balance supporting agricultural innovation and safeguarding local biodiversity and traditional knowledge, this lends a regrettable uncertainty to their development of any *sui generis* regime. It is suggested that resolution of these issues would be valuable as it would allow developing states to address their local food and nutritional security concerns with certainty that they are not in breach of their TRIPS obligations.

2.4 Options for plant-based innovations under TRIPS

As has been noted, at the time of entry into force of the TRIPS Agreement a large number of lower- and middle-income states had rejected many forms of intellectual and industrial property protection. This included IP protection for to plant-based innovations.[123] As a result, TRIPS was the direct motivation for the introduction of intellectual property protection for plant-based innovations in many states. Thus, TRIPS left a considerable number of lower- and middle- income states with the options of either

[122] WTO Ministerial Conference, 'Doha Ministerial Declaration', (14th November 2001) available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm

[123] For example, Malaysia, the country considered in the case study in chapters six and seven, had opted to make patent protection available through the Patents Act 1983 (Act 291), however this does not apply to plant-based innovations. At the time of entry into force of the TRIPS Agreement, Malaysia had not yet opted to introduce PVP style intellectual property rights.

adapting its patent law to accommodate plant-based innovations, adopting *sui generis* protection, or both.[124]

Plant specific patent protection is an option that has been adopted in a number of countries. Under art. 27.3(b) it is possible for innovations based upon other aspects of plant material to be protected by ordinary patent protection where it meets the normal requirements; for example, inventions concerning plant genetic material.[125] Similarly, it is also within the scope of the article for plant varieties themselves to be protected under ordinary patent law where it has been drafted in a manner that accommodates plant varieties.[126]

One possible option for implementing *sui generis* intellectual property protection for plant-based innovations is for states to adopt one of the Enactments of the International Union for the Protection of New Varieties of Plants (UPOV). UPOV was the internationally established model of *sui generis* PVP during the negotiation of the TRIPS Agreement. To a certain extent, UPOV may be considered a default *sui generis* option for PVP. However, TRIPS does not require member states to implement UPOV. There are a number of reasons for this. First, article 1.1 TRIPS gives member states the freedom to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice. To require member states to subscribe to a specific *sui generis* system of PVP would fundamentally undercut this freedom. The fact that TRIPS does not stipulate UPOV is in itself significant, as where the drafters of the Agreement intended member states to follow the principles set out in an existing international IP

[124] Art. 2.1 of the 1978 UPOV Enactment provides that protection may be provided by a special title or patent but not both; however, the 1991 UPOV Enactment is silent on the issue of double protection.
[125] For example, article 53(b) and rule 28 of the European Patent Convention prohibits the patenting of plant varieties. However, it does permit the patenting of plants that are produced by a technical process which modifies the genetic characteristic of the plant, thereby constituting an invention. This explicitly excludes essentially biological processes and processes where technical means are used to enable or assist an essentially biological process.
[126] The example of the United States illustrates a number of these options. Firstly, it is an example of a dualist system, whereby both patent and plant variety protection are available for plant varieties. Patent protection is available for asexually reproduced plant varieties under Title 35 United States Code, Section 161 (patent). The US is also signatory to the 1991 UPOV Enactment, and UPOV style plant variety protection is available through the Plant Variety Protection Act 1970, 7 U.S.C. §§ 2321-2582. In addition, since the mid-1980s, the United States Patent and Trademarks Office has permitted plant breeders to seek standard utility patents for plant varieties. Breeders/inventors are also able to seek both forms of protection for the same variety.

treaty, they are explicitly referred to in the text of the TRIPS Agreement.[127] Of particular relevance to this point is article 2.1 TRIPS, which stipulates that 'In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19 of the Paris Convention (1967)'. Thus, if the drafters had intended compliance with UPOV in the meaning of article 27.3(b), it would state as much.

As has been previously noted, TRIPS was the impetus for many states, and in particular, lower- and middle- income states, to implement any type of IP protection for plant varieties. There was a strong preference among many lower- and middle- income states for the previous 1978 UPOV Enactment which offered more flexibility than the version of *sui generis* PVP contained in the 1991 Enactment, which favours the breeders' rights over other competing interests. Therefore, many lower- and middle- income states were resistant to the notion of adopting the later enactment.

Linked with this, was the fact that at the same time that the TRIPS Agreement was being negotiated, the UPOV Council was in the process of producing the (then) new 1991 UPOV Enactment. A pragmatic reason for the lack of reference to the UPOV Convention was timing: it was considered premature to refer to the 1991 Enactment, which was not yet in force; and outdated to refer to the 1978 Enactment that was being replaced.[128]

A further reason why TRIPS does not prescribe UPOV as an effective *sui generis* system of PVP is that TRIPS requires states parties to structure their laws in ways that the UPOV Enactments do not. For example, article 3 TRIPS requires member states to adopt the principle of national treatment. This principle is also expressed in the 1978 and 1991 UPOV Enactments.[129] However, the principle as espoused under UPOV only applies to other states parties to the UPOV members, whereas TRIPS requires the principle be extended to all WTO members. Therefore, compelling member states to merely subscribe

[127] For example, article 1.3 TRIPS stipulates that the eligibility of a legal or natural person to hold an IPR is to be understood as the persons who meet that criteria under Paris Convention, the Berne Convention, the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits.
[128] Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries,* (Kluwer Law International, 2001) at 14
[129] UPOV 1978, art. 3; UPOV 1991, art. 4 UPOV

to either of the UPOV Enactments would leave them in violation of their wider TRIPS obligations.[130]

If states chose to reject both patent protection for plant varieties and the model of plant variety protection provided for by the UPOV Enactments, then the alternative is that states are able to develop their own *sui generis* system for the protection of plant-based innovations, in line with their national needs and priorities. This approach has successfully been adopted in a number of states, such as India, Thailand, the Philippines, and Malaysia, among others.[131] The issue as to what constitutes effective *sui generis* protection is considered in section 2.5 below.

However, the ability of member states to develop an appropriate *sui generis* solution for their implementation of article 27.3(b) may be limited by so called 'TRIPS Plus' Agreements. These are bi- and multilateral trade agreements between states parties which form part of the wider body of WTO and TRIPS law and require states to implement more extensive levels and standards of IP protection than are required by the TRIPS Agreement. They may also require signatories interpret the TRIPS Agreement in a narrower manner, in order to ensure greater compliance with the Agreement.[132] These higher standards of IP protection are often promoted by industrialised nations, such as the United States or the European Union in their trade agreements.

In the case of plant-based innovations, they may restrict the freedom available to member states under article 27.3(b) by requiring states parties to accede to the UPOV Enactments. This effectively denies states the flexibility to adopt a solution that might be better suited to their national needs and priorities. For example, the North American Free Trade Agreement (NAFTA) requires that signatories 'give effect to' either UPOV 1978 or UPOV 1991.[133] This at least, gave some scope for signatories to pursue the most appropriate PVP solution. As a developing state with considerable rural population and

[130] Laurence R. Helfer, *Intellectual Property Rights in Plant Varieties: International Legal Regimes and Policy Options for National Governments* (Rome, FAO, 2004) at 2.3.3.2
[131] This list is by no means exhaustive.
[132] Mohammed El-Said, 'The road from TRIPS-Minus to TRIPS-Plus' (2005) 8(1) The Journal of World Intellectual Property 53 at V
[133] NAFTA, Article 1701 of Chapter 17

agricultural economy, Mexico opted to accede to UPOV 1978 when it became a member of NAFTA and retained some of the flexibilities present the 1978 Enactment. Since it is no longer possible to accede to UPOV 1978, this small flexibility is no longer available. The recently failed Trans-Pacific Partnership (TPP) would have required several states, including Malaysia, to accede to UPOV 1991 which had implemented their own *sui generis* PVP solutions.[134] Continuing the previous example, the TPP would have required Mexico to update its UPOV membership to the 1991 Enactment, and thus further limited its flexibility. Its successor, the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), also mandates membership to the 1991 Enactment.[135] However, at the time of writing, several of the states that would be required to join UPOV 1991, including Malaysia, are undergoing a period of consultation as to whether the agreement should be ratified.[136]

2.5 The issue of effective *sui generis* protection

Since the scope of patentability is evident in the text of the Agreement, the question to be considered is the scope of 'an effective *sui generis*' form or system of IP protection. Neither TRIPS nor its *travaux préparatoires* provides guidance upon what the components of an effective *sui generis* system ought to be.[137] Furthermore, the TRIPS Agreement makes no mention of the UPOV system of protection and as such, there is no requirement to accede to the UPOV Conventions. Nonetheless, there is a near universal consensus that UPOV is an example of an effective *sui generis* system. Interestingly, in its latest iteration, UPOV appears to have 'rebranded' itself in the light of the TRIPS Agreement; having taken

[134] TPP, article 18.7.2(d)
[135] CPTPP, article 18.7.2(d)
[136] Ministry of International Trade and Industry, 'Trans-Pacific Partnership Agreement (TPP) & Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)' available at: 'https://fta.miti.gov.my/index.php/pages/view/71 (accessed: 2nd April 2021)
[137] Daniel Leskien & Micheal Flitner, 'Intellectual Property Rights and Plant Genetic Resources: Options for a *Sui Generis* System' *Issues in Genetic Resources No. 6* (Rome, International Plant Genetic Resources Institute, 1997), at 35

to describing its mission as being 'to provide and promote an effective system of plant variety protection'.[138]

Logically then, the only characteristics that can concretely be attributed to a *sui generis* IPR are the same as other rights mandated by the TRIPS Agreement: that they are private rights and in relation to certain acts covered by an IPR, and confer no further exclusive right other than equitable remuneration for the rights holder.[139] This fits with the view offered by Leskien and Flitner, who suggest that effectiveness refers to a level of protection in the system, and thus a *sui generis* right requires certain minimum substantial rights which allow for effective action against any infringement as required by Articles 42-49 TRIPS (Civil and Administrative Procedures and Remedies).[140] Therefore the onus upon member states is only to provide judicial procedures; TRIPS minimum standards require rights holders themselves to be responsible for discovering any breach of their rights and bringing action should they so wish.

However, prominent plant breeding associations such as ASSINSEL[141] have asserted that for a *sui generis* system to be considered effective it must incorporate the standards of uniformity, distinctiveness and stability (i.e. the criteria utilised by the UPOV system for assessing suitability for plant variety protection) otherwise a variety is unsuitable to be the subject of a legal right, in its view.[142] Nevertheless when considering the weight of such an opinion, it must be borne in mind that the membership and nature of such organisations possesses a vested interest in the availability of traditional plant variety protection. Therefore, its view cannot be considered authoritative.

The most compelling argument is put forward by Biswajit Dhar, who purports that it is the availability of protection that decides its effectiveness. Dhar suggests that the

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[138] UPOV, 'Mission Statement' available at http://upov.int/about/en/mission.html (accessed: 15th July 2020). This phrase is missing from the previous Enactments. The previous 1961 and 1978 Enactments merely describe the purpose of the Union as being 'to recognise and to ensure to the breeder of a new plant variety ... a right' (article 1.1).

[139] Sean C. Butler, *A guide to UK and EU plant variety rights* (Cambridge, Cambridge University Press, 2005) at 1

[140] Leskien & Flitner, n137 above, at 32

[141] Association Internationale des Sélectionneurs pour la Protection des Obtentions Végétales (Association of Plant Breeders for the Protection of Plant Varieties)

[142] ASSINSEL, 'Fostering Plant Innovation: A brief on Review of TRIPS art 27.3b' available through www.worldseed.org (accessed: 15th July 2020)

measure of an effective regime is one that offers protection for the largest number of new varieties. This is only possible if the system engages with the largest possible number of stakeholders in plant breeding, which should include formal plant breeders and traditional and small scale farmers. [143] This proposal holds weight when considered in the light of the much cited justification for the availability of IP protection in the sphere of plant breeding and indeed in general: that the availability of IPRs should stimulate innovation and lead to an increased number of available plant varieties. This in turn, should lead to a greater number of options available to address food security concerns. Furthermore, when combined with the minimal standards required of an intellectual property right, this definition of effectiveness is a useful tool for determining the most suitable implementation of art. 27.3(b) in a manner that is relative to the agricultural landscape of a given state. Using this effectiveness criterion, it appears obvious that states with predominantly industrial agricultural practices would adopt UPOV, whereas states with diverse or principally subsistence agricultural practices would have the freedom to engineer a unique solution.

When viewed in this light, the content of article 27.3(b) appears to be something of an achievement. Even though the wording of the provision originated from the developed economies of the European Community, *per se* the provision is sufficiently flexible to be adapted to developing states national needs and priorities. However, the regime has been criticised, primarily by developing states, for failing to address the wider issues associated with IP protection for biotechnology and plant breeding activities. Plant breeding based developments do not exist in isolation; but rather are intrinsically linked with biodiversity conservation and traditional resource rights especially for many genetically rich developing states. Accordingly, it has been argued that an 'effective *sui generis* system' is not only composed of a *sui generis* IPR but a collection of overlapping voluntary and non-voluntary obligations.[144] However valid this criticism may be, and given

[143] Biswajit Dhar, *Sui Generis Systems for Plant Variety Protection- Options Under TRIPS* (Geneva, Quaker United Nations Office, 2002) at 8

[144] Philippe Cullet 'Revision of the TRIPS Agreement concerning the Protection of Plant Varieties: Lessons From India Concerning the Development of a *Sui Generis* System' (1999) 2(4) Journal of World Intellectual Property 617 at 626

the existence of binding international agreements concerning access to and use of genetic resources[145] and the continued discourse on the protection of traditional knowledge,[146] its validity appears obvious, in its current format, it simply remains beyond the scope of the TRIPS Agreement. Nonetheless this does not excuse the lack of clarity on the relationship between these matters, which was raised during the review of art. 27.3(b).

2.6 Implementation and enforcement of TRIPS

As has been noted above, the TRIPS Agreement provides minimum standards for available IP protection and as such, relies upon individual member states implementation of the provisions. To that end, the Agreement contains several mechanisms intended to promote implementation and compliance. They are: transparency and compliance monitoring, dispute prevention and the dispute settlement mechanism.

Concerning transparency, art. 63.1 requires member states to publish all laws, regulations, final judicial decisions, and administrative rulings relevant to the subject matter of the Agreement, including bilateral agreements and other agreements. This primarily serves to facilitate the enforcement provisions of the Agreement (arts. 41-60).[147] Alongside which, art. 63.2 requires that member states notify the TRIPS Council of the laws and regulations outlined in art. 63.1, in order to facilitate its review of the operation of the Agreement. In addition, members have taken to providing a Checklist of Issues on Enforcement[148] to provide further information on how they are currently meeting obligations, given that much of the pertinent information is found outside IP law.[149] This information then provides the basis for review by the TRIPS Council, by means of question and response, and allows the development of a comprehensive picture about the implementation of IP laws at the national level.[150] It also allows examination by other

[145] See, chapters four and five, below
[146] See, WIPO, 'Traditional Knowledge' http://www.wipo.int/tk/en/ (accessed: 15th July 2020)
[147] Jerome H. Reichman, 'Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement' in Correa and Yusuf (eds) n87 above, at 68
[148] Document IP/C/5
[149] Taubman, Wager & Watal (eds), n102 above, a 31
[150] Antony Taubman, *A Practical Guide to Working with TRIPS* (Oxford, Oxford University Press, 2011) at 120

members via the same medium.[151] This provides member states with the opportunity to seek advice on their implementation of TRIPS provisions, but the continued review of national law also gives member states the opportunity to address identified issues and to avoid potential formal action at a later stage.

Art.64 provides the so called 'teeth of TRIPS';[152] as it applies Articles XXII and XXIII of the GATT 94 as applied and elaborated upon by the Dispute Settlement Understanding (DSU) to disputes arising under the TRIPS Agreement. Non-compliance with TRIPS does not produce an automatic response; rather it is necessary for another member state to be sufficiently concerned by a states IP laws and practice to raise a dispute with the Dispute Settlement Body. A finding of non-compliance exposes states parties to trade sanctions, even though in practice the threat is rarely felt, as thus far the WTO has not authorised sanctions for non-compliance with TRIPS. During the negotiation of the Agreement, there existed widespread concern among developing states about the use of the DSU as a mechanism by developed states to leverage stronger IP protection and to legitimize trade retaliation.[153] However, its impact has not been as severe as anticipated.

The primary reason for this is that in combination with the review mechanism, the TRIPS Council advocates a dispute prevention rather than settlement approach.[154] The dispute settlement procedures begin with a mandatory consultation period of at least sixty days before the dispute proceeds to a dispute settlement panel. During which, member states are encouraged to find a resolution to their dispute. Thus, the dispute settlement procedure aims to avoid formal disputes where possible. Secondly, in practice, developing states have not been targeted for dispute settlement in the way in which it was originally imagined; the majority of disputes that have reached a dispute settlement panel have in fact been complaints between developed economies.[155] Third, in the evaluation of developing states intellectual property regimes, it is necessary to take in to consideration

[151] Taubman, Wager & Watal (eds), n102 above, at 32
[152] Taubman, n150 above, at 130
[153] Mohamed Omar Gad, 'TRIPS Dispute Settlement and Developing Country Issues' in Correa and Yusuf (eds) n87 above, at 332
[154] Matthew Kennedy, *WTO Dispute Settlement and the TRIPS Agreement: Applying Intellectual Property Standards in a Trade Law Framework* (Cambridge, Cambridge University Press, 2016) at 72-74
[155] See, WTO, 'Disputes by Agreement- Intellectual Property (TRIPS)' available at https://www.wto.org/english/tratop_e/dispu_e/dispu_agreements_index_e.htm (accessed: 15th July 2020)

arts. 7 and 8 of the Agreement, concerning its objectives and principles. These provisions provide an overall framework for judging the adequacy and effectiveness of intellectual property regime; serving to balance available protection for rights holders against measures undertaken for social and economic welfare.[156] Accordingly they may provide 'a shield' for defending choices made in the implementation of art. 27.3(b)

Taubman notes that while emphasis is often placed on the Dispute Settlement Understanding, in practice it is rarely used. Conversely, while the transparency provisions are largely overlooked, they are in fact extensively used.[157] Nonetheless, given the past willingness of member states such as the US to utilize trade sanctions to enforce IP compliance and the ambiguity of surrounding the wording of art. 27.3(b), the threat of formal action under TRIPS undoubtedly feels very real and as such, is likely to impact the choices made by developing states in implementing the provision.

2.7 Summary

It is clear from the early sections of this chapter that the standards set by the TRIPS Agreement largely reflect the IP standards of western states, such as the United States and the member states of the European Union. The wording of article 27.3(b) has left the scope of the article and its obligations open to considerable debate. These questions, which include the relevance of articles 7 and 8 TRIPS in the interpretation of article 27.3(b), have not been adequately addressed either through the formal review process for the article or by the Dispute Settlement Body. Therefore, we must deduce that article 27.3(b) grants states considerable freedom in how they interpret and implement the provision. States are given the choice between patent protection for plant-based innovations and an effective *sui generis* system of intellectual property protection, or both. Yet there exist different interpretations as to what constitutes an 'effective *sui generis* system' of IP protection. On examining the arguments, it is obvious that the only qualities that can be attributed to an effective system of *sui generis* IP protection under TRIPS is the availability of an intellectual property right that satisfies the minimum

[156] Yusuf, in Correa & Yusuf (eds) n87 above, at 13
[157] Taubman, n150 above, at 117

substantial rights required under TRIPS and allows for effective action against infringement.

Thus, states which opt for *sui generis* protection for plant-based innovations are left with the option to choose between adopting UPOV standards for plant variety protection, or to develop their own regime in line with their needs and priorities. However, in recent years, bi- and multilateral trade agreements have been used to force states into acceding to the UPOV system, even where it may not be the best option for a given state. Therefore, while the minimum standards approach of TRIPS provides considerable freedom, the reality is that states option in implementing article 27.3(b) may be limited by other political and economic factors.

Chapter 3 - The Conventions of the International Union for the Protection of New Varieties of Plants

3.1 - Introduction

The various conventions of the International Union for the Protection of New Varieties of Plants[158] (UPOV) are to date, the only international instruments that pertain to the protection of plant-based innovations. As a result, acceding to the UPOV regime is the *de facto* default option for compliance with article 27.3(b) TRIPS. In the context of this investigation into the role of intellectual property (IP) protection in developing underutilised crop varieties, this creates several fundamental questions that must be addressed. First, what is plant variety protection (PVP), the intellectual property right for plant-based innovations available under the UPOV regime, and what types of plant-based innovations does it support? Second, does the UPOV system constitute an effective *sui generis* system of protection for plant-based innovations, as required by article 27.3(b)? In considering this, it is essential to recall from the previous chapter that the only qualities that it is possible to ascribe to an 'effective *sui generis* system of intellectual property protection' is the availability of minimum substantial rights which allow for effective action against infringement. Third, is there a relationship between UPOV plant variety protection and addressing food security concerns?

In order to begin to answer these questions, it is necessary to explore the origins and development of this unique IP right. The first part of this chapter will broadly consider the history and the development of the UPOV regime, including its membership and institutions. It will then examine the construct of a 'plant variety' and 'plant variety protection'. The second part of the chapter will explore the content and scope of UPOV plant variety protection and will also serve to lay the groundwork for the discussion in chapter six. Finally, the third part of the chapter will then return to discuss the possible links between UPOV and addressing food insecurity.

[158] Original French: *Union internationale pour la protection des obtentions végétales*

3.2.1 Background to the UPOV Conventions

Modern plant variety protection is essentially European in origin. The idea of protecting plant varieties through a specialist intellectual or industrial property right emerged around the late 19th and early 20th century, at the same time that plant breeding was emerging as a scientific discipline.[159] Initially, there were several unsuccessful attempts to introduce specialist protection for plant varieties in France and Germany.[160] This began to change around the 1920s with some countries, such as Germany[161] and the US,[162] adapting their patent laws to accommodate plants.[163] At the same time, a number of countries[164] began to offer patent protection for plant varieties through ordinary patent law, although evidence suggests that the number of applications and grants was quite limited.[165]

Other countries began to offer different formats of legal protection for varieties. For example, in France protection was made available through a licensing regime based upon a combination of trademarking and official seed certification.[166] However, this did not amount to a state-granted property right.[167] It also became common for breeders in a number of European states to seek trademark protection as a means of achieving exclusivity over their variety.

Towards the middle of the 20th century, new forms of intellectual property protection for plant varieties began to emerge that would lay the foundation for the modern plant variety protection. In 1941, the Netherlands adopted the Plant Breeders' Decree which offered protection to varieties which were new and sufficiently homogenous.[168]

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[159] Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung (Federal Ministry for Economic Cooperation and Development of Germany, or BMZ), *The UPOV Convention, Farmers' Rights and Human Rights: An Assessment of Potentially Conflicting Legal Frameworks* (Deutsche Gesellschaft für Internationale Zusammenarbeit GMBH, 2015) at 21
[160] Margaret Llewelyn & Mike Adcock, *European Plant Intellectual Property* (Oxford, Hart Publishing, 2006) at 136-137
[161] Decision of 19 September 1932, GRUR 1932 1114
[162] The Plant Patent Act of 1930, 35 U.S.C. Ch. 15
[163] Llewelyn & Adcock, n160 above, at 136-137
[164] Examples include: Belgium, France, Germany, Italy, Spain, Sweden and the United Kingdom, among others
[165] Sean C. Butler, *A guide to UK and EU plant variety rights* (Cambridge, Cambridge University Press, 2005) at 7-8
[166] ibid, at 8
[167] Llewelyn & Adcock, n160 above, at 139
[168] Plant Breeders' Decree of the Netherlands "Kwerkersbesluit" 1941; see: Butler, n165 above, at 6

Similarly, Germany introduced the Seed Law of 1953[169] which created protection for plant varieties that were distinct, stable and of agricultural value.[170] As such, these were limited forms of plant variety protection.[171]

The concerns over food security that emerged all over Europe in the aftermath of the Second World War were the impetus for the development of a coordinated approach to IP protection for plant varieties. It was generally held that the development of new, more productive crop varieties would secure food production, and that IP protection for plant varieties would encourage this. Thus, the correlation between the availability of IP protection for plant varieties and addressing food security concerns has existed for a considerable period of time; and was a catalyst for the UPOV regime.

The actual process that would lead to the original UPOV Convention began in 1956 when the International Association of Professional Plant Breeders (ASSINEL)[172] raised its concerns about the lack of opportunities for the reward of plant breeders' efforts with the French government.[173] This led to the First Diplomatic Conference in 1957 on the protection of new plant varieties. This was attended by twelve European states,[174] alongside United International Bureau for the Protection of Intellectual Property (BIRPI)[175], the UN Food and Agriculture Organisation (FAO) and the Organisation for European Economic Cooperation (OEEC). The first Conference did not yield an agreement but laid the foundation for further preparatory work.[176] Most notably, it was agreed that plant varieties should be protected by a new, *sui generis* intellectual property right rather than attempt to accommodate plant-based innovations through the revision of existing patent laws. The Conference parties recognized of the difficulty of applying the traditional criteria for patentability to plant-based developments.

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[169] Gesetz über Sortenschutz und Saatgut von Kulturpflazen BGB ('Act on the Protection of Varieties and Seeds of Cultured Plants') June 27, 1953
[170] Butler, n165 above, at 6-7
[171] S. A. Bent, *Intellectual Property Rights in Biotechnology Worldwide* (Basingstoke, Macmillan, 1987) at 45
[172] *Association Internationale des Sélectionneurs pour la Protection des Obtentions Végétales*, now part of the International Seed Federation (ISF)
[173] Butler, n165 above, at 11
[174] Austria, Belgium, Denmark, France, the Federal Republic of Germany, Holland, Italy, Norway, Spain, Sweden, Switzerland, and the United Kingdom took part in the First Conference
[175] *Bureaux Internationaux Réunis pour la Protection de la Propriété Intellectuelle*
[176] UPOV, 'History, Development and Main Provisions of the UPOV Convention' (1987) 7(8) Industrial Property 320 at 320

During the interim period between the Conferences, a series of expert meetings took place. The subject of these meeting was discerning the substance of the new IP right, and the criteria for its grant. Attention was also given to the question as to whether the subject matter of plant varieties should fall within the scope of the Paris Convention.[177] It was felt among participants that the products of agricultural plant breeding should not be the subject of an industrial property right. Therefore, plant varieties would become the subject of a new convention.[178]

A second Diplomatic Conference took place in 1961. This Conference was attended by representatives from the European Community (EC), the International Association for the Protection of Intellectual Property (AIPPI),[179] the International Community of Breeders of Asexually Produced Ornamental and Fruit Varieties (CIOPORA),[180] and Federation of the International Seed Trade (FIS).[181] Thus, the draft Convention under consideration at the Conference reflected the view of all of the major stakeholders in European plant breeding. Its draft was adopted subject to non-substantive amendments.[182]

The first UPOV Convention eventually came into force on 26th November 1968 upon its ratification by the Federal Republic of Germany. It is important to note that it was not the purpose of the UPOV Convention to create plant variety rights *per se*, but rather to establish a set of common principles for national PVP regimes that could be harmoniously implemented.[183] Indeed, this continues to be the case: the UPOV Enactments set the standard for plant variety protection in its member states. This point will be returned to in section 3.4.

[177] Paris Convention for the Protection of Industrial Property (20 March 1883, Paris, France). The Paris Convention applies to Industrial Property in the widest sense. Its subject matter includes patents, trademarks, industrial designs, utility models, service marks, trade names, geographical indicators, and the repression of unfair competition.
[178] Llewelyn & Adcock, n160 above, at 144-145
[179] *Association Internationale pour la Protection de la Propriété Intellectuelle*
[180] *Communauté Internationale des Obtenteurs de Plantes Ornamentales et Frutières à Reproduction Asexuée*
[181] *Fédération Internationale du Commerce des Semences.* Also now part of the ISF
[182] Llewelyn & Adcock, n160 above, at 145
[183] Butler, n165 above, at 11

3.2.2 Historical development of the UPOV Enactments

Similar to other international instruments in the sphere of IP protection, such as the Paris Convention and the Berne Convention,[184] the UPOV Convention has been subject to three revisions. These took place in 1972, 1978 and 1991. The adjustments made by the 1972 Enactment were limited to the administrative aspect of the treaty and therefore, do not merit discussion here.[185] The 1978 Enactment introduced substantive changes to the Convention. These included the expansion of plant breeders' rights.[186] The amendments were also intended to facilitate the accession of certain states, most notably the US, to the Convention.[187] In particular, the introduction of a provision allowing plant varieties to be protected under both PVP and patent regimes.[188] Broadly speaking, the changes introduced in the 1991 Enactment serves to strengthen plant breeders' rights and widen the scope of the Convention. These changes were made necessary by the considerable advances in the plant bioscience industry and the field of genetic engineering in the time between the two Enactments. It is worth noting at this stage that in the drafting of the 1991 Enactment, that the drafters opted to describe it as '*effective*[189] system of plant variety protection'.[190] The choice of this particular descriptor is not surprising given that the 1991 Enactment was being drafted during the same period of the TRIPS Agreement; it appears to be a deliberate choice to brand itself as a solution to implementing article 27.3(b).

States parties continue to be bound to the Enactment to which they acceded, unless they chose to ratify a later Enactment. Thus, there exist discrepancies between the standard of plant variety protection adopted by UPOV members across the UPOV system. A few states remain party to the 1961/1972 Enactment. The option to accede to the 1978 Enactment remained available until the 1991 Enactment came into force.[191] Thus both

[184] Berne Convention for the Protection of Artistic and Literary Works (9 September 1886, Berne, Switzerland)
[185] More specifically, the changes made by the 1972 Enactment concerned voting procedures and the system of contributions, see Jördens, n192 below, at 233-234
[186] Butler, n165 above, at 26
[187] UPOV, n176 above, at 321
[188] UPOV 1978, art.37
[189] Emphasis added
[190] UPOV, 'Mission Statement' available at http://upov.int/about/en/ (accessed: 15 July 2020)
[191] UPOV 1991, art. 37(3)

texts continue to be relevant. Therefore, the substance of both the 1978 and 1991 Enactments is discussed in this chapter.

3.2.3 Membership of the UPOV Convention

After the entry into force of the original convention, membership was more or less confined to the initial European states parties. This continued, with only ten members of the Union by the time that the second set of revisions to the Convention was beginning to be discussed in 1978.[192] The modifications made by the 1978 Enactment served to entice an increase in uptake of the UPOV system.[193] However, membership remained limited throughout the 1980s and 1990s, during which time the Convention came under considerable criticism for being an 'outmoded impediment'.[194] The more substantial amendments made by the 1991 Enactment were in part, effected in order to address these criticisms. Additionally, the period in which it was possible to choose to accede to either the 1978 or 1991 Enactments was intended to entice further membership.

At present, there are 76 states and organisations that are party to the Conventions;[195] and 20 states and one organisation in the process of acceding to the Convention.[196] A further 24 states and one organisation have requested assistance from the Office of the Union in developing law based on the UPOV system.[197][198] Thus, while considerable, membership is far from universal.

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[192] Rolf Jördens, 'Progress of plant variety protection based upon the International Convention for the Protection of New Varieties of Plants (UPOV Convention)' 2005 (27) World Patent Information 232 at 234; Jördens also notes however, that 27 non-member states were involved with the discussions for the 1978 revisions. 18 of which, have since become states parties

[193] ibid, at 236

[194] William Cornish, *Intellectual Property: Patents, Copyright, Trademarks and Allied Rights* (London, Sweet & Maxwell, 2nd ed, 1989); see also Llewelyn, n216 below, generally

[195] UPOV, 'Membership of the International Union for the Protection of New Varieties of Plants- status February 3, 2020' available at https://www.upov.int/edocs/pubdocs/en/upov_pub_423.pdf (accessed 4th July 2020)

[196] UPOV, 'Status in Relation to the International Union for the Protection of New Varieties of Plants (UPOV) *as of April 28, 2020'* available at http://upov.int/export/sites/upov/members/en/pdf/status.pdf (accessed 4th July 2020)

[197] ibid

[198] It should be noted that states that have requested assistance from the UPOV office may not necessarily on a path to UPOV membership: for example, Thailand has requested technical and legal assistance, however it also has developed a comprehensive plant variety protection regime (Plant Varieties Protection Act B. E. 2542 (1999)) that contains provisions for alternative forms of plant variety protection. Subject to art. 5(2) of UPOV 1991, the existence of these alternative plant variety protection precludes Thailand from being granted membership status.

Unsurprisingly, there has also been gradual uptake in membership since the entry into force of the TRIPS Agreement. Some of this has been voluntary accession undertaken by states as a solution to fulfilling their obligations under article 27.3(b) TRIPS. However, as noted previously in chapter two,[199] a considerable percentage of the uptake is the product of bilateral or regional trade or investment agreements,[200] or TRIPS plus agreements. The effect of this is that states and organisations that had previously been resistant to the UPOV regime due to its substantive content have been obliged to join the regime.[201] Thus, although the Convention's membership has moved away from its Eurocentric roots, this is not necessarily an indication of a shift in values. Rather, it signals the global export of the UPOV system. The result of this is that states that have adopted UPOV as a result of external obligations may find themselves with a protection system for plant varieties that does not necessarily reflect their needs.

It is important to note, that just because states are not parties to the UPOV regime, does not necessarily mean that UPOV style plant variety protection is not available in that state. This may be because the state in question has not elected to join the UPOV system. This is the case in India: protection for new varieties[202] tracks the UPOV requirement for PVP.[203] Alternatively, it may be that the state is in conflict with the UPOV over other aspects of its PVP regime. This is the case in Malaysia and will be returned to in chapter six.

3.2.4 UPOV Institutions

The permanent organs of the Convention are the UPOV Council and the UPOV Office.[204] The Council consists of a representative of each member of the Union[205] and is responsible for, *inter alia*, encouraging the development of the Union,[206] and other tasks

[199] See, section 2.4 above
[200] Laurence R. Helfer, *Intellectual property rights in plant varieties: International legal regimes and policy options for national governments* (Rome, FAO, 2004) at 30
[201] Helfer, n200 above, at 30
[202] Protection of Plant Varieties and Farmers Rights Act 2001, s. 15
[203] Srividhya Ragavan & Jamie Mayer O'Shields, 'Has India Addressed Its Farmers' Woes- A Story of Plant Protection Issues' [2007] 20 Georgetown International Environmental Law Rev 97 at 111
[204] UPOV 1991, art. 25
[205] UPOV 1991, art. 26(2)
[206] UPOV 1991, art. 26(5)(i)

as necessary for the functioning of the Union.[207] *Prima facie*, the role of the Office is simply to carry out the tasks assigned to it by the Council.[208] Despite this vague mandate, the Office is an organ of considerable importance within the UPOV system.

It is responsible for producing and implementing numerous substantive aspects of the UPOV system that are not contained within the enactments. This includes the production of the DUS Test Guidelines;[209] thus the UPOV office effectively sets the standards for plant variety protection. The UPOV Office issues Explanatory Notes which present an official interpretation of many important issues.[210] It also reviews the PVP regimes of member states and potential member states and assesses their compatibility with the UPOV enactments. It provides guidance how to integrate UPOV standards into state parties' national PVP regimes prior to approval for the grant of membership. Thus, the Office wields considerable power within the UPOV system, as it sets the standard for PVP for its members. It is important to bear in mind that the standards set by the Office are not strictly derived from the text of the Convention itself, but upon how it has been interpreted by the Council and the Office. Accordingly, the Office has the opportunity to determine how plant variety protection is developed across the UPOV system. This point will be returned to in section 3.3.5 below.

3.2.5 'Plant varieties'

As is outlined above, the concept of plant variety protection is a product of the UPOV regime. Under the original enactment 'plant variety' was defined as 'any cultivar, clone, line, stock or hybrid which is capable of cultivation and which satisfies' the provisions of art. 6(1)(c) and art. 6(1)(d): namely, homogeneity and stability. The focus on plant

[207] UPOV 1991, art. 26(5)(x); see art. 26 generally
[208] UPOV 1991, art. 27(1)
[209] 'Test Guidelines' is a general term for the technical documentation produced by the UPOV Office in order to support member states implementation of the technical aspects of the UPOV system which are not detailed in the text of the Convention. These include, *inter alia,* the 'General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants' available at http://www.upov.int/export/sites/upov/resource/en/tg_1_3.pdf (accessed: 15th July 2020) and more specific guidance targeted towards particular plant species.
[210] ibid, at 49-50

varieties is unique to the UPOV system, as opposed to traits genes or breeding techniques which may be the subject of other forms of intellectual property right.[211]

A definition of the term is not present in the 1978 Act. The reason for this is that there existed sufficient consensus among plant breeders as to what constituted a plant variety.[212] Interestingly, AIPPI noted that the absence of a definition had not caused any difficulties.[213] A definition returned in the 1991 Act. The motivation for its reintroduction was the increased need to demarcate UPOV based plant variety laws from patent law. Changes in science and technology, along with the increased use of patent protection for plant-based innovations had caused the boundary between the two to blur in the time period between the Enactments.[214] Art. 1(iv) of the 1991 Enactment defines a plant variety as:

> 'a plant grouping within a single botanical taxon of the lowest rank, which irrespective of whether the conditions for the grant of a breeder's right are fully met, can be:
>
> defined by the characteristics resulting from a given genotype or combination of genotypes,
>
> distinguished from any other plant grouping by the expression of at least one of the said characteristics and
>
> considered as a unit with regard to its suitability for being propagated unchanged'

A variation in the lowest botanical taxon is, in scientific terms, known as a cultivar. Thus, the concept of a 'plant variety' is a legal rather than scientific. This is an essential point to note: the drafters of the UPOV Conventions invented the notion of the plant variety. Thus, not only has UPOV invented both the constructs of plant varieties and plant variety protection, but it also sets the criteria against which they are judged. It is particularly important not to lose sight of this point when considering the alternatives to UPOV.

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[211] BMZ, n159 above, at 18
[212] Llewelyn & Adcock, n160 above, at 161
[213] Jay Sanderson, *Plants, People and Practices: The Nature and History of the UPOV Convention* (New York, Cambridge University Press, 2017) 124
[214] ibid, at 125

It is also necessary to observe the inclusion of the phrase 'irrespective of whether the conditions for the grant of a breeder's right can be fully met'. Thus, the regime foresees the existence of varieties that do not meet the thresholds for plant variety protection, or alternatively, the existence of unregistered varieties. This is a deliberate feature of the drafting of the provision.[215] The existence of varieties that are not suitable for registration is necessary to accommodate the newly included concept of essentially derived varieties. Varieties that are unsuitable for registration may also be useful in assessing the novelty and distinctiveness of applicant varieties.[216] Therefore, the recognition of varieties that are unsuitable for registration serves a functional role in the UPOV system. However, it does raise the issue as to whether these varieties are capable of being the subject of other types of IPR. This issue will be returned to section 3.3.5 below, and in chapter six.

3.2.6 Plant variety protection vs. plant breeders' rights

Generally speaking, the terms 'plant variety protection' and 'plant breeders' right' are considered to be interchangeable. However, an interesting point noted by Margaret Llewelyn is that there has been a gradual shift in use of terminology from plant breeders' rights towards plant variety protection. She observes that this is likely a result of developments in breeding technology and in a shift in the perceived value of plant breeders' work being the subject of importance towards plant varieties as material.[217] Alongside which, there has been a transformation, although not universal, of the commercial plant breeder from a small scale enterprise to multi-national companies.[218] Thus, she argues that a reversal of emphasis has taken place, and rather than the UPOV system favouring a specific interest group, it now protects a specific type of valuable material regardless of its origin.[219]

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[215] ibid
[216] Margaret Llewelyn, 'From 'outmoded impediment' to global player; the evolution of plant variety rights' in David Vaver and Lionel Bently (eds) *Intellectual Property in the New Millennium: Essays in honour of William R. Cornish* (Cambridge, Cambridge University Press, 2004) at 140
[217] ibid, at 144-145
[218] Llewelyn, n216 above, at 145
[219] Llewelyn, n216 above, at 146

This is interesting, because it provides clear evidence that the UPOV system treats plant breeding as a commercial industry, rather than as a practice undertaken by individual, farm-based innovators. It reflects the scientific and technical developments that have taken place in the sphere of agricultural innovation.

The point of these comments is not to suggest that one term is more appropriate than the other; it is simply to highlight that the shift in emphasis towards the value of the product rather than the owner of the IPR is reflective of the direction taken by UPOV since its inception.

3.3 Plant variety protection available under UPOV 1978 and UPOV 1991

3.3.1 Protectable subject matter

Under the 1978 Enactment, all botanical genera and species may be the subject of PVP as defined by the Convention.[220] States parties were required to apply the Convention to at least five genera or species at the time the Convention entered into force;[221] with a view to eventually applying the provisions of the Convention to as many genera or species as possible.[222] To that end, the 1978 Enactment sets out a timescale for the gradual inclusion of further genera or species.[223] There is no requirement to introduce protection for any specific genera or species; this can be determined in line with national needs and priorities. Thus, the 1978 regime proposes a fairly gentle submersion into the waters of plant variety protection.

On the other hand, the 1991 Enactment requires 15 genera or species to be eligible for protection at the time of entry into force of the Convention;[224] and the provisions of the Convention to apply to all genera or species within 10 years.[225] The all-encompassing approach taken in the 1991 Convention can be considered problematic for lower and middle income states parties.[226] This is because is likely to be onerous on the state organs

[220] UPOV 1978, art.4(1)
[221] UPOV 1978, art. 4(3)(a)
[222] UPOV 1978, art. 4(2)
[223] Subject to UPOV 1978, art. 4(3)(b), states parties are required to expand protectable genera or species as follows: ten within three years; 18 within six years; and 24 within eight years. This may be reduced for prevailing ecological or economic conditions, subject to the approval of the UPOV Council (art. 4(4))
[224] UPOV 1991, art. 3(2)(i)
[225] UPOV 1991, art. 3(2)(ii)
[226] See, section 6.2 below

responsible for the implementation of UPOV and the grant of PVP as they may not have sufficient technical expertise in many genera or species. This includes both the development of appropriate testing guidelines and the availability of examiners with the expertise necessary to evaluate applicant varieties. Indeed, it can delay the entry into force of a PVP regime considerably.[227]

This is somewhat mitigated by the support of the UPOV office in compiling and disseminating technical guidelines for many genera and species which are regularly updated.[228] It is also anticipated that there will be a level of technical cooperation and information sharing between the rights granting offices of states parties. This includes the option to purchase Reports on Examination conducted by other members.[229] This should be of some benefits to states which do not have the capacity or expertise for field testing certain species. It may offer a shortcut to member states to give effect to their PVP regime by providing them with the means to offer PVP for a sufficient number of species for the state to meet its obligations under UPOV. However, the effect of this will be limited, as this will ultimately need to be supported by adequate scientific and technical expertise as well as testing capacity.

Whether or not the approach adopted by UPOV 1991 is considered to be burdensome, it is necessary to emphasise that the listing of genera and species for protection is a crucial feature of the UPOV regime. In chapter two it was concluded that the only features that can definitively be attributed to *sui generis* IP protection for plant varieties are the availability of a minimum substantial right and the effective means for enforcing that right. Thus, making protection available for at least a minimum number of plant species or genera is necessary for PVP to meet the criterion of effective under TRIPS.[230] Without it, the principles of plant variety protection are meaningless. It is arguable that without the inclusion of the minimum number of varieties, that a state party

[227] For example, the Malaysian Protection of New Varieties of Plants Act 2004 did not enter into force for four years
[228] Llewelyn & Adcock, n160 above, at 169
[229] Sanderson, n213 above, at 176
[230] It is worth noting that this is an issue from which traditional IPRS (copyright, patents and trademarks) are exempt.

would fail to meet its obligations under article 27.3(b) TRIPS, even if it had otherwise implemented appropriate plant variety protection legislation.

It is not possible to predict how many species would need to be included in a PVP regime in order for it to be considered to be truly effective. When viewed in the light of the efficacy requirement, the push towards including as many varieties as possible makes a greater degree of sense. Even so, the push towards including all genera and species within a 10-year period in the 1991 Enactment still appears to be unnecessarily taxing as opposed to the aim to include as many varieties as possible, espoused in its predecessor.

3.3.2 Content of a plant breeders' right

Generally speaking, the focus of plant variety protection is the control over commercial dealings with reproductive material.[231] Under the 1978 Enactment, PVP offered the breeder of a plant variety an exclusive right over the production for the purposes of commercial marketing; offering for sale; or marketing of the propagating material of the protected variety.[232] The breeder may authorise third party use subject to whatever conditions they deem appropriate.[233] States parties are given the option to allow more extensive protection over certain varieties, such as the marketing of specific products derived from plant varieties.[234]

The 1991 Enactment extends plant variety protection to include, in addition to the above, the production or reproduction; conditioning for purposes of propagation; exporting; importing; or stocking of a protected variety.[235] It also broadens protection to include harvested material acquired through propagation;[236] and products made directly from harvested material,[237] where harvested material has been acquired without the breeders' permission.

[231] Butler, n165 above, at 16-17
[232] UPOV 1978, art. 5(1)
[233] UPOV 1978, art. 5(2)
[234] UPOV 1978, art. 5(4), art. 29
[235] UPOV 1991, art. 14(1)(a)
[236] UPOV 1991, art. 14(2)
[237] UPOV 1991, art. 14(3)

3.3.3 Limitations of plant variety protection

i) Public interest: Both the 1978 and the 1991 Acts allow states parties to restrict a breeders' right for the purposes of public interest; provided that where the restriction is made to ensure widespread distribution of the variety all possible measures are taken to remunerate the breeder.[238]

ii) Research exemption: The 1978 Act permitted the use of a protected variety for the purposes of the initial development of a new variety but restricted its use for commercial production without the breeders' authorisation.[239] The 1991 Enactment better explicates the 'acts for research purposes' as being acts done privately and for non-commercial purposes; acts for experimental purposes; and acts for the purpose of breeding other varieties.[240]

iii) Essentially derived varieties: The 1991 Enactment introduces the concept of an essentially derived variety (EDV). An essentially derived variety is defined as being clearly distinguishable from the original variety, while being predominantly derived from the initial variety[241] and displaying the essential characteristics of the first variety, aside from the differences which mark the derivation. It has a number of purposes. Firstly, it serves to counter balance the exemption allowing the use of a registered variety for the purpose of breeding other varieties, as it prevents breeders from utilising a registered variety for the repeated production of another variety and thus exploiting the research exemption.[242]

Secondly, it serves to prevent the registration of varieties that are insufficiently distinct from the original variety.[243] It is pertinent to note that central to the idea of an essentially derived variety is that it is derived from a *single* registered

[238] UPOV 1978, art. 9
[239] UPOV 1978, art. 5(3)
[240] UPOV 1991, art 15(1)
[241] Or a first generation essentially derived variety
[242] UPOV 1991, art. 14(5)(a)(iii)
[243] UPOV 1991, art. 14(5)(a)(ii)

variety.[244] Thus, it does not include cross breeding the initial variety with another variety.[245] Third, it is intended to circumvent breeders' capitalising on registered varieties by altering them in such a manner as to make them distinct whilst the essential characteristic and thus their commercial appeal remains that of the original registered variety.[246]

Art 14(5) provides a list of possibilities as to how an EDV may come about. Examples of this include selection of a colour mutation from an ornamental variety or the insertion of a single gene via laboratory-based methods.[247] Beyond this, the Convention does not address what might constitute an EDV. UPOV has issued explanatory notes on essentially derived varieties[248] however this only makes a limited contribution to the discussion.[249] A number of different approaches to assessing EDV have been suggested by key organisations in the international plant breeding sphere. For example, the ISF has produced a 'Code of Conduct' for establishing genetic variation and the 'Regulation for the Arbitration of Disputes concerning Essential Derivation (RED)'.[250] Interestingly, while PVP itself remains strictly assessed on morphology, there are numerous suggestions that genotype should be a factor in assessing whether a variety constitutes an EDV. This, however, raises a number of technical concerns. The most prominent of which is: what percentage of genetic similarity is considered acceptable? Equally difficult to address is the practical aspect of establishing a database of extant varieties for comparison. As such, 'essentially derived varieties' is a hybrid legal/scientific concept, many of the details of which remain unresolved.

Thus, the key idea is that essentially derived varieties serve to prevent the narrowing of PVP. This should benefit to PVP holders. It is important to note

[244] Llewelyn & Adcock, n160 above, at 181
[245] ibid, at 183
[246] UPOV 1991, art. 14(5)(i)
[247] Barry Greengrass, 'The 1991 Act of the UPOV Convention' [1991] EIPR 466 at 470
[248] UPOV Council, 'Explanatory notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention' 6th April 2017, available at: http://www.upov.int/edocs/expndocs/en/upov_exn_edv.pdf (accessed: 15th July 2020)
[249] Sanderson, n213 above, at 9.3.3
[250] Available at (http://www.worldseed.org/wp-content/uploads/2015/10/RED_Arbitration_EDV.pdf (accessed: 15th July 2020)

however, that whether a variety can be considered to be an EDV is not to be determined by the examining office at the point of application. Rather it is for breeders themselves to regulate and resolve, either through negotiation or legal proceedings.[251] This is where the additional protection offered by the prohibition of EDVs may vary dependent upon the resources of the PVP holder, as the ability to enforce their right requires the PVP holder to have the resources to do so. To that end, it may even prove an issue for commercial plant breeders, as many are small and medium enterprises.

iv) Farmers' rights/seed saving exemption: The 1978 Enactment does not explicitly touch upon the idea of seed saving exemptions. However, this is largely because the idea of farmers' privilege was largely accepted at the time of drafting and is therefore generally considered to be implied into the text.[252] Thus, farmers remained at liberty to save and re-sow commercially acquired seed year on year. The 1991 Act adopted a more restrictive approach by explicitly addressed the issue. Art. 15(2) permits contracting parties to restrict breeders' rights in order to permit farmers to use protected material they have obtained from harvesting for propagating purposes on their own holdings within reasonable limits and safeguarding the legitimate interests of the breeder. This provision does not remove the possibility of farmers reusing seed year upon year; however, it does considerably restrict it. It leaves it open to contracting parties to determine what is a reasonable amount of seed reuse without remunerating the breeder. The fact that it is restricted to farmers' own lands indicates that saved seed must be for a non-commercial use.[253] The construction of the provision has the potential to impede on farm breeding activity, as it is impossible to separate breeding and seed production.[254] If restrictively interpreted, the provision has the potential to render

[251] Greengrass, n247 above, at 471
[252] Sanderson, n213 above, at 235
[253] Llewelyn & Adcock, n160 above, at 191
[254] BMZ, n159 above, at 7

some traditional farming practices illegal.[255] A common critique of art. 15(2) is that saving farm produced seed is an essential practice for small scale farmers and that the limitation placed on the seed saving exemption is likely to be to the detriment of the less affluent. Nonetheless, art. 15(2) does provide a potential safeguard for farmers' individual food production needs. Thus, the success of this balance is likely to be dependent upon the judgment of states parties in implementing the provision.

3.3.4 - Criteria for plant variety protection

There are four criteria for the grant of plant variety protection within the UPOV system; to be eligible a plant variety must be new, distinct, uniform and stable (DUS).[256] These are assessed on the basis of a technical examination executed by the national granting office.[257] In addition, there is the implicit criterion that varieties will be given a name on registration.[258] The DUS criteria will be considered in turn.

- New: The 1978 Enactment does not explicitly refer to novelty as a requirement but does prevent varieties that have previously been available for sale from being granted PVP. Under the 1991 Enactment, a variety is considered new if it has not been offered for sale in the territory of the state of application in the last year, or in another state in the last four years.[259] It is important to note that novelty here is not the same requirement as in patent law; rather it is an issue of commercial novelty.[260] This is made explicit by the clarification provided by art. 6 of the 1991 Act.[261] An issue that arises as a result of novelty being conceived in a strictly commercial sense is that unlike patent protection, it does not require the origin of the material used to develop the

[255] BMZ, n159 above, at 8
[256] UPOV 1991, art 5(1); UPOV 1978 art. 6
[257] Or, in certain cases, on the basis of data from a foreign national granting authority.
[258] UPOV 1978, art. 13; UPOV 1991, art. 20
[259] UPOV 1991, art. 6
[260] Llewelyn & Adcock, n160 above, at 172
[261] ibid

variety.[262] This leaves the potential for the appropriation of crop varieties which have not been commercialised, such as farmers' varieties.[263]

- Distinct: under both the 1978 and the 1991 Acts, a new plant variety is considered distinct if it is clearly identifiable by one or more important characteristics from any other variety in common knowledge (for example, having been entered in an official register of varieties) at the time of application.[264] "Characteristics" may be defined as morphological or physiological characteristics, and must be capable of precise description and recognition. Of special note is the qualification "important". This permits states parties to implement regulation that may prevent the frivolous grant of rights over a new variety with only minimal differences from existing protected varieties. It also serves to allow PVP offices to determine what characteristics are relevant to distinguishing a new variety on a species by species basis. As Butler points out, the distinctive characteristics of a rose are very different from that of a potato.[265] Broadly speaking, the issue of distinctiveness is a technical matter and therefore is generally based upon expert knowledge of a given crop variety.[266] Distinctiveness therefore, is largely a matter of science.

  The difficulty with the distinctiveness criterion is that while there may be a general understanding as to what constitutes 'common knowledge' for the purpose of assessing distinctiveness, there is no comprehensive frame of reference to ensure that this assessment is accurate. Possible solutions include collections of germplasm or cultivated varieties that would serve to aid the assessment as to whether a variety is common knowledge or not.[267] Indeed, the ISF has suggested one potential solution to

[262] Graham Dutfield, *Food, Biological Diversity & Intellectual Property: The Role of the International Union for the Protection of New Varieties of Plants (UPOV)* (Geneva, Quaker United Nations Office, 2011) at 8
[263] BMZ, n159 above, at 7
[264] UPOV 1991, art.7; UPOV 1978, art. 6(1)(a)
[265] Butler, n165 above, at 13
[266] The technical elaboration of the 'Distinct' criterion is to be found in the species appropriate test guidelines, either produced by the UPOV office (see n119 below) or national granting offices
[267] Llewelyn & Adcock, n160 above, at 164

this issue might be the establishment of a worldwide database of phenotypical descriptions of varieties in common.[268]

- Uniform: under the 1978 Act, a new variety should be "sufficiently homogenous", in particular relating to its reproductive or propagative characteristics.[269] The only modification made by the 1991 Act is that the requirement is that a variety is 'sufficiently uniform in its relevant characteristics'.[270] The difference appears to be minimal, although it is arguable that the 1991 version may in fact allow for a slightly looser interpretation of the criterion albeit subject to the requirements of the Test Guidelines. Alternatively, Llewelyn and Adcock suggest that the difference between the two enactments is actually representative of a shift towards a presumption of grant of PVP.[271]

  The uniformity criterion is clear cut, as it is essentially a technical issue to be assessed during the official examination. Nonetheless, it has the potential to be problematic for varieties developed for difficult cultivation environments; or for low input varieties which are prone to diversification based on environmental conditions and therefore risks hindering progress in this arena.[272]

- Stable: a new variety should be stable in its essential characteristics, and remain so through subsequent generations after repeated reproduction or propagation.[273] It is perhaps the most straightforward criterion. The assessment of stability of the essential characteristics is relative to the plant species in question. Therefore the provisions in the Conventions are deliberately vague as stability is a technical matter largely dealt within the Test Guidelines. In the same vein as uniformity, stability has the potential to prove problematic for varieties cultivated in difficult environments.

[268] ibid
[269] UPOV 1978, art. 6(1)(c),
[270] UPOV 1991, art. 8
[271] Llewelyn & Adcock, n160 above, at 168
[272] BMZ, n159 above, at 7
[273] UPOV 1991, art.9; UPOV 1978, art. 6(1)(d)

3.3.5 - Further limitation of criteria for plant variety protection

Aside from the criteria discussed above, UPOV explicitly mandates that protection can be subject to no further conditions provided the applicant complies with the formal requirements of the convention and pays the necessary fees.[274] This appears to be a reasonable restriction in order to ensure the predictability and consistency of plant breeders' rights across all parties to the UPOV system. However, the effect of this is to restrict contracting parties from offering other types of plant variety protection in their national frameworks.

Effectively, state parties are left with a choice. Either allow only plant variety protection for varieties that are able to meet the DUS criteria or be excluded from the UPOV system. This makes it very difficult for states parties to adapt their national regimes to meet their needs and priorities,[275] as it removes the possibility of protection for traditional or local varieties, or varieties not meeting the DUS criteria. This is even more problematic where a state party is obliged to implement UPOV as a result of TRIPS plus obligations.[276]

Malaysia provides a good example of this issue. The Protection of New Plant Variety Act 2004[277] contains two options for the protection of new varieties of plants. The first relies on DUS criteria and mimics UPOV style PVP.[278] The second is based on the separate criteria of Distinctiveness and Identifiability.[279] The criterion of identifiability is a lower threshold than that of uniformity and stability, as it only requires that an applicant variety possess one identifiable characteristic across a grouping.[280] The second type is only available to certain group, such as farmers, local communities or indigenous peoples;[281] and has a shorter duration of protection.[282] It is clear that this form of protection is aimed

[274] UPOV 1991, art. 5(2)
[275] BMZ, n159 above, at 6
[276] See, section 2.4 above
[277] Laws of Malaysia, Protection of New Plant Varieties Act 2004
[278] PNVP 2004, art. 14(1)
[279] PNVP 2004, art. 14(2)
[280] PNVP 2004, art. 14(3)(i)
[281] PNVP 2004, art. 14(2)
[282] PNVP 2004, art. 32(1)

at plant varieties incapable of fulfilling the DUS criteria, and that it is not intended to serve commercial plant breeders in the same way as traditional plant variety protection.

However, the availability of the alternative PVP is a significant hurdle to Malaysia's membership to UPOV as it contravenes the prohibition of further criteria for PVP. Indeed, in its assessment, the UPOV Council suggested that it would be more appropriate for the alternative DI protection to be the subject an entirely separate regime.[283] Yet this is not easily reconciled with UPOV's recognition of plant varieties that do not meet the DUS criteria. This issue is returned to in chapter seven.

This strict approach to what is allowed to be protected by members of the UPOV system emphasises again the commercial focus of UPOV style PVP. It raises doubts about UPOV's role in supporting innovation and potentially addressing food security concerns: if the only acceptable forms of plant-based innovations are those capable of meeting the DUS criteria, then the only way that it can be useful in addressing food insecurity is where the need can be met by commercial varieties

It is also arguable that this is to the detriment of the very people UPOV is intended to benefit, i.e. plant breeders. Once a variety is registered, the breeders' exemption serves to make it available for research purposes. Thus, by narrowing the scope of acceptable intellectual property protection for plant-based innovations, it can be asserted that UPOV is actually restricting the material available to breeders.

A related issue resulting from the prohibition of further criteria is that it prevents states parties from incorporating disclosure of origin or similar provisions into their plant variety protection regimes. This prevents UPOV based PVP systems from effectively controlling whether the material used in developing an applicant variety was legally obtained by the breeder. [284] This is not a necessary feature of an intellectual property regime, nor is it a strict requirement of an effective system of *sui generis* IP protection as discussed in chapter two. However, there have been repeated calls for increased cooperation and re-

[283] UPOV Council, 'Twenty-Second Extraordinary Session, Geneva, April 8, 2005. Examination of the Protection of New Varieties of Plants Act 2004 of Malaysia with the 1991 Act of the UPOV Convention' available at: http://www.upov.int/edocs/mdocs/upov/en/c_extr/22/c_extr_22_2.pdf (accessed: 15th July 2020)
[284] BMZ, n159 above, at 7

evaluation of the relationship between intellectual property rights and genetic resources and traditional knowledge.[285] The inclusion of such a requirement would allow UPOV members to develop PVP solutions that meet the broader definitions of effective *sui generis* protection and to proactively fulfil their obligations arising out of the Convention on Biological Diversity and its Nagoya Protocol. Thus, the restriction on further criteria appears to unnecessarily isolate the UPOV regime from the other interrelated and substantive obligations of contracting parties which may in turn make it difficult for states parties or potential states parties to effectively balance competing responsibilities.

3.4 UPOV as a tool for addressing food security concerns

It was observed in section 3.2.1 that one of the driving forces for the development of an intellectual property right for plant-based innovations was the food insecurity experienced in Europe in the post war period. One of the questions central to this research is whether IP protection for plant-based innovations is a useful tool for encouraging innovations and addressing food security concerns. To that end, the utility of UPOV in tackling food security concerns is considered here.

The answer from UPOV's vantage point appears to be a resounding yes. However, this is only true from a specific vantage point. In 2005, UPOV published its own study on the impact of introducing a system of plant variety protection, titled the 'UPOV Report on the Impact of Plant Variety Protection' (impact study).[286] The study describes the aim of the UPOV system as encouraging innovation in the field of plant breeding.[287] It is based upon five case studies of contracting parties[288] and considers the situation re commercial seed production in those countries before and after the introduction of UPOV PVP.

The study contains four key messages that are of interest to the present investigation. First, it notes that UPOV considers the availability of an effective system of PVP to be an impetus for the development of new varieties where there is commercial

[285] WTO Ministerial Conference, 'Doha Ministerial Declaration', 14th November 2001 available at: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm (accessed: 15th July 202)
[286] UPOV, 'Report on the Impact of Plant Variety Protection' (2005) available at: https://www.upov.int/edocs/pubdocs/en/upov_pub_353.pdf (accessed: 15th July 2020)
[287] ibid, at 11
[288] The contracting parties are Argentina, China, Kenya, Poland and the Republic of Korea.

viability for those varieties.[289] There are two important points to note here: the first is the explicit link between commercial viability of varieties and the usefulness of IP protection for plant varieties. This emphasises the fact that UPOV PVP is in fact aimed at industrial agriculture. The second is that UPOV itself does not consider IP protection to be an adequate stimulus for plant-based innovation. This is a direct contradiction of the position taken by the Global Forum for Agricultural Research (GFAR),[290] and appears to somewhat contradict the original aims of the Convention. However, as Butler points out, one of the original purposes of the UPOV system was to address the need to protect staple cereal crops or *grandes cultures,* with rights for other breeders as a positive by-product.[291] Thus, although UPOV has its origins in food insecurity, it is not necessarily the same food insecurity that might be addressed by underutilised or niche crop species. This is supported by the evidence in the impact study of the increased availability of commercial staple crops in Poland[292] and China.[293] Thus, UPOV PVP is a market driven, industrial property right. Therefore, by-products such as greater innovation and increased food security are secondary to the regime.

Second, it argues that the introduction of a UPOV PVP system has brought about an increase in available germplasm in the countries analysed.[294] Specifically, it suggests that PVP brings about increased foreign germplasm and that this supports plant-based innovation. It is almost impossible to substantiate the veracity of this claim, as to do so would require proving a counterfactual. However, if this is the case, then the success of UPOV in stimulating innovation relies upon the global implementation of UPOV style PVP. This is because the increased flow of foreign germplasm is necessarily dependent upon protected plant varieties being developed elsewhere, and subsequently being available to developers under the breeders' exemption.

[289] UPOV, n286 above, at 11
[290] See, section 1.1.3 above
[291] Butler, n165 above, at 13
[292] UPOV, n286 above, at 15. Increased uptake in Poland of crops including potatoes, tomatoes, and ornamental varieties.
[293] UPOV, n286 above, at 47. Increased registration of species including maize, peonies, and rice
[294] UPOV, n286 above, at 13

Third, the impact study makes it clear that even though it may be a commercially oriented intellectual property right, UPOV style PVP can still be a useful tool for supporting developments in underutilised crop species provided that there is a commercial market for that crop species in the state in question. For example, varieties of crops which are generally considered to be underutilised, such as sorghum and lucerne, are the subject of plant breeders' rights in Argentina. This is because they are mainstream crops in Argentina.[295] This again, reinforces the link between the utility of PVP and a commercial market for a crop species. This is also true for millet and sorghum in Kenya.[296] Essentially, UPOV style PVP can work for underutilised crop species in the same way that it does for any commercial crop, although this will only work if the crop is identified as a national priority and the relevant guidelines are developed. Therefore, it is perhaps more accurate to state that UPOV style PVP can work for crops that are considered to be underutilised globally, but are of importance in specific countries or regions, such as the Bambara groundnut. This will be returned to in chapter seven. However, it seems implausible that the necessary development and funding will be applied to lesser underutilised and niche crop species for UPOV PVP to be a viable opportunity.

Fourth, the impact study demonstrates that is possible for a UPOV style system of PVP to be implemented in a way that is useful and meaningful for states which continue to rely upon traditional farming practices. In Kenya, the titles to numerous protected plant varieties are publicly owned, and there is provision in the national PVP law that gives local and subsistence farmers the privilege of using the propagated material of protected varieties and allowing the material to be distributed through traditional channels.[297] This arguably, does support addressing food security concerns as it facilitates the flow of germplasm and gives it the potential to support the innovations of small scale farmers. Thus, it is possible to implement a UPOV style system of PVP which accommodates subsistence agriculture. Yet we should not grant the Kenyan model too much credit in this regard as it does not introduce fundamental changes into the structure of UPOV PVP;

[295] UPOV, n286 above, at 43
[296] UPOV, n286 above, at 58
[297] UPOV, n286 above, at 55

rather it creates a work around by assigning the plant breeders' rights in question to public bodies. Therefore, whilst this is an interesting solution, it is not necessarily something that can be extended universally.

All of the evidence that is considered here has been considered cautiously, as after all, it is only natural for a UPOV commissioned study to emphasise the successes of the system. However, the evidence not is as important *per se* as what it allows us to understand about the UPOV system. Specifically, it suggests that it is possible for UPOV PVP to support innovations in underutilised crops and that if it is a tool for addressing food security concerns, it is a limited one and one that is dependent upon the availability of market for the crop in question.

3.5 Summary

UPOV appears to have successfully branded itself as an effective *sui generis* system of plant variety protection and indeed, and it is clear that UPOV PVP does constitute effective *sui generis* IP protection on the literal reading of article 27.3(b) TRIPS. However, the extent to which it can be considered to be effective is limited to the number of plant species and genera for which protection is available in a given member state. It is clear that plant variety protection as conceived by UPOV is intended for commercially produced varieties. The regime has been criticised for not taking into account the diverse needs of its expanded membership[298] and for the strict approach adopted by the UPOV organs. Yet it is important to note that the structure of PVP under UPOV does not in itself preclude it from being useful in supporting developments in underutilised crop species. This will be dependent upon the availability of adequate DUS testing guidelines and can be developed in line with national needs and priorities. That being said, there does need to be a commercial market in a given country for a crop in order for UPOV style PVP to play a role in incentivising development.

[298] Dutfield, n262 above, at 10

Chapter 4: The International Treaty on Plant Genetic Resources for Food and Agriculture

4.1 Introduction

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA, or plant treaty) is the first internationally binding treaty pertaining exclusively to the use and management of crop genetic resources. It is the product of decades of discussions within the FAO concerning the technical, scientific, economic and social aspects of the international exchange of germplasm.[299] The treaty is intended to serve two objectives: the conservation and sustainable use of plant genetic resources (PGR) for food and agriculture; and the fair and equitable sharing of the benefits arising from their use, for sustainable agriculture and food security.[300] It introduces two mechanisms in pursuit of these aims: the Multilateral System of Access and Benefit Sharing ('the multilateral system' or MS) and the formalisation of Farmers' rights in international Law. This chapter will consider how these developments might support and promote agricultural research and development, both generally and for niche crops. It will also analyse the compatibility of the mechanisms created by plant treaty with the international norms governing intellectual property protection.

4.1.1 Background to the Plant Treaty: the International Undertaking on Plant Genetic Resources

Broadly speaking, there were two streams of concern that led to the eventual adoption of the plant treaty: technical and scientific concern over the maintenance and conservation of plant and genetic resources; and political and legal concern over the ownership of genetic resources and products derived thereof. As far back as the 1950s widespread concern existed over the global erosion of genetic diversity.[301] In particular, the increase in monoculture practices that occurred as a product of the Green Revolution

[299]José T. Esquinas-Alcázar, Christine Frison & Francisco López, 'A Treaty to Fight Hunger- Past Negotiations, Present Situations and Future Challenges' in Christine Frison, Francisco López & José T. Esquinas-Alcázar (eds.) *Plant Genetic Resources and Food Security: Stakeholder Perspectives on the International Treaty on Plant Genetic Resources for Food and Agriculture* (Oxon, Earthscan, 2011) at 7

[300] ITPGRFA, art. 1.1

[301] José Esquinas-Alcázar, Angela Hilmi & Isabel López Noriega, 'A brief history of the negotiations on the International Treaty on Plant Genetic Resources for Food and Agriculture' in Michael Halewood et al., n299 below, at 136

in the 1960s led to increased awareness of the further decline in genetic diversity.[302] This led to the FAO and the International Biological Program holding the first technical conference on plant genetic resources in 1967; the aim of which was to achieve a consensus on the importance conservation of germplasm.[303] While the conference managed to successfully put PGFRA on the international agenda, it achieved little concrete progress on conservation.[304] At this time, *ex situ* germplasm was largely held either in national collections or the private collections of research institutes, with access to and exchange of PGRFA occurred almost exclusively on a bilateral basis. The Conference met again in 1973 and 1981 to discuss the technical aspects of germplasm collection, conservation and exchange.[305] During the same period several key international organisations in the field emerged: of particular note are the Consultative Group on International Agricultural Research (CGIAR) in 1971 and the International Board of Plant Genetic Resources (IBPGR)[306] in 1974.

The 1979 FAO Conference marked the beginning of the process of negotiations that would lead to the adoption of the International Undertaking on Plant Genetic Resources (the International Undertaking, or IU) at the FAO Conference in November 1983.[307] Alongside which, the FAO established the intergovernmental Commission on genetic resources for the purposes of monitoring the arrangements included in the International Undertaking and reviewing all matters under the auspices of the FAO relating to in the field of plant genetic resources.[308]

The International Undertaking was a non-binding instrument intended to ensure the conservation, and preservation of plant genetic resources of social, economic or

[302] ibid
[303] Michael Halewood, Isabel López Noriega & Selim Louafi, 'The global crop commons and access and benefit sharing laws: examining the limits of international policy support for the collective pooling and management of genetic resources' in Michael Halewood, Isabel López Noriega & Selim Louafi (eds) *Crop Genetic Resources as Global Commons: Challenges in International Law and Governance* (Oxon, Routledge, 2013) at 4
[304] ibid
[305] Esquinas-Alcázar, Hilmi & Noriega, n301 above at 136; FAO, *FAO Technical Conference on Crop Genetic* Resources: 12-16 March 1973 (Rome, FAO, 1973); FAO, 'Technical Conference on Crop Genetic Resources, Rome 6-10 April 1981' FAO/UNEP/IBPGR (Rome, FAO, 1981)
[306] Now known as Bioversity International
[307] FAO Conference Resolution 8/8, International Undertaking on Plant Genetic Resources (23rd November 1983)
[308] FAO Conference Resolution 9/83, Establishment of a Commission on Plant Genetic Resources (23rd November 1983)

agricultural interest and to make germplasm freely available for plant breeding or scientific purposes without restriction,[309] including cultivated varieties, wild, obsolete or primitive varieties and specialist breeders' varieties.[310] The critical feature of the IU is article 7. Article 7 sets out the objective of the further developing the existing international arrangements for the conservation and exchange of germplasm into a coordinated global network under the auspices of the FAO, intended to facilitate PGR exchange and support the agricultural development; and the expansion and improvement of institutional capacity in the field of PGR of developing states. PGRs accessed through the system were to be made available on the basis of mutual exchange or mutually agreed terms.[311]

As a non-binding instrument, the International Undertaking relied upon international cooperation and the voluntary compliance of contracting parties. Indeed, the IU was approved with a number of reservations.[312] Whilst the IU encouraged the free flow of germplasm in order to support agricultural development, it did not touch upon ownership PGRs, either of wild varieties or developed cultivars. This is likely a result of the fact that the Undertaking was based upon the principle that plant genetic resources constituted the heritage of mankind.[313]

4.1.2 Negotiation of the ITPGRFA

The discourse on ownership of PGRFA served as the impetus for the eventual negotiation of a binding agreement. More specifically, the increased recognition of the unequal flow of germplasm between the technologically advanced north and genetically rich south[314] combined with the formal acknowledgement of state sovereignty over genetic resources[315] meant that the provisions of the soft law provisions of the International

[309] n307 above, art 1
[310] n307 above, art 2.1(a)
[311] n307 above, art 7.2
[312] The states that entered reservations were Canada, France, Germany, Japan, New Zealand, Switzerland, the UK and the USA. (Twenty-second Session of the FAO Conference, Rome, 5-23 November 1983, C 83/REP, paras. 275-285) It is noteworthy that the states that entered reservations were also those with a strong history of plant breeder protection.
[313] n307 above, art 1
[314] See, Patrick Mooney, 'International Non-Governmental Organisations: The Hundred Year (or so) Seed War- Seeds, Sovereignty and Civil Society- A Historical Perspective on the Law of the Seed' in Frison, López & Esquinas-Alcázar, n299 above
[315] For example, in 1992 the Convention on Biological Diversity recognised contracting parties' sovereign right to exploit their own resources pursuant to their own environmental policies (article 3) and that authority to determine access to genetic resources rests with national governments (article 15.1)

Undertaking were no longer adequate. The IU had already come into conflict with industrialised nations and commercial agriculture over concerns that the free exchange of germplasm conflicted with plant breeders' rights. This lead to the Agreed Interpretation[316] by the FAO Commission on Food and Agriculture, which declared that the free exchange of PGRFA and plant breeders' rights were not incompatible.[317] However, this was not sufficient to alleviate the tensions between provider and recipient states.

The issue of farmers' rights had entered the debate on PGRFA at the 1983 Conference,[318] as a loosely formed concept intended to assert ownership of farmer innovation and redress the unequal balance between on farm innovators and the holders of plant breeders' rights.[319] By large, the idea was rejected by high income states in the north; however it gained traction with the south, in particular Latin America, from states with a much higher percentage of the population engaged with agriculture. Its continued presence in the discourse on PGRFA eventually resulted in an FAO resolution on Farmers Rights in 1989;[320] which was intended, alongside the Agreed Interpretation to redress some of the concerns surrounding the balance between breeders and farmers, developed and developing states.[321] During this period the issue of access to PGFRA had arisen in the negotiation of the Convention on Biological Diversity (CBD); while the CBD concerned all biological diversity, contracting parties had recognised the unique nature of agricultural biodiversity, including the management of *ex situ* collections of PGR and the question of farmers' rights. Consequently, at the same time as adopting the CBD, contracting parties also adopted Resolution 3 of the Nairobi Final Act, which requested that the FAO address these outstanding issues.[322] Subsequently, FAO Conference 1993 formally requested that the Commission negotiate a revision of the International Undertaking.[323] The discussions

[316] Agreed Interpretation of the International Undertaking (FAO Resolution 4/89, adopted 29th November 1989)
[317] ibid, art 1
[318] Mooney, n314 above, at 140-141
[319] ibid
[320] Farmers' Rights (FAO Resolution 5/89, adopted 29th November 1989)
[321] FAO Commission on Genetic Resources for Food and Agriculture, 'History' http://www.fao.org/nr/cgrfa/cgrfa-about/cgrfa-history/en/ (accessed: 12th July 2020)
[322] The Nairobi Final Act of the Conference for the Adoption of the Agreed Text of Convention on Biological Diversity, Resolution 3, available at https://www.cbd.int/doc/handbook/cbd-hb-09-en.pdf (accessed: 12th July 2020)
[323] José Esquinas-Alcázar, 'Protecting crop genetic diversity for food security: political, ethical and technical challenges' (2005) 6 Nature Reviews Genetics 945 at 947

within the framework of the CBD and the entry into force of the TRIPS Agreement served to demonstrate to the agricultural sector that a non-binding agreement was no longer sufficient.

Thus, as a result of various pressures from the agricultural sector and NGOs, as well as both developed and developing states, the negotiation of the treaty began in 1994. The adoption of the premise of the multilateral system with a list of crop species available to be accessed as a solution for regulating access to PGRFA took place early in the negotiation of the treaty.[324] This then raised the issue as to which crops should be included in the list (Annex I). Lower and middle income states viewed Annex I as a test of the value and efficacy of the new system, whereas developed states were keen to promote access to genetic resources as an end in itself. [325] The final 64 crops included in Annex I represented a compromise between the extremes of the minimalist proposal of nine crops made by the African region and the comprehensive list of 287 submitted by the European region.[326] The final text was adopted at the thirty-first conference of the FAO in 2001 and came into force on 29th June 2004.[327]

4.1.3 Structure of the ITPGRFA

To date, the Treaty has 146 contracting parties.[328] Thus, it is near global in application. The decision making organ is the Governing Body of the Treaty, which is constituted of representatives from each contracting party.[329] The Governing Body is also responsible for maintaining the multilateral system (see below, 4.2).[330] Decisions are made by consensus.[331] Compliance with Treaty obligations is overseen by the Compliance

[324] Commission on Genetic Resources for Food and Agriculture, 'Report by the Chairman of Eleventh Session of the Working Group of the Commission on Genetic Resources for Food and Agriculture' (Rome, 9-13 December 1996) CGRFA-EX3/96/3 at paras 9-16
[325] Bert Visser, 'The moving scope of Annex I: The list of crops covered under the multilateral system' in Halewood, López Noriega & Louafi (eds) n303 above, at 265-266
[326] ibid
[327] FAO, 'Overview', available at: http://www.fao.org/plant-treaty/overview/en/ (accessed: 12th July 2020)
[328] FAO, 'Official List of Contracting Parties (15th May 2019)' http://www.fao.org/fileadmin/user_upload/legal/docs/033s-e.pdf (accessed: 12th July 2020)
[329] ITPGRFA, art. 19
[330] Daniele Manzella, 'The Design and Mechanics of the Multilateral System' in Halewood et al., n303 above at 157
[331] ITPGRFA, 'Rules of Procedure for the Governing Body' Rule VI, available at http://www.fao.org/3/a-be467e.pdf (accessed: 12th July 2020)

Committee[332] and on the basis of voluntary reporting by states parties of measures taken to ensure compliance with the treaty.[333] Consequently, the effective implementation of the plant treaty is dependent upon the good faith of contracting parties. This is potentially problematic for end users: as a result of the new form of multilateralism created by the multilateral system, the plant treaty goes beyond the traditional reach of international law. The system incorporates both public and private sector entities by means of the Standard Material Transfer Agreement, and thus elevates non-state entities to the plane of international law. Consequently, the system is not static in nature.[334] The multilateral system is in the early stages of operation, and as such, the implications of its unique structural arrangement are not clear at this stage.

4.2 The Multilateral System of Access and Benefit Sharing

The multilateral system of access and benefit sharing is the legal mechanism created by the plant treaty intended to facilitate access to germplasm by providing a near global standardised approach to access to PGRFA that recognises the need for reciprocity in agricultural innovation and development. All PGRFA are within the scope of the multilateral system[335]. However, the substantive obligations contained within part IV of the treaty only apply to crops listed in Annex I of the treaty which are under the control of state parties or the public domain;[336] as well as the collections held by international gene banks of the Consultative Group on International Agricultural Research. The 64 crops listed in Annex I are considered to be the most essential crops for human nutrition and food security, comprising up to 80% of total human consumption of plants.[337] The fact that many crop varieties are not included in Annex I does not exclude them from being

[332] IT/GB-1/06/Report, Resolution 3/2006 'Compliance', art 1
[333] Fourth Session of the Governing Body of ITPGRFA, 'Procedures and Operational Mechanisms to Promote Compliance and Address Issues of Non-Compliance' Resolution 2/2011
[334] Manzella, n330 above at 160
[335] ITPGRFA, art. 3
[336] ITPGRFA, art. 11.2
[337] FAO, 'What is the Multilateral System?' available at http://www.fao.org/plant-treaty/areas-of-work/the-multilateral-system/overview/en/ (accessed: 12th July 2020)

accessed through the multilateral system; rather, non-Annex I crops simply require voluntary inclusion by either the state party or institution that possesses them.[338]

PGRFA included in the multilateral system may be accessed by on the basis of the Standard Material Transfer Agreement, which governs the terms of access and benefit sharing (below, 4.2.1). Use of genetic material accessed through the multilateral system is strictly limited to agricultural purposes.[339] This is in order to avoid overlap with other access and benefit sharing systems, such as that established under the Nagoya Protocol.[340] States parties agree to facilitate access to publicly owned PGFRA, which in effect creates a global commons. Restricting the scope of the substantive obligations to Annex I crops in the public domain effectively minimises issues arising from potential conflicts with intellectual property rights which might arise should privately held germplasm be available through the multilateral system and thus streamlines the system. However, the limited number of crops included in the system curtails its potential to support agricultural research and development. The relatively low number of crop species included in Annex I is a justifiable compromise, between the inclusive approach argued for by high income states and the more restrictive approach advocated in by low and middle income states, especially given the concerns raised during the negotiation of the treaty by developing states about the historical appropriation of germplasm.[341] Yet it is arguable that it is developing states that are likely to be deprived as a result of the limited amount of genetic material available through the system. This point is considered in the discussion of the standard material transfer agreement, below.

4.2.1 The Standard Material Transfer Agreement

Per article 12.4 of the plant treaty, access to genetic resources under the multilateral system is regulated by the standard material transfer agreement.[342] After the adoption of the treaty, the Commission on Genetic Resources for Food and Agriculture

[338] Indeed, the International Agricultural Research Centres of the CGIAR use the SMTA to regulate access to non-Annex I crops. See, FAO, 'Agreements concluded under article 15', available at: http://www.fao.org/plant-treaty/areas-of-work/the-multilateral-system/overview/en/ (accessed: 12th July 2020)
[339] SMTA, art. 6.1
[340] See section 6.7 below
[341] See, section 4.1.2 above
[342] The text of the SMTA is available at: http://www.fao.org/3/a-bc083e.pdf (accessed: 12th July 2020)

established an expert group to develop such an agreement, including terms for the commercial benefit sharing.[343] The basic outline of the SMTA was created by the Expert Group on the Terms of Standard Material Transfer Agreement; it was subsequently revised by the Contact Group for the Drafting of the SMTA before the final version was adopted on 16 June 2006.[344] As the agreement is intended to facilitate access to germplasm and to negate the need for bilateral agreements between parties, it may not be varied or abbreviated in any way.[345] Thus the SMTA functions contractually at the international level.

The agreement regulates the relationship between the provider and the recipient of genetic material.[346] Access to PGRFA is without charge (excluding meeting minimal costs)[347] provided that the material accessed is used only for agricultural research, breeding or training;[348] subject to the conditions that the recipient will not claim any IPRs or other rights over material received from the system.[349] Should a recipient develop and commercialise a product using material accessed from the system, the recipient is required to pay into the benefit sharing mechanism specified in Annex II,[350] which is the Benefit Sharing Fund.[351]

The SMTA contains two options for payment. The first is to pay a fixed percentage of 0.7%[352] on the sale of the product developed using accessed material during the period of restriction (ie. the period during which it is the subject of an IPR).[353]

Alternatively, the recipient may opt for the payment scheme under art. 6.11. The alternative payment scheme can be effectively described as a subscription service. Under this scheme, the recipient makes payments at a discounted rate of 0.5% for a period of

[343] FAO, 'Drafting of the Standard Material Transfer Agreement' available at http://www.fao.org/plant-treaty/areas-of-work/the-multilateral-system/the-smta/en/ (accessed: 12th July 2020)
[344] Resolution 1/2006
[345] FAO, 'What is the SMTA?' available at http://www.fao.org/plant-treaty/areas-of-work/the-multilateral-system/the-smta/en/ (accessed: 12th July 2020)
[346] SMTA, art 1.2
[347] SMTA, art 5 (a)
[348] SMTA, art. 6.1
[349] SMTA, art. 6.2
[350] SMTA, art 6.7
[351] See, 4.2.2 below
[352] Per Annex 2.1 of the SMTA, recipients are to pay 1.1% of the sale of the product minus 30%, therefore approximately 0.7%
[353] SMTA, art 6.7

ten years.[354] Payment is to be made regardless of whether the product is available without restriction. The reward for this greater obligation is further access to other genetic material of the same crop without further financial obligation.[355] The period of ten years is subject to renewal by the recipient.[356] If at the end of the ten year period the recipient chooses not to continue making payments under art. 6.11, then the recipient will be required to continue making discounted payments for any products containing accessed material that have been commercialised that are subject to restriction.[357]

The condition of access that recipients do not claim intellectual property rights or other rights that restrict access to PGRFA, its genetic parts or components thereof in the form they were received from the multilateral system is of particular interest for the present analysis. As Michael Blakeney points out, this does not prevent recipients from claiming IPRs over modified derivatives of material accessed through the system.[358] This is necessary feature of a system intended generally to facilitate access to[359] and support the research, development and sustainable use of PGRFA.[360] However, this then raises the question: at what point genetic material accessed can be considered to have been sufficiently modified? Blakeney suggests that a test similar to that present in laws derived from the Enactments of the International Union for the Protection of New Varieties of Plants (UPOV) as to whether a variety is "essentially derived" from a protected variety is the most likely approach.[361]

The example of the Australian chickpeas provides a useful illustration of the issues that can arise as a result of the absence of guidance as to what constitutes a sufficiently modified derivative. This concerned the attempt to acquire plant variety protection (PVP) for two varieties of chickpeas derived from Indian chickpea lines by two Australian government agricultural agencies. Agriculture Western Australia and the Grains Research and Development Corporation applied for PVP for two varieties of chickpeas derived from

[354] SMTA, Annex 3.1
[355] SMTA, Annex 3.5
[356] SMTA, art 6.11(b)
[357] SMTA, art. 6.11(g)
[358] Michael Blakeney, *Intellectual Property Rights and Food Security* (Wallingford, CABI, 2009) at 113
[359] ITPGRFA, art. 12.1
[360] ITPGRFA, art. 1.1
[361] Blakeney, n358 above

material obtained from the International Crop Research Institute for the Semi-Arid Tropics (ICRISAT) under the Australian Plant Breeder's Rights Act 1994, the local codification of the 1978 UPOV Enactment.[362] The material was obtained on the basis of a material transfer agreement with ICRISAT.[363] The material submitted fulfilled the statutory requirements for a new plant variety:[364] the varieties submitted were distinct, uniform and stable, and had not or had only recently been exploited. The application was withdrawn by the applicants due to public outcry that occurred after the whistle was blown on the actions of Agriculture Western Australia and the Grains Research and Development Corporation by the Rural Advancement Foundation International (RAFI). Therefore the application did not have the opportunity to be determined on its merits by the Australian Plant Breeder's Rights Office. [365] This also means that substance of the material transfer agreement by which the material was obtained was not scrutinised in any way.

The case of the Australian chickpeas predates the ITPGRFA, as it took place in 1998. Nonetheless, it demonstrates clearly that without sufficiently rigorous guidance as to what constitutes a modified derivative of genetic material accessed through the MS, the material made available through the system is insufficiently protected from appropriation. Neither the ITPGRFA nor the SMTA provide this. It was noted at the time of the controversy that even with a legally binding treaty regulating the exchange of germplasm that the monitoring of abuses would be difficult as neither the FAO nor the CGIAR have the resources to truly manage the extent of germplasm held on trust by international gene banks.[366] Since the entry into force of the ITPGRFA, it could be argued that the limitation of Annex I to 64 crops might make this task more manageable, although the scope of the MS is not strictly limited to Annex I crops. This suggests that the complete absence of a

[362] Australia acceded to the 1991 Enactment on 20th January 2000. See, UPOV, 'Members of the International Union for the Protection of New Varieties of Plants' available at: https://www.upov.int/export/sites/upov/members/en/pdf/pub423.pdf (accessed: 15th July 2020)
[363] ICTSD, 'Bio-Piracy: Australian case highlights debate on Intellectual Property' BRIDGES, 2nd February 1998 vol. 2(3)
[364] s. 43
[365] Michael Blakeney, 'Intellectual Property Rights in the Genetic Resources of International Agricultural Research Institutes- some recent problems' (1998) 2(1) Bio-Science Law Review 3 at 3
[366] ICTSD, n363 above

concept of sufficiently modified derivatives is a serious inadequacy, at least from the perspective of providers of genetic material.

It is interesting to note that as late as 2010, the test for 'predominantly derived' in Australian PVP legislation was held to be 'insufficiently rigorous'.[367] This highlights the fact plant variety protection legislation, including that based on the various UPOV Enactments, can play mutually supportive role in ensuring that material accessed through the MS is not unjustly appropriated. It is submitted that the multilateral system would benefit from the development of a shared concept of modified derivatives. In the same vein as the UPOV system, such an inclusion would lend a degree of certainty to both end users and providers of PGRFA. While it is highly unlikely that such an addition might find its way into the text of the treaty itself, there is scope for the requirement to be included in the SMTA, given that this is the mechanism which sets out parties' responsibilities concerning access to PGRFA within the multilateral system. The practical challenge that would arise out of the inclusion of the modified derivatives requirement would be the provision of appropriate technical guidance. Nonetheless, using SMTA to contractually oblige parties to adhere to guidance as to what constitutes a sufficiently modified derivative would also have the advantage of being flexible if required, as it could allow the concept to be adjusted in a similar matter as how the UPOV Council routinely updates it Explanatory Notes on Essentially Derived Varieties.[368] This is particularly relevant given that compliance with the SMTA is regulated by the Governing Body of the Treaty.

The lack of guidance from the treaty bodies as to what constitutes a modified derivative of genetic material accessed through the system is detrimental to establishing a properly functioning multilateral system, as ambiguity remains around parties' obligations to pay into the system. This has two potential consequences. It could serve to deter research and development involving material included in the multilateral system,

[367] Michael Blakeney, 'Trends in Intellectual Property Rights Relating to Genetic Resources for Food and Agriculture' FAO Background Study no. 58, July 2011, available at: http://www.fao.org/docrep/meeting/022/mb684e.pdf (accessed; 12th July 2020) at 4, 14

[368] UPOV Council, 'Explanatory notes on Essentially Derived Varieties under the 1991 Act of the UPOV Convention' 6th April 2017, available at: http://www.upov.int/edocs/expndocs/en/upov_exn_edv.pdf (accessed: 15th July 2020)

as uncertainty as to their potential contractual obligations is unlikely to encourage either private or public actors to seek IP protection from developments made with genetic material from the MS. This in turn, will limit the extent to which payment is made into the benefit sharing fund.

On the other hand, the lack of definition of a modified derivative may in fact serve to encourage plant breeders to acquire IP protection for varieties derived from material accessed from the MS with minimal development or modification. This is particularly true given that the authorities responsible for granting IP protection over plant varieties (such as the Plant Variety Rights Office[369] or in some states, the local patent office[370]) will not necessarily have access to material acquired from gene banks or third-party institutions in order to consider it as prior art for the purposes of the application for the IPR. The issue as to whether this is of any benefit to the MS will depend upon whether the holder of the IPR in question chooses to continue to make the new variety available for further research purposes or not. If the variety is not available for research purposes, then the right holder will be required to make financial contributions into the Benefit Sharing Mechanism. In this situation, it is arguable at least, that some benefit is being redirected through the MS. If, however, the right holder commercialises a crop variety that is minimally derived from genetic material accessed from the MS and chooses to make the new variety available for research purposes, then the absence of a clear definition as to what constitutes a modified derivative has arguably created a loophole through which it is possible to commercialise, with minimal effort, material accessed through the MS without contributing in any way to the regime. It is possible to assert that the rights holder has contributed to the MS by making the protected variety available for research purposes, and has thus conferred the benefit of additional options for addressing food security concerns. However, this is untenable in the case of a minimally developed variety as it will not be significantly different from the material from which it was derived and therefore, cannot fairly be said to be a research-based contribution.

[369] As is the case in the United Kingdom
[370] Such as the United States Patent and Trademark Office (for asexually propagated plants and genes, traits, methods, plant parts, or varieties. See, 35 USC s.161)

The real possibility of breeders taking advantage of a lack of minimum standards for modification of genetic material acquired through the MS is illustrated by the patenting of several varieties of rice derived from Basmati rice from Pakistani Basmati genetic material.[371] A US based corporation, RiceTec, sought patents over a number of varieties derived from Basmati rice under the names of Texmati, Kasmati and Jasmati;[372] the patents in question would have granted RiceTec a commercial monopoly over the production of Basmati Rice in the US. The patents were granted in 1997.[373] Of particular controversy was the fact that the genetic material used to breed the varieties at issue was derived from 22 Pakistani Basmati rice lines acquired from the World Germplasm Collection of the United States Department of Agriculture (USDA).[374] Similarly, the involvement of Hank Beachell, a former breeder at the International Rice Research Institute (IRRI), who was credited as one of the 'inventors' of the strain in question also raised eyebrows.[375] The acquisition of the germplasm in question was perfectly legal, as it took place before the entry into force of the Convention on Biological Diversity and prior to the negotiation of the ITPGRFA. Nonetheless, the grant of the patents provoked an adverse reaction from both non-governmental organisations, such as RAFI and Research Foundation for Science, Technology and Environment (RFSTE), as well as developing states with a vested interest in safeguarding their local varieties and genetic heritage, most notably India. Significant concerns were raised over the ethics of patenting a "new" variety of Basmati rice, but also as to the technical legal questions concerning whether such varieties were capable of fulfilling the requirements of novelty and inventive step.[376] In challenging this, the Indian government submitted to the US Patent and Trademark Office some 50,000 pages of scientific evidence detailing how existing high quality basmati varieties already possessed

[371] Both the Australian chickpeas dispute (above) and the Indian/Pakistani Basmati rice dispute also serve to highlight the potential role of Geographical Indications in protecting crop varieties from being appropriated by means of patenting or plant breeders' rights. See, Blakeney, n367 above
[372] S. Lall, 'India and Pakistan. Geographical Indications – The Basmati Issue' as cited in Blakeney, n358 above, at 187
[373] US patent no. 5,663,484 granted on 2 September 1997
[374] Dwijen Rangnekar and Sanjay Kumar, 'Another look at Basmati: Genericity and the Problems of a Transborder Geographical Indication' (2010) 13(2) Journal of World Intellectual Property 202 at 214
[375] RAFI, 'Basmati Rice Patent: The (Merchant) Prince and the (Punjabi) Paupers' 31st March 1998
[376] Rangnekar & Kumar, n374 above, at 215-216

the characteristics for which the new varieties has been granted patent protection.[377] Ultimately, RiceTec surrendered its claims to the patents when the US government filed for re-examination in 2000.[378] What the Basmati rice case serves to highlight, regardless of the fact that it predates the ITPGRFA, is that without more precise contractual obligations regulating access to genetic material, the providers of genetic resources will need to rely upon local IP Offices to divine whether a new variety is sufficiently distinct from the material from which it was derived. This may not be possible based upon the information available at the time of examination. If, like in the Basmati rice case, an IPR is challenged after the grant, this may require considerable resources and take years to resolve. Indeed, the Basmati rice case required no less than the intervention of the Indian government. It is also possible that the outcome of the resolution of the dispute will be dependent upon the local domestic IP regime and its examiners being favourable. Whereas the existence of a contractual requirement for sufficient modification of derivatives would be of benefit to both providers and recipients of genetic material as it would afford assurance to the former that genetic material they have provided will not be unfairly commercialised and provide the later with clarity and legal certainty over their obligations towards genetic material accessed through the MS. Additionally, it would provide alternative recourse for dispute resolution. It is not suggested that the modification of the access regime to support a concept of modified derivatives would be either a quick or a simple process. However, given the quantity of scientific data provided to challenge the patents in the Basmati rice case, the existence of some guidelines on the matter may serve to prevent such long and complex disputes from arising.

4.2.2 Benefit Sharing

There are two aspects to benefit sharing within the framework of the ITPGRFA. The first of which is the agreement that developments made using material accessed through

[377] Anthony Browne, 'India Fights US basmati rice patent' The Guardian, 25th June 2000, available at: https://www.theguardian.com/world/2000/jun/25/anthonybrowne.theobserver (accessed: 15th July 2020)
[378] The US PTO considered on the basis of the evidence submitted by the Indian government, *inter alia*, that the particulars of the application were too broadly drafted. The examiner also decided to remove 'Basmati' from the title of the remaining patents. See, Rangnekar & Kumar, n374 above, at 216-217

the system will be freely available (where payment into the system for commercial benefits is not made).[379] Thus, in theory, everyone should benefit from the newly available knowledge. This in turn, will support the achievement of the wider aims of the Treaty in addressing food security concerns.

The second type of benefit sharing is the redistribution of the financial benefits arising from the commercialisation of products developed using material accessed through the system. As is outlined in section 4.2.1 above, parties are required to make pro rata payments to the Benefit Sharing Fund, which sit alongside voluntary contributions from contracting parties and the private sector.[380] As such, the Benefit Sharing Fund is a third party beneficiary to the SMTA.[381] Financial benefits are not redistributed on the basis of the origin of germplasm accessed through the system. Rather, it is directed towards specific projects which are intended to address specific PGFRA concerns, such as conservation, sustainable use and adaptability to climate change, with emphasis on supporting projects not being pursued elsewhere.[382] This creates a parallel system of financial support for agricultural research and development which may serve to promote innovation where a recognised commercial market may not exist, or it may support the early stages of research which may not lead to the development of a commercially viable crop variety but may nonetheless support the alleviation of food security concerns.

Funding is distributed on the basis of calls for project proposals made by the Treaty Bureau; proposals are independently selected and approved by experts before being approved by the Treaty Bureau.[383] The ITPGRFA Secretariat is then responsible for establishing a contractual relationship with the executives of the funded project and for subsequent reporting and monitoring.[384] To date, there have been four calls for

[379] SMTA, art. 5(2)
[380] Governing Body of the ITPGRFA, 'Funding Strategy for the Implementation of The International Treaty On Plant Genetic Resources For Food and Agriculture- Annex I: Priorities for the use of resources under the funding strategy' at 15; available at http://www.fao.org/3/I8698EN/i8698en.pdf (accessed: 12th July 2020)
[381] Gerald Moore, 'Protecting the interests of the multilateral system under the Standard Material Transfer Agreement: The third-party beneficiary' in Halewood, López Noriega and Louafi (eds.) n303 above, at 167-168. Moore points out that although it is not explicitly referred to in the text of the treaty, the notion of the third-party beneficiary is factually established by the provisions concerning the MS and the SMTA
[382] ibid, at iii
[383] FAO, 'The Treaty's Grant Making Process' available at: http://www.fao.org/plant-treaty/areas-of-work/benefit-sharing-fund/overview/en/ (accessed: 12th July 2020)
[384] ibid

proposals.[385] 11 small scale projects were funded by the first cycle of funding;[386] 19 projects by the second cycle;[387] 22 projects by the third cycle of funding[388] and 20 projects under the fourth cycle.[389] It is noteworthy that under each round of funding there have been a number of projects funded that engage with underutilised and landrace crop varieties, or supporting small scale and local agriculture funded.[390]

Thus, the salient attribute of the benefit sharing regime under the plant treaty is that it is not concerned with direct remuneration for originators of germplasm in the system. Rather, its limited resources are devoted to addressing food security concerns more generally. This is clearly demonstrated by the fact that the financial aspect of benefit sharing under the regime is also oriented towards funding the creation of agricultural knowledge and the maintenance of agrobiodiversity.

4.3 Farmers' Rights

Prior to the entry into force of the ITPGRFA, the concept of farmers' rights had not found expression in international law. As noted in section 4.1.2 above, the idea found its way into the debate on plant genetic resources during the 1980s, and was adopted by many developing states and promoted by NGOs as a potential means of addressing the perceived unequal flow of germplasm between developed and developing states.[391] The forum for this discussion was the Food and Agriculture Organisation of the United Nations, which continued to host the discussion surrounding PGRFA after the adoption of the International Undertaking.[392] The notion of farmers' rights was formally acknowledged for the first time by a resolution of the Conference in 1989 which loosely defined farmers'

[385] The first call for proposals took place in December 2008; the second took place in 2010; the third in March-July 2014; and the fourth from March-July 2020.
[386] FAO, 'BSF Project- First Cycle' available at: http://www.fao.org/plant-treaty/areas-of-work/benefit-sharing-fund/projects-funded/bsf-first-cycle/en/ (accessed: 12th July 2020)
[387] FAO, 'BSF Project- Second Cycle' available at: http://www.fao.org/plant-treaty/areas-of-work/benefit-sharing-fund/projects-funded/bsf-second-cycle/en/ (accessed: 12th July 2020)
[388] FAO, 'BSF Project – Third cycle' available at: http://www.fao.org/plant-treaty/areas-of-work/benefit-sharing-fund/projects-funded/bsf-third-cycle/en/ (accessed: 12th July 2020)
[389] FAO, 'BSF Project – Fourth cycle' available at: http://www.fao.org/plant-treaty/areas-of-work/benefit-sharing-fund/projects-funded/bsf-fourth-cycle/en/ (accessed 12th July 2020)
[390] See, for example: 'Conservation of agrobiodiversity of local cultivars: millet, maize, sorghum through improved participatory for food and agriculture in Senegal' under the first cycle; 'Sustainable use of landraces and genetic resources to improve wheat tolerance to heat stress' under the second cycle; and 'Genetic trait characterisation of farmer and gene bank sources of Bambara groundnut for the development of drought tolerant lines in sub-Saharan Africa and Southeast Asia' under the third cycle, among others.
[391] Mooney, n314 above, at 138
[392] Esquinas-Alcazar, Frison & Lopez, n299 above, at 8

rights as those arising out of 'the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources'.[393] The initial endorsement of the concept recognised *inter alia:* the necessity of promoting the need for conservation globally alongside adequate funds to ensure this; the need to assist farmers, especially in the developing world in to protect and conserve their plant genetic resources; and to allow farmers in the developing world to participate fully in the benefits derived from the improved use of plant genetic resources.[394] Further discussion of the concept in 1991, affirmed national sovereignty over genetic resources and that farmers' right would be implemented through an international fund for PGRFA, that would support conservation and utilisation programmes.[395] Although the idea that farmers' rights should serve as a counter balance to formal intellectual property rights arose during the negotiation of the IU, it did not gain traction during the negotiation of the final instrument.[396] This can be explained, at least in part, by the considerable difficulty achieving any consensus on the issue of farmers' rights. It can also be attributed to a lack of mandate to address intellectual property issues, the implications of which are discussed below.

Farmers' rights are contained within article 9 of the ITPGRFA, which marks the first and only binding provision on the subject contained in an international instrument. Article 9.1 recognises the role and continued contribution of local and indigenous communities to the conservation and development of PGRFA. Secondly, and more significantly, article 9.1 unequivocally places responsibility for the realisation and promotion of farmers' rights squarely at the feet of contracting parties, so that they may be developed in accordance with national needs and priorities. Third, the article acknowledges the need to protect TK relating to PGRFA;[397] in addition to giving local and indigenous farmers the right to participate in benefits arising from the use of PGRFA[398] and the right to participate in decision making relevant to the conservation and sustainable use of PGRFA at the national

[393] Resolution 5/89, 25th session of the FAO Conference, Rome, 11-29 November 1989
[394] ibid
[395] Resolution 3/91
[396] Mooney, n314 above, at 141-147
[397] art. 9.2(a)
[398] art. 9.2(b)

level.[399] Furthermore, article 9 does not limit any seed saving or exchange rights that farmers may have under national law.[400]

The version of farmers rights embodied in article 9 is a relatively restricted view of the construct. This is because it only addresses the three issues outlined above; whereas the term 'farmers' rights' has been applied to a much broader range of social, economic, political and cultural rights.[401] Article 9 does identify several elements which are almost universally recognised as being core concerns of rural and indigenous farmers, such as seed saving and exchange practices and the need to preserve TK. However, the only concrete rights identified under the ITPGRFA are procedural concerns: namely the right to participate in decision making relevant to the conservation and use of PGRFA. Thus, the treaty's version of farmers' rights is somewhat vague.[402] Moreover, as a result of the national implementation approach adopted in article 9.1, it is possible for the provisions to become further diluted. This in turn, places serious limitations on our ability to assess the impact of article 9. First, because the variation in implementation yields a lack of comparability and second, because legislation and regulation developed at the national level have much greater impact on either breeders or small farmers.[403] Indeed, this approach has been criticised by farmers' rights campaigners as mitigating the strong, affirmative nature of farmers' rights.[404] However, other stakeholders in the global food chain, such as the International Seed Federation (ISF), argue that the Plant Treaty's approach to farmers' rights is correct, given the variation in national policy approaches to seed saving and exchange practices, in order to avoid any farmers' privileges impinging upon plant breeders' rights.[405] Whilst this may very well be true, this position serves to limit the discourse on farmers' rights to just seed saving and exchange practices, rather than their wider social, economic and cultural implications. To a certain extent, it is

[399] art. 9.2(c)
[400] art. 9.3
[401] Pelegrina & Salazar, n403 below, at 176
[402] Shakeel Bhatti & Olivier De Shutter, 'Foreword' in Frison, López & Esquinas-Alcázar, n299 above, at xxviii
[403] Wilhelmina R. Pelegrina & Renato Salazar, 'Farmers' Communities: A reflection on the Treaty from small farmers' perspectives' in Frison, López & Esquinas-Alcázar, n299 above, at 175
[404] Mooney, n314 above, at 146-147
[405] ISF, 'Farmers' Rights' May 2009, available at http://www.worldseed.org/wp-content/uploads/2015/10/Farmers_Rights_2009.pdf (accessed: 12th July 2020)

possible to justify the exclusion of the wider reaching aspects of farmers' rights by reference to the fact that the treaty was negotiated under the auspices of the FAO, and as a result is limited to the subject matter within its mandate. Prior to and throughout the negotiation history of the ITPGRFA, the implementation of farmers' rights was centred upon the creation of fund for the conservation and utilisation of PGRFA,[406] rather than the establishment of specific individual or community rights for farmers. To that end, it is arguable that the manifestation of farmers' rights in article 9 is entirely adequate.

Nonetheless, article 9 still fails to address one critical aspect of farmers' rights: that is, the role of farmers and on farm innovation. The article makes the explicit assumption that farmers have an active role in conserving local and traditional landrace varieties; however it does not acknowledge the existence of on farm innovation.[407] Curiously, the role of on farm and farmer innovation is recognised, albeit obliquely, by the Governing Body of the Treaty.[408] This inconsistency appears to reflect the prolonged difficulty and concessions made during the negotiation of the treaty.[409] Even so, the result of the omission from article 9 is that there is a lack of foundation for the protection of farmers' and local varieties. Arguably, it fails to adequately recognise the dynamic nature of seed systems and potentially impedes the realisation of farmers' rights. This is somewhat troubling given the fact that the treaty was both negotiated and is administered under the auspices of the FAO, a forum that includes and encourages participation by agricultural stakeholders, including NGOs representing small farmers and farmers from developing states. It is arguable that the failure to address the IP related aspects of farmers' rights has been excluded on the basis that the provision of proprietary rights is outside the purview of the FAO, an organisation whose primary aim is to eliminate hunger, food security and malnutrition.[410] Linked with this, it is can be contended that there are other more appropriate forums, such as the World Intellectual Property Organisation (WIPO) or

[406] Resolution 3/91
[407] Pelegrina & Salazar, n403 above, at 179
[408] See for example, Governing Body of the IPGRFA, 'First session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture' (2006) IT/GB-1/06/Report, Appendix B, Resolution 6/2009
[409] See generally Mooney, n314 above
[410] FAO, 'About the FAO: What we do' available at: http://www.fao.org/about/what-we-do/en/ (accessed: 12th July 2020)

the World Trade Organisation (WTO) for the discussion and development of the IP related aspects of farmers' rights. However, it is difficult to see how either WIPO or the WTO is a suitable forum for those discussions in practice. Considering the two organisations in turn, WIPO defines its mission as the development of a balanced and effective system of intellectual property protection, which enables innovation and creativity for the benefit of all.[411] Therefore, the advancement of the IP related aspects of farmers' rights is clearly within its ambit. However, based upon historical evidence, it is difficult to view WIPO as a forum that will yield significant developments in this regard, as the IP related aspects of farmers' rights appear to fall outside of WIPO's agenda. Although the issues related to the realisation of the IP aspect of farmers' rights have been under discussion by of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore[412] (WIPO IGC) since 2001, no WIPO administered instruments have addressed the issues arising from the implementation of farmers' rights.[413] Nor does its current methodology for the 'Development of National Intellectual Property Strategies'[414] ask any questions or provide any information pertaining to farmers' rights or the realization of their IP related aspects. The purpose of the Development of National Intellectual Property Strategies is to support the main aim of WIPO to assist developing and least developed countries in the formulation of national IP institutions, infrastructure and resources.[415] It seems logical that such a device would take into account the concerns of states which need to be balanced against the development of the local IP framework, such as food security concerns, so that framework can be appropriately formulated to local needs. However, the development referred to appears to be conceived in a strict, technical sense rather than focused on substantial issues. The methodology does raise the issue of plant breeders' rights; however, it does so in a manner that reflects UPOV style

[411] WIPO, 'About WIPO' available at: https://www.wipo.int/about-wipo/en/ (accessed: 12th July 2020)
[412] WIPO IGC, 'Matters concerning Intellectual Property Protection and Genetic Resources, Traditional Knowledge and Folklore- An Overview' (Geneva, 30 April- 3 May 2001) available at: https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=1662 (accessed: 15th July 2020)
[413] South Centre, 'Towards a more coherent international legal system on Farmer's Rights: The relationship of the FAO ITPGRFA, UPOV and WIPO' Policy brief no. 17, March 2015
[414] WIPO, (2014) available at: https://www.wipo.int/edocs/pubdocs/en/intproperty/958/wipo_pub_958_1.pdf (accessed: 12th July 2020)
[415] Ibid, at 1.3

institutional arrangements.[416] It does not consider or promote existing non-UPOV forms of plant variety protection, such as those developed by India, Thailand or Malaysia.[417] This brings into question the extent to which the methodology is intended to aid the development of a unique national IP framework appropriate to local needs.

Secondly, as previously outlined in chapter 2[418] and in section 4.4 below, the facet of the WTO that pertains to intellectual property rights, is concerned with the Trade Related Aspects of Intellectual Property (TRIPS). TRIPS, is centred upon the universal availability of minimum standards of IP protection across states parties[419] in order to reduce distortions and impediments to international trade.[420] Accordingly, the WTO is not concerned with the development of IP standards beyond the implementation of minimum standards, or addressing specific concerns which do not pertain to trade. Given that non-UPOV *sui generis* IP protection for farmers or local varieties is a niche form of IP protection, and that is unlikely to be used for trade on more than a limited scale, the development of IP protection for farmers' varieties can be said to be outside the remit of the WTO. Thus, from the vantage point of improving food security concerns, it is difficult to envisage how either forum is more appropriate than the FAO for the development of the IP related aspects of farmers' rights.

However, it is perhaps unwise to take article 9 at its face value. Rather, it might be better understood as supporting a 'human rights based approach' to farmers' rights.[421][422] From this vantage point, farmers rights set out in article 9 should be viewed

[416] For example, the methodology refers to the implementation of a Plant Varieties Act which is administered by a plant breeders' rights office (at 2.1.2), which reflects the UPOV framework. It also refers to plant breeders' rights in the context of the seed industry (at 37).
[417] South Centre, n409 above
[418] See, section 2.4
[419] TRIPS, art. 1.1
[420] TRIPS, preamble
[421] Pelegrina & Salazar, n403 above, at 177
[422] A Human Rights Based Approach to development is centred upon the interdependence between the fulfilment of human rights and the development process, which is operationally directed towards promoting and protecting international human rights standards. The aim of this approach is to analyse and redress the inequalities unjust distributions of power which are the centre of development problems and impede development progress. The approach is based upon participation and empowerment of disadvantaged rights holders (in the present context, rural and subsistence farmers) in order to identify and remedy any legal, social, administrative or institutional barriers to the realisation of the rights in question.
This approach has been recognised by the UNDP as being relevant to realising all aspects of human rights and development.
See, UNDP 'A Human Rights Based Approach to Development Programming in UNDP – Adding the Missing Link' (2002) available at http://www.undp.org/content/undp/en/home/librarypage/democratic-

as a normative standard towards which parties should aim in order to effectively fulfil farmers' rights; thus they are normative rather than prescriptive. This approach would suggest a more positive and successful outcome of article 9. It would also reflect the approach taken more broadly in the Treaty: given the new approach to multilateralism undertaken in the ITPGRFA, it might be suggested that the aim of article 9 is to improve the standing of farmers and farmers groups within the ambit of the multilateral system, rather than as a finite statement of farmers' rights. Furthermore, this is supported by the work undertaken towards implementing article 9 within the framework of the treaty.

The development of farmers' rights has remained a constant item on the agenda of the Governing Body since its first meeting.[423] Although during the early meetings little was achieved in this area other than acknowledging the need to engage with stakeholders,[424] later sessions have produced more substantial resolutions on the implementation of article 9. At the third meeting, the governing body adopted Resolution 6/2009, which called for regional consultations on the national implementation and realisation of farmers' rights.[425] Consultations did not take place due to a lack of financial resources and capacity. Nonetheless the Governing Body continues to encourage contracting parties and other relevant organisations to feedback their views, experiences and best practices on the implementation of article 9 in consultation with farmers groups and other stakeholders.[426] Subsequent meetings have similarly emphasised voluntary participation and review of the implementation of farmers' rights by contracting parties. Most recently, the governing body has encouraged contracting parties to convene their own workshops and consultations in order to feedback experiences and views on national implementation of farmers' rights which will contribute to a body of knowledge that may be of wider benefit to other states parties in their implementation and development of

governance/human_rights/a-human-rights-based-approach-to-development-programming-in-undp.html (accessed: 12th July 2020)
Brigitte I. Hamm, 'A Human Rights Approach to Development' (2011) 23(4) Human Rights Quarterly 1005
[423] FAO, 'First session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture' Madrid, 12-16 June 2006, IT/GB-1/06/Report
[424] ibid
[425]Governing Body of the IPGRFA, 'Resolution 6/2009 Implementation of Article 9: *Farmers' Rights'* available at: http://www.fao.org/3/a-be080e.pdf (accessed: 12th July 2020)
[426] ibid

article 9.[427] This should in turn facilitate the elevation of stakeholder concerns at the international level.

The approach undertaken by the Governing Body based upon encouraging consultation and participation by stakeholder groups is consistent with the human rights based approach and thus suggest that this is the yardstick by which the success of article 9 should be judged. Viewed in context, it can undoubtedly be said to be more successful than when judged on content alone, even if it is somewhat handicapped by the voluntary nature of farmers' rights development. However, if article 9 is successful because it is driven by a human rights based approach, then the omission of the concept of farmer innovation from article 9 is even more difficult to reconcile. This is because a human rights based approach is driven by reconciling stakeholder concerns with the norms laid out in the Treaty by addressing the barriers to their realisation. As such, without the normative recognition of on farm innovation it is unlikely that discussion and development of this essential aspect of farmers' rights will be undertaken either by contracting parties or stakeholders.

4.4 ITPGRFA and intellectual property protection

While as an instrument, the ITPGRFA is not specifically concerned with intellectual property protection, it is clear from what has been discussed above that it touches upon several areas directly linked with intellectual property protection. Namely, intellectual property protection for innovations arising out of material accessed through the multilateral system and IP salient aspects of farmers' rights. These aspects overlap with the commitments of contracting parties to the UPOV Conventions and states parties' obligations under article 27.3(b) TRIPS.

The issue that then arises is reconciling the norms arising under the ITPGRFA and TRIPS and the UPOV Conventions, since while they touch upon the same subject matter,

[427] Governing Body of the ITPGRFA, 'Resolution 5/2015 Implementation of Article 9 *Farmers Rights*' available at http://www.fao.org/3/a-bl144e.pdf (accessed: 12th July 2020)

they do not have the same ideology or objectives.[428] Both TRIPS and the various UPOV Enactments are IP-centred instruments that are founded on the idea that the availability of intellectual property protection should provide incentives for investment in agricultural biotechnology, whereas the ITPGRFA aims to maintain an open access system of PGRFA and redistribute commercial benefits arising from the use of those resources.[429] As examined in section 4.3 above, the ITPGRFA avoids dealing with the aspects of farmers' rights relating to ownership of farmers' varieties. However, article 9.3 does provide for a potential seed saving exemption that needs to be considered in the light of the pertinent IP instruments. More prominently, there is a need to review the questions pertaining to IP protection arising out of the multilateral system in the context of the overlap between the ITPGRFA, and TRIPS and the various UPOV Enactments. Issues arise out of article 12.3(d) ITPGRFA, which restricts the recipients of genetic material from the multilateral system from claiming intellectual property rights over the material acquired through the multilateral system or components thereof. Also at issue is article 13.2(d)(ii) ITPGRFA, which requires that recipients who commercialise a product that is PGFRA and incorporates material accesses through the MS pay into the benefit sharing mechanism where the product is not available without restriction, or to make voluntary contributions where commercialised material is freely available.[430] This can be divided into two separate issues: the availability of commercialised material for further breeding and research activities and the requirement to pay into the benefit sharing mechanism in order to commercialise a product using material derived from the multilateral system. The compatibility of these provisions with TRIPS and UPOV are considered in turn.

[428] Dora Schaffrin, Benjamin Görlach & Christine Gersetter, 'The International Treaty on Plant Genetic Resources for Food and Agriculture- Implications for Developing Countries and Interdependence with International Biodiversity and Intellectual Property Law' (Ecologic, November 2006) at 36
[429] ibid
[430] Likewise, article 6.7 of the SMTA requires that recipients who commercialise a product using material received from the MLS which is not available without restriction make payments into the benefit sharing mechanism. Similarly, article 6.8 of the SMTA encourages voluntary payments into the benefit sharing mechanism where material is available for research purposes without restriction.

4.4.1 TRIPS

As considered in chapter two, the purpose of the TRIPS Agreement is the harmonization of intellectual property protection with the aim towards facilitating international trade. Article 27.3(b) TRIPS provides that patent protection is to be available for inventions that are new, non-obvious and useful, which may be excluded for plant varieties if *sui generis* intellectual property protection (such as plant variety protection) is available. Thus, states parties are obligated to provide some form of IP protection for plant varieties without restriction, save for the possible exception provided for in article 8.1 TRIPS, which allows WTO members to adopt measures necessary to protect public health and nutrition, so long as they are consistent with the provisions of the TRIPS Agreement. Aside from this, the obligations arising out of TRIPS are relatively limited to the TRIPS provisions that govern intellectual property rights generally, as the requirement that IP protection for plant-based innovations exists as an exception to patentability. These general obligations include the requirement to provide permit effective action against infringement, including remedies, and fair and equitable enforcement procedures.[431] They also include broader guiding conventions of international law, such as the principles of national treatment[432] and most favoured nation treatment.[433] However, there is no conflict between these provisions and the substantial obligations of the plant treaty, as they dictate the national governance of IPRs as opposed to the standards for IP protection.

Article 12.3(d) ITPGRFA serves to impose limitations on the availability of intellectual property protection for plant genetic resources or genetic material in the form it was accessed through the multilateral system. However, this is entirely compatible with the requirements of TRIPS, as intellectual property protection need only be available for novel inventions. Nonetheless, some practical difficulty may arise where a domestic IP framework sets a low threshold for novelty. For example, in some jurisdictions it is

[431] TRIPS, art. 41, as further elaborated in arts. 42-49 TRIPS concerning Civil and Administrative Procedures.
[432] TRIPS, art. 3
[433] TRIPS, art. 4

possible for an isolated DNA sequence to meet the novelty criteria.[434] Considering the benefit sharing and research promoting spirit of the ITPGRFA, this is likely the type of practice that the limitation in article 12.3(d) seeks to curb, or at least, benefit from. This, however, does raise practical considerations at the level of the domestic intellectual property framework, such as the need for prior art or disclosure of origin requirements.

The compatibility between the standards imposed by the TRIPS Agreement and the requirement in article 13.2(d)(ii) ITPGRFA for recipients who subsequently commercialise a product derived from PGRFA received through the MS to contribute to the benefit sharing fund, or otherwise make the product without restriction is dependent upon the extent and flexibility of research exemptions in national law. That is to say, it may not be possible, within a given domestic IP framework for the recipients of genetic material who subsequently commercialise a product to offer it freely for research and development purposes in the manner envisaged by the IPGRFA.[435] However, there is no particular issue arising out of the requirement for recipients of PGRFA to pay into the benefit sharing system as TRIPS does not concern itself with the financial administration of IPRs. To that end, contributions made to the benefit sharing system can simply be viewed as an additional fee for acquiring the IPR in question.

There is limited potential conflict between article 9.3 ITPGRFA and TRIPS, as article 9.3 purports that nothing in article 9 should be interpreted as limiting any rights that farmers may have under national law to save, use, exchange and sell farm-saved seed or propagating material. The negative drafting of this provision restricts its impact to upholding existing seed saving exemptions in national law; therefore, it should not impose upon IPR holders' rights *per se.* However, certain seed saving exemptions may be formulated so as to permit the sharing of seeds which are the subject of a third party's IPR. It could be argued that allowing such a seed saving exception might be considered an exception for the purposes of public health and nutrition under article 8. However, it is unlikely that article 8 TRIPS can be used as basis for the creation of such a broad

[434] For example, it is possible for isolated DNA sequences to be patented under the European Patent Convention. See, *Relaxin/Howard Florey Institute* T0272/95, 23 October 2002
[435] Schraffin, Görlach & Gersetter, n428 above, at 44

exception.[436] To that end, article 9.3 is potentially problematic; however, this will depend upon its implementation in the national law of states' parties.

4.4.2 UPOV

As is discussed in chapter three, the various enactments of the UPOV Convention are intended to provide uniform standards of *sui generis* intellectual property protection in line with the guidance provided by the UPOV Council. Therefore, the question that needs to be addressed is whether there is a conflict between these standards and the highlighted provisions of the ITPGRFA.

The article 12.3(d) ITPGRFA restriction on claiming intellectual property rights over material accessed through the Multilateral System can be read as constraining the availability of intellectual property protection to plant breeders. However, this limitation does not conflict with the principles of the UPOV Enactments. This is because in order for a breeder to claim UPOV style plant variety protection, they need to be able to demonstrate that the variety meets the requirement of being new and distinct.[437] Therefore, UPOV-based plant variety protection would not be available for material in the form that it was derived from the MS should not be able to satisfy the new and distinct. Moreover, while UPOV prescribes standards for plant variety protection be available in member states, plant breeders are in no way obliged to seek PVP for their developments. Therefore, the only situation in which a conflict should arise between the provisions is through deliberate attempts to acquire rights over PGRFA as it is received from the MS.

Much in the same vein as with the TRIPS Agreement, there is potential conflict between UPOV and article 13.2(d)(ii) ITPGRFA. The requirement for recipients of PGRFA who develop a product therefrom to either pay into the benefit sharing fund or make the product freely available for further research and development will be problematic if there is no scope in a given UPOV member state's PVP regime for protected varieties to be

[436] Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4th ed., London, Sweet & Maxwell, 2012) at 238-239. Gervais also points out that while a WTO panel or the Appellate Body is unlikely to challenge determinations made by member states as to its public interest or what constitutes a sector of vital importance, they would analyse the compatibility of any measures taken for their compliance and compatibility with TRIPS.
[437] See, section 3.3.4 above

available freely for research and development purposes. This will depend upon the domestic implementation of UPOV standards. However, the most recent iteration of UPOV contains exceptions to the breeder's right, which include acts done for experimental purposes or for the purpose of breeding other varieties.[438] This would seem to be a harmonious counterpart to article 13.2(d)(ii) ITPGRFA, although there remains the question as to whether the grant of PVP would automatically trigger benefit sharing obligations.[439] Furthermore, nothing within the UPOV Enactments produces any difficulty with the requirement to pay into the benefit sharing mechanism, as a requirement for obtaining PVP.

The seed saving exemption in article 9.3 ITPGRFA has greater potential for difficulty in the context of UPOV. On the surface, it appears to be in direct conflict with exclusive PVP for plant breeders. This is mitigated by a number of factors. First, the UPOV conventions only apply to varieties that are the subject of plant variety protection. Therefore, there is a spectrum of crop varieties (including unprotected varieties, land races and wild relatives) that do not fall within the ambit of the UPOV convention but may be relevance within the ITPGRFA framework or for food security purposes.[440] Secondly and in the same vein, UPOV does not require farmers to grow protected varieties. [441] Third, the most recent UPOV 1991 Enactment contains both a mandatory exception for acts done privately and for non-commercial purposes[442] and an optional exception for states parties to restrict a breeder's right to allow farmers to propagate the product they have obtained from planting a protected variety on their land. [443] This appears to deliberately mirror article 9.3 of the ITPGRFA and it stands to reason that the same states that wish to uphold farmers' seed saving rights would also opt for such an exception in their national PVP framework. Finally, as discussed in section 4.3 above, article 9.3 serves only to affirm existing farmers' rights in domestic legal regimes. It does not confer rights where they

[438] UPOV 1991, art. 15.1(ii), art. 15.1(iii)
[439] Schraffin, Görlach & Gersetter, n428 above, at 40
[440] Governing Body of the ITPGRFA, 'Proceedings of the Symposium on Possible Interrelations between the International Treaty on Plant Genetic Resources for Food and Agriculture and the International Convention for the Protection of New Varieties of Plants' (Kigali, Rwanda 30th October-3rd November 2017) at 13
[441] ibid
[442] UPOV 1991, art. 15.1(i)
[443] UPOV 1991, art. 15.2

do not already exist. Thus, article 9.3 presents no particular difficulties from the perspective of UPOV, provided they are implemented harmoniously into domestic IP regimes.

4.5 Small farmers' innovations and the MLS

An issue that was avoided by the SMTA was the relationship between small farmers and intellectual property protection for developments derived from genetic resources accessed through the multilateral system. The issue as to whether small farmers should be given special consideration concerning financial contributions into the benefits sharing mechanism in article 13 was considered by the Expert Group on the Terms of the Standard Material Transfer Agreement. The opinions considered included, *inter alia,* that the concept of small farmers varies from country to country, and only those recognised as small farmers by national legislation should be exempt;[444] that small farmers in developing countries and economies in transition were primarily concerned with small scale and subsistence agriculture and therefore unlikely to engage in the breeding activities envisaged;[445] and, should small farmers find themselves so fortuitous as to be benefiting financially from a variety that they have developed using material from the MS through the mechanism of a proprietary right over that variety, then such small farmers were to be considered as a breeders and required to pay into the multilateral system.[446] It is interesting to note alongside this is that the ISF considered the question concerning small farmers to be irrelevant as small farmers simply would not be paying into the Benefit Sharing Mechanism.[447] Furthermore, because according to this line of reasoning, small farmers would not be paying into the benefit sharing mechanism, the ISF argued that the only way it would be possible to effect an exemption for farmers or small breeders would be as a financial exemption for small farmers could only exist as a subsidy for seed

[444] FAO Commission on Genetic Resources for Food and Agriculture, 'Report on the Outcome of the Expert Group on the terms of the Standard Material Transfer Agreement' 4-8 October 2004 CGRFA/IC/MTA-01/04/Rep at 44
[445] ibid, at 45
[446] n444 above, at 47
[447] ISF, 'Contribution of ISF to the establishment of a Material Transfer Agreement (MTA) for the Multilateral System (MS) provided for in Part IV of the International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA)' (June 2003) available at: http://www.worldseed.org/wp-content/uploads/2015/10/MTA_for_the_International_Treaty_on_PGRFA.pdf (accessed: 12th July 2020) at B.3

companies selling to small farmers, thereby providing them with an equivalent financial benefit.[448] This, it argued, would be almost impossibly complex and open to fraud.

However, small farmers were to receive no special mention in the final text of the SMTA, leaving the conclusion to be drawn that the view that small farmers who acquired IP rights over varieties they have developed were to be considered simply as commercial plant breeders and therefore any exception would be inappropriate. This is undoubtedly the simplest approach as it does not require additional development of the matter either at treaty or domestic level and is not incorrect *per se*. However, it is somewhat disappointing, if not in its outcome, but in what it expresses about how, both contracting parties and the governing body of the treaty view the function and purpose of the MS. Taking the viewpoint that the roles of breeders and farmers are separate but may potentially overlap in a small number of circumstances appears to indicate that even though the purpose of the MS is to support agricultural research and development it has evolved in a way that *de facto* is better suited to supporting commercial agricultural development. This is because it assumes that all crop development and subsequent application of intellectual property protection follows a specific archetype. It does not appear to accommodate alternative models of agricultural development. Despite the multitude of agricultural interests, the treaty purports to represent, it is actually caught in a very traditional paradigm concerning the flow of germplasm, i.e. from centres of origin to industrialised nations. That is, it does not yet at least, appear to have fully recognised the potential for material accessed through the system to benefit crop research and development activities taking place in other states or by other institutions. This is especially true in the case of subsistence crops, where the availability of PGRFA may be mutually beneficial to research and development and consequently help address food security concerns. For example, in the case of the Bambara groundnut[449] (*vigna subterranea)* the availability of material developed in West Africa may be of benefit to research taking place in South Africa or south east Asia. This is viewpoint is surprisingly

[448] ibid
[449] The genus of which includes this species, *vigna* or cowpea, is included in Annex I

supported by the ISF, a non-governmental organisation whose membership is drawn from professional seed producer associations.[450] The ISF argues that the limited number of genetic resources included within the MS is more detrimental to germplasm exchange between developing countries than for commercial plant breeders, as commercial breeders have other means of developing crop varieties than the introduction of new genetic material.[451] While it is important to note that despite this assertion, the introduction of further genetic material into the MS would still be to the benefit of ISF members, the point that the MS as it stands, has not been developed in such a way as to support smaller scale crop development (which in turn, might supplement food security concerns).

It is important not to judge the ITPGRFA too harshly for this, as is outlined in section 4.1.2 above, the final text represents an almost impossible compromise of competing interests and priorities. To a certain extent, it could be argued that developing states and states with high biodiversity may have perpetuated this dynamic in their understandable attempts to maintain sovereign control over their genetic resources. Against this background, it is difficult to reconcile the inclusion of additional crop species. However, the increased availability of genetic material through the MS combined with a reconsideration of the relationship between the roles of farmer and breeder within the ITPGFRA framework should serve to promote smaller scale innovation, and begin to address the primary concerns of the treaty, encouraging crop diversity and alleviating food security concerns. It is also possible for domestic ABS and PVP to effectively bridge the divide in the international framework between farmers and breeders. This can be achieved by designing national frameworks which adequately balance the competing priorities of the commercial seed industry and small scale developers. Perhaps the best example of this is the Protection of Plant Varieties and Farmers Rights Act 2001 (PPVFRA) of India.[452]

[450] ISF, 'Members map' available at: http://www.worldseed.org/members/members-map/ (accessed: 5th May 2021)
[451] ISF, n447 above, Annex I. ISF suggests that such restrictions are less likely to affect commercial breeders as there is the possibility of access to genetic material from secondary and tertiary sources of diversification; that they do not consider land races and wild relatives to be particularly useful for the purposes of commercial crop breeding; and that new technologies could be used to introduce resistance and quality traits into varieties rather than exotic germplasm.
[452] No. 53 of 2001

The PPVFRA attempts balance the diverse agricultural needs of the state. [453] It contains three distinct forms of plant variety protection in order to so. The first, Protection for New Varieties, tracks the UPOV standards for plant variety protection.[454][455] However, it is modified to allow the joint registration of a variety.[456] It also allows any breeder, including farmers, groups of farmers, communities and agricultural institutions to register a plant variety. This is balanced against the requirement to register the geographical origin of genetic material involved in the development of the variety, including all information pertaining to the contributions of farmers, communities or organisations involved in the development of the variety,[457] including traditionally conserved material from rural communities.[458] This is subject to a declaration that the material has been legally obtained.[459] As such, the registration of a new variety requires a benefit sharing agreement to have been reached with the originators of genetic material used in developing the variety. This provides an appropriate opportunity for financial considerations, including those pertaining to payments into the benefit sharing fund to be addressed as a part of the process of acquiring a plant breeders' right. Thus, the Indian model of plant variety protection for new varieties successfully achieves an equilibrium which recognises the role of both the commercial seed sector and small scale developers, which are in turn balanced against benefit sharing and conservation objectives. Likewise, the second two forms of plant variety protection included in the PPVFRA, Protection for Extant Varieties[460] and Protection for Farmers' Varieties[461] are tailored to specific national needs and provide IP protection for known extant and farmers' varieties, respectively. Thus, it is possible for a domestic PVP framework to adequately support more than one kind of plant-based innovator. However, the issue remains that not all developing states or states in the process of developing their domestic IP regime for plant varieties have the

[453] Srividhya Ragavan & Jamie Mayer O'Shields, 'Has India Addressed Its Farmers' Woes- A Story of Plant Protection Issues' [2007] 20 Georgetown International Environmental Law Review 97 at 98
[454] PPVFRA, s.15
[455] Ragavan & O'Shields, n453 above, at 98
[456] PPVFRA, s.16
[457] PPVFRA, s.18(1)(e)
[458] PPVFRA, s.40
[459] PPVFRA, s.18(1)(e)
[460] PPVFRA, s.15(2)
[461] PPVFRA, s.14

same resources or expertise available as India in terms of tailoring their domestic regimes to their specific national needs, therefore, more comprehensive guidance from the international framework would be beneficial.

4.6 Summary

To a certain extent, this chapter has not focused upon the issue of food security concerns. This is because the aim of addressing food security concerns is intrinsic to the ITPGRFA, and thus it is more appropriate to turn our attention to how the regime serves to promote agricultural innovation.

The plant treaty represents real progress in the sphere of agricultural biodiversity. Although the treaty has been in force for over a decade, the necessary developments to establish the operational aspects of the treaty have only recently come into effect, and as such, its youth makes it very difficult to assess the success of the regime. Additionally, the structure of the access and benefit sharing regime will continue to make it difficult to quantify the impact of the regime.

Nonetheless, it can be stated with certainty that the mechanisms introduced by the multilateral system have provided a means of facilitate access to publicly held germplasm and as such, should support plant-based innovations, provided that this is supported by adequate safeguarding measures in a state party's national IP regime. Where the benefit sharing aspect of the plant treaty is concerned, its role in helping to address food security concerns will be dependent upon the success of the projects funded by the mechanism. The role of both the access and benefit sharing mechanisms of the MLS will be returned to in chapter seven.

Furthermore, we have assessed that there should be no compatibility issues between the ITPGRFA and the requirements of TRIPS and UPOV, provided that they are implemented by states parties in a manner sensitive to one another. It is possible for them to co-exist as part of a wider *sui generis* system of IP and access and benefit sharing.

Finally, while the fact that farmers' rights have been included in the treaty is a positive, the drafting of article 9 means that it will be difficult to determine if their inclusion

has any effect. As such, it is not possible to speculate upon the impact of article 9 upon addressing food security concerns.

Chapter 5: The Convention on Biological Diversity and its Nagoya Protocol

5.1 Introduction

The purpose of this chapter is to widen the scope of the current exploration of the international legal frameworks that apply to genetic resources. In the previous chapter, we considered the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), a specialist regime that applies specifically to plant genetic resources for food and agriculture. In this chapter we will consider the regimes that apply to access to genetic resources generally: the 1992 Convention on Biological Diversity[462] (CBD) and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from the Utilization (NP). The CBD was the first international treaty to explicitly address all aspects of biodiversity, including the sustainable use of biological resources and access to biotechnology.[463] Its objectives are: the conservation of biological diversity; the sustainable use of its components; and the fair and equitable sharing of benefits arising out of the utilization of genetic resources.[464] Since being opened for signature at the United Nations Conference on Environment and Development in Rio,[465] it has achieved near universal membership.[466] Thus, it is of unparalleled relevance to the conservation and use of genetic resources. The 2014 Nagoya Protocol builds upon the foundations of the CBD, to produce a binding international access and benefit sharing (ABS) regime. To that end, it has greater impact upon the development of states parties' national ABS frameworks, and it is possible to evaluate with greater certainty its significance for research and development involving genetic resources. For these reasons, the Nagoya Protocol warrants more in-depth analysis.

This chapter is split into two main parts: the first, shorter part will consider the Convention on Biological Diversity. This exploration will be limited to its effect upon access to genetic resources and associated traditional knowledge, and the benefits arising from

[462] 5th June 1992
[463] Michael Bowman, Peter Davies & Catherine Redgwell, *Lyster's International Wildlife Law* (2nded) (Cambridge, Cambridge University Press, 2010) at 593
[464] CBD, art. 1
[465] Also referred to informally as 'the Earth Summit'
[466] The exceptions being the Holy See and the United States. See, 'List of Parties' available at: https://www.cbd.int/information/parties.shtml (accessed: 10th July 2020)

their use. It will consider the development of the biodiversity concept in international law; the status of the CBD as a 'framework' convention' and the consequences of this arrangement; before discussing ABS under the Convention. Finally, it will consider the relationship between the CBD and intellectual property. The first part will provide building blocks for the discussion of the Nagoya Protocol in the second part. It is important to note at this stage that in 2002, the Conference of the Parties to the CBD adopted the Bonn Guidelines on Access to Genetic Resources and Benefit Sharing. These voluntary guidelines built upon the ABS principles enshrined in the CBD. However, they have been effectively superseded in states that have acceded to the Nagoya Protocol. Therefore, they will not be discussed here.

The second part will consider the emergence of a binding ABS regime, and the effect of this on the content and substance of the obligations arising out of Convention on Biological Diversity. It will then analyse the principles access to genetic resources and traditional knowledge, direct and indirect benefit sharing as developed in the Protocol; before considering the various compliance mechanisms introduced by the Protocol. Finally, it will consider how the ABS principles and regimes under both the Nagoya Protocol and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) interact with one another.

5.2 The Convention on Biological Diversity

5.2.1 History and background to the Convention

There were several distinct initiatives that stimulated the negotiation of an internationally binding agreement concerning biological diversity. In 1980, the 'World Conservation Strategy'[467] produced by International Union for the Conservation of Nature (IUCN), the United Nations Environment Programme (UNEP) and the World Wildlife Fund (WWF) created the 'real foundation' for the biodiversity concept in international law.[468] It contained three specific objectives for living resource conservation; the second of which,

[467] IUCN/UNEP/WWF with FAO and UNESCO, *World Conservation Strategy: Living Resource Conservation for Sustainable Development* (IUCN, 1980) at 1.7
[468] Bowman, Davies & Redgwell, n463 above, at 589

'to preserve genetic diversity' represents the essence of the biodiversity concept[469] and was subsequently developed into the provision for the conservation of the Earth's vitality and diversity as a component of sustainable living, which made explicit reference to the conservation of biodiversity, when the World Conservation Strategy was revised.[470] Equally, the third objective, 'to ensure the sustainable utilization of species and ecosystems' can be viewed as a clear predecessor of the aims later expressed in the CBD. In the same vein, in 1982 the UN General Assembly adopted the World Charter for Nature[471] which asserted the general principle that the 'genetic viability of the Earth should not be compromised.'[472]

The international concern for maintenance of biodiversity crystallised at the 14th meeting of UNEP's Governing Council (the GC) in 1987. In the weeks prior to the GC, the World Commission on Environment and Development presented its report 'Our Common Future' (otherwise known as the Brundtland Report).[473] The report highlighted, *inter alia*, the need for new imperative for international cooperation in the environmental sphere and for economic development based upon policies that sustain and expand the natural environmental resource base. In essence, the preservation of biodiversity is essential for sustainable development. It suggested that, as the only intergovernmental organisation with universal membership, the UN should take the lead in developing this cooperation. The report also advocated the need for formal recognition of rights and responsibilities concerning environmental protection and sustainable development. The recommendation of the report was a universal declaration on environmental protection and sustainable development, to be followed up by a binding convention within three to five years.[474] Indeed, the report contained a list of proposed legal principles for environmental protection

[469] ibid
[470] IUCN/UNEP/WWF, *Caring for the Earth: A Strategy for Sustainable Living* (Gland, IUCN/UNEP/WWF, 1991) at 9
[471] UN/GA/RES/37/7, 28th October 1982
[472] ibid, at 1.2
[473] World Commission on Environment and Development, *Our Common Future* (Oxford, Oxford University Press, 1987)
[474] ibid, at 5.2

and sustainable development.[475] However, due to the proximity of the publication to the GC, the laying of 'the foundation stone' to the CBD went virtually unnoticed.[476]

At the GC meeting, the United States put forward an initiative for a global umbrella convention on biological diversity.[477] At the same time, the IUCN was working on the drafting of a global convention on the *in situ* conservation of flora and fauna between 1984 and 1989.[478] It is useful to note, that at that point in time, there was no suggestion of a linkage between biodiversity and biotechnology.[479] This is indicative of the era in which the Convention was negotiated.

The starting point for the CBD can be regarded as being the meeting of an *Ad Hoc* working group of experts convened by the Executive Director of UNEP in 1988 to investigate the proposals made by the US and the IUCN.[480] The meeting concluded that the extent of existing conventions could not address the full range of issues associated with biodiversity and therefore action was required.[481] Thus, in 1989 the GC initiated the drafting of a convention on the conservation of biological diversity,[482] which was to include the proper consideration of the financial and technological transfers from the beneficiaries of biological resource exploitation to the owners of biological resources.[483] This was subsequently folded into the mandate for United Nations Conference on the Environment and Development to be held in Rio de Janeiro in 1992.[484]

[475] n473 above, at Annex 1
[476] Fiona McConnell, *The Biodiversity Convention: A Negotiating History* (London, Kluwer Law International, 1996) at 4-5
[477] CBD, 'Chapter 2: The Convention on Biological Diversity' available at https://www.cbd.int/gbo1/chap-02.shtml (accessed 10th July 2020)
[478] IUCN, 'Draft Articles prepared by IUCN for inclusion in a proposed Convention on the conservation of Biological Diversity and for the establishment of a fund for that purpose and explanatory notes' (Bonn, IUCN Environmental Law Centre, 1989)
[479] McConnell, n476 above, at 6
[480] Veit Koester, 'The Biodiversity Convention Negotiation Process and Some Comments on the Outcome' (1997) 27(3) Environmental Policy and Law 175 at 176
[481] ibid, at 176-177
[482] Resolution 15/34 of the UNEP Governing Council, while recognising the need for co-ordinated and effective implementation of existing legal instruments and agreements, also endorsed the adoption of a further legal instrument which might be in the form of a framework convention for the global conservation of biological diversity.
[483] ibid
[484] Bowman, Davies & Redgwell, n463 above, at 593

The negotiation of the CBD took place over a series of ten meetings, nine of which took place between 1990 and 1992. This represents an unusually short period of negotiation for a multilateral environmental agreement.[485] The majority of key issues were laid out in the course of the first meeting. The two most relevant aspects for present purposes, intellectual property rights and *ex situ* conservation were included at the second meeting. Alongside many of the other key issues, these remained contentious until the end of the negotiations.[486] Indeed, the final meeting opened with issues remaining in twenty seven of the forty two articles of the Convention.[487] Many of which were only resolved through diplomatic pressure and under the threat of the Rio deadline.[488] In order to reach a final text many of the key provisions of the Convention had only been agreed upon as a result of specific and deliberate concessions made in the Sub-Working Groups.[489] Some of the consequences of which are discussed below. Nonetheless, the Convention was opened for signature at the Rio Earth Summit and came into force on 29th December 1993.

The ultimate result of hasty negotiation of the Convention is that the substantive content of the CBD is, generally speaking, framed in aspirational language and soft obligations. For example, the qualification 'as far as possible and as appropriate'[490] appears eight times in the Convention text in relation to substantive obligations. Similarly, soft phrases such as 'promote and encourage' [491]'promote and cooperate'[492] and 'support'[493] among others are laced throughout the text.

Indeed, the final text of the Convention has been polarising among commentators. While some, such as Desiree McGraw,[494] highlight the success of the CBD through the concessions achieved by developing states; others, such as Alan E. Boyle[495] criticise the

[485] Désirée McGraw, 'The CBD – Key Characteristics and Implications for Implementation' (2002) 11(2) Review of European, Comparative and International Environmental Law 17 at 21
[486] Koester, n480 above, at 177
[487] Koester, n480 above, at 179
[488] McConnell, n476 above, at 82-99
[489] Koester, n480 above, at 179-180
[490] CBD, art. 5; art. 6(b); arts. 7-11; art. 14
[491] CBD, art. 10(c); art. 12(b)
[492] CBD, art. 12(c)
[493] CBD, art. 10(d)
[494] McGraw, n485 above
[495] Alan E. Boyle, 'The Rio Convention on Biological Diversity' in Micheal Bowman and Catherine Redgwell (eds) *International Law and Conservation of Biological Diversity* (London, Kluwer Law International, 1996) at 48-49

final treaty as being a poor interpretation of customary international law and weaker than its contemporaries, both in terms of guiding principles and institutional structure. Boyle is also cynical of its role in reorienting economic benefits to the developing world. Thus, the compromises achieved by the Convention left much to be desired.

5.2.2 'The Framework Convention on Biological Diversity'

The adoption of the CBD was a milestone for the recognition of the importance of the conservation of biodiversity and the recognition of stakeholder interests in biodiversity. However, as is noted above, it is largely composed of soft obligations. To that end, it is necessary to consider the legal character of the final agreement

Unlike its contemporary, the UN Framework Convention on Climate Change,[496] (UNFCCC) the CBD does not expressly define itself as a framework convention. Nonetheless, its role in relation to existing multilateral environmental agreements was a point of deliberation during the negotiation of the Convention. More specifically, the mandate of the original *ad hoc* working group was to investigate a potential umbrella convention which might serve to organise the various activities in the sphere of biodiversity conservation and incorporate other relevant areas.[497] However, the final text of the Convention is widely conceived as being a framework agreement.[498] This is because rather than adopting a prescriptive approach and encompassing previous agreements, the CBD lays down guiding principles at the international level which states parties are then obliged to take into account when developing national law and policy.[499] As such, it seeks to fill in the biodiversity gaps in existing regulation[500] and with the option to address specific

[496] 9th May 1992
[497] McGraw, n485 above, at page 18, footnote 9
[498] McGraw (n485 above), Birnie, Boyle and Redgwell (n499 below), Morgera and Tsioumani (n509 below) and Bowman, Davies and Redgwell (n463 above) all present analyses agreeing that the CBD is a framework, as opposed to an umbrella convention
[499] Patricia W. Birnie, Alan E. Boyle and Catherine J. Redgwell, *International law and the Environment* (Oxford, Oxford University Press, 2009) at 616
[500] Bowman, Davies & Redgwell, n463 above, at 594

issues by means of subsequent supplementary agreements.[501] Indeed, the negotiation and adoption of annexes and protocols to the Convention is envisioned in article 23.4.

The framework character of the Convention makes the implementation of the Convention at the national level particularly important, as it is concerned with the management of resources over which states have sovereignty.[502] Accordingly, it is appropriate to briefly consider the compliance mechanisms and the institutional framework of the CBD, so that it is possible to properly evaluate the scope of states parties' obligations in the context of substantial provisions of the Convention.

Article 23.1 provides for the establishment of the Conference of the Parties as the body of the treaty and for regular meetings of the COP. Alongside which, it also establishes a Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), 503 which is charged with providing scientific and technical advice to the COP.[504] The primary function of the COP is to keep under review the implementation of the Convention.[505] This is broadly defined so as to include, *inter alia*: the review of scientific, technical and technological advice provided by the SBSTTA;[506] the adoption and amendment of annexes and protocols to the CBD;[507] and a rather open-ended provision to 'consider and undertake any action that may be required for the achievement of the purposes of this Convention in the light of the experiences gained in its operation.'[508] Indeed, the basic institutional structure has been supplemented by a number of specialist working groups,[509] including the Working Group on Access and Benefit-Sharing;[510] the Working Group on Review of Implementation of the Convention;[511] the Working Group on Protected Areas;[512] and the

[501] In the case of the CBD, its supplementary agreements are the Cartagena Protocol on Biosafety and the Nagoya Protocol on Access and Benefit Sharing
[502] S. Johnston, 'The Convention on Biological Diversity: The next phase' (1997) 6 Review of European Community and International Environmental Law 219 at 226-227
[503] CBD, art. 25.1
[504] CBD, art. 25.2
[505] CBD, art. 23.4
[506] CBD, art. 23.4(b)
[507] CBD, arts. 23.4 (c)-(f)
[508] CBD, art. 23.4(i)
[509] Elisa Morgera and Elsa Tsioumani, 'Yesterday, Today and Tomorrow: Looking Afresh at the Convention on Biological Diversity' (2011) 21 Yearbook of International Environmental Law 3 at 4
[510] UNEP/CBD/COP/5/23, Decision V/26
[511] UNEP/CBD/COP/7/21, Decision VII/30
[512] UNEP/CBD/COP/7/21, Decision VII/28

Working Group on Article 8(j).[513] All of which have been supplemented by various ad hoc technical groups.[514] The Working Groups have produced a number of formal outputs. They have also provided a forum for the continued debate and development of the principles established in the Convention. Thus, the Working Groups have served to expand upon and clarify the issues arising under the CBD and to incorporate the views of non-state actors.

While the flexible mandate assigned to the COP and the SBSTTA are appropriate given the framework nature of the CBD, institutionally it lacks a more rigorous mechanism intended to systematically and effectively monitor national implementation and compliance.[515] This is true both in terms of the original Convention and any subsequent developments arising from the Working Groups. States parties are required to submit reports at regular intervals to the COP;[516] however no mechanism has been developed to either formally encourage states parties to improve their compliance or to chastise them for not doing so. Additionally, there is no arrangement in place for the systematic review of the reports submitted by states parties.[517] Instead, the system is based around encouraging cooperation. Thus, it is unlikely that this vague system of review can be successful as a means of monitoring states parties' implementation of their obligations.[518]

On this basis, the institutional framework of the CBD must be viewed as seriously curbing the efficacy of any of the provision of the convention. When combined with the soft language of the text, this then raises the question as to whether any of the content of the Convention carries real normative force or if it is best viewed instead as agreed guidelines on best practice in the fields it encompasses.

[513] UNEP/CBD/COP/4/27, Decision IV/9
[514] Morgera & Tsioumani, n509 above, at 5
[515] Morgera & Tsioumani, n509 above, at 6
[516] CBD, art. 26
[517] Yibin Xiang and Sandra Meehan, 'Financial Cooperation, Rio Conventions and Common Concerns' (2005) 14 Review of European Community and International Environmental Law 212 at 218
[518] Morgera & Tsioumani, n509 above, at 6

5.2.3 Access and Benefit Sharing under the CBD

The fair and equitable sharing of the benefits arising out of the utilization of genetic resources is one of the primary objectives of the Convention, as is established by article 1. The Convention's entry into force represented a paradigm shift from the previously widely recognised status of genetic resources as forming the common heritage of humanity towards exclusive state sovereignty over their genetic resources.[519] To that end, in drafting the Convention states parties sought to establish principles governing the access to genetic resources and potential benefits to be shared with states providing genetic resources that could form the basis of domestic law concerning ABS. Interestingly, the preamble makes an explicit link between access to and sharing of genetic resources with the conservation of and sustainable use of biological diversity for the purposes of meeting the food (and other) needs of the world's population. Accordingly, the regulation of access and benefit sharing is not limited to research-based activities but is inherently linked with all of the aims of the Convention.

5.2.3.1 Access to Genetic Resources

The Convention defines 'genetic resources' as 'genetic material of actual or potential value';[520] with 'genetic material' being defined as any plant, animal, microbial or other material containing functional units of heredity.[521] Thus, for present purposes, the scope of the CBD includes all plant genetic material of actual or potential value, including that found in seed form. The CBD applies to genetic resources both *in situ*[522] and *ex situ*.[523] However, it does not extend to cover derivatives. As such, potentially commercially valuable biologically derived chemicals are excluded from the scope of the CBD. This does not preclude states parties from including derivatives in their national (or regional access) legislation. However, it does present a considerable loop hole given that

[519] UNCTAD, *BioTrade and Access and Benefit Sharing: From Concept to Practice – A handbook for Policy makers and Regulators* (United Nations, Geneva, 2017) at vii
[520] CBD, art. 2
[521] ibid
[522] CBD, art. 8
[523] CBD, art 9

derivatives may be the source of benefits arising from the utilization of genetic resources, as opposed to raw genetic resources *per se*.[524]

Article 15 addresses access to genetic resources. Under article 15, states parties are recognised as having sovereignty over their genetic resources and the authority for determining access rests with the national government. However, states parties are required to 'endeavour to create conditions' to facilitate access to genetic resources and not to impose restrictions that run counter to the principles of the Convention.[525] Where access is granted, it is to be on the basis of mutually agreed terms (MAT)[526] and subject to the prior informed consent (PIC) of the providing party.[527] As such, whilst article 15 establishes states parties' sovereignty over their resources, the prevailing sentiment of the provision is directed towards encouraging the sharing of genetic resources, at the same time as defining the two pillars of access to genetic resources. Accordingly, the wording of the provision is relatively dilute and aspirational. Thus, while article 15 does impose substantial obligations upon states parties, its primary achievement is to redefine ownership of genetic resources in international law rather than to impose concrete obligations. As the substance of the provision is directed towards national governments, there exists a relatively straightforward opportunity for states parties to comply with article 15 without fully developing a nation level ABS regime. It is within the scope of article 15 to implement 'enabling legislation', which charges a competent national authority with the task of examining the issues arising under article 15 and with the future implementation of more specific guidelines or regulations.[528] Lyle Glowka notes that in a number of his examples, the enabling legislation did not address the key issues of PIC and MAT.[529] Indeed, a survey of nation implementation approaches conducted by Glowka in 1997, four years after the entry into force of the Convention, suggested that this approach was popular with a number of states in complying with their obligations under the

[524] See, section 5.3.2.1 below
[525] CBD, art. 15(2)
[526] CBD, art. 15(4)
[527] CBD, art. 15(5)
[528] Lyle Glowka, 'Emerging legislative approaches to article 15 of the Convention on Biological Diversity' (1997) 6(3) RECIEL 249 at 249
[529] ibid

Convention.[530] Glowka's study is particularly helpful in directing our attention towards appropriate post-CBD ABS legislation and regulation, as ABS developments that have emerged since the signature of the CBD[531] make it difficult to retrospectively analyse the actual effect of the CBD in encouraging the development and implementation of ABS at the national level. As such, it provides a useful snapshot of ABS approaches at the time.[532]

The option to implement enabling legislation serves to demonstrate that strictly interpreted, compliance with article 15 is relatively meaningless. This is because enabling legislation represents sufficient compliance with an obligation to 'endeavour to create conditions' to facilitate access to genetic resources. However, if we return to Glowka's study, we can see that enabling legislation is only the first of five categories of approaches to ABS implementation.[533]

The second category includes states that had opted to implement framework biodiversity laws intended to implement the concepts embodied in the CBD.[534] The biodiversity regimes in these states tended to be more comprehensively drafted than the enabling legislation and implemented the CBD by clearly establish PIC and MAT requirements. The third and most comprehensive approach is that adopted by the Philippines,[535] which is a collection of the national instruments intended to regulate access to genetic resources.[536] What is particularly distinctive about the Philippines' regime is that it is uniquely thorough and precise in its drafting. This approach is particularly comprehensive as it submits all wild flora and fauna are owned by the state and the

[530] Glowka cites the Gambia (National Environmental Management Act (1995)), Kenya ((Draft Environmental Management and Coordination Bill (1995)), Malawi (Environmental Management Bill (1995)), South Korea (National Environment Preservation Act (1991) as amended (1994)) and Uganda (National Environmental Statute (1995)) as contemporary examples of enabling legislation.
[531] Namely, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilization in 2002 and the Nagoya Protocol in 2010
[532] Glowka's study is used to direct the present analysis as to the state of implementation of national regimes at the time of his writing, in 1997
[533] Although we must be careful to give the categories an appropriate weighting, as some only contain one or two examples
[534] Glowka, n528 above, at 250. Examples include the Wildlife Conservation Law (1992) of Costa Rica; the Second draft Eritrean Proclamation on the Conservation of Biological Diversity (1996); the Draft Sustainable Development Bill (1997) of Fiji; the Environmental Act (1996) of Mexico; and the Draft Law for the Conservation and Sustainable Use of Biodiversity (1997) of Peru.
[535] Executive Order 247 (1995); Department of Environment and Natural Resources Administrative Order 96-20 (Implementing Rules and Regulations on the Prospecting of Biological and Genetic Resources (June 21,1996)) of the Philippines
[536] Glowka, n528 above, at 250

'disposition, development and utilization thereof' are subject to full state supervision and control.[537] The regime is particularly successful in addressing not only conceptual issues[538] but also in exhaustively laying out the related procedural requirements.[539] For example, the regime requires a separate agreement to be made for the transfer of royalties, benefits and technology.[540] Of particular note is the fact that the regime sets out measures to penalise non-compliance.[541]

The fourth approach taken was the modification of existing laws, usually existing regulation concerning the conservation of National Parks, to better reflect concerns over access to and the removal of genetic resources.[542] This approach has also been adopted at the subnational level. This was the approach initially adopted by the Malaysian state of Sarawak.[543] Essentially, this is a very basic approach, although one with more precise requirements than enabling legislation. The final category is the development of a regional regime on access to genetic resources. The only contemporary example of which was the Andean Pact's Decision 391[544] which provided for the implantation of minimum standards across the five member states. As such, member states were able to implement more comprehensive regimes concerning access to genetic resources.

What all of these examples have in common is that they originate in biodiversity rich states which had a manifest interest in controlling access to biodiversity, with particular emphasis on regulating bioprospecting and protecting their national resources from biopiracy. Indeed, these are the laws and draft laws of the states which argued fervidly for the recognition of state sovereignty over genetic resources during the

[537] Administrative Order no. 96-20, (n535 above) art. 1.1
[538] For example, 'benefit sharing' is defined as the sharing of the results of bioprospecting activity and benefits arising from the utilization or commercialization of biological or genetic resources fairly and equitably with the indigenous cultural community/local community/protected area/private land owner and the national government. Possible benefits to be shared include payment for access to specimens, royalties, data, technology, capacity building and joint research (art. 2.1(e)). Article 2.1 also contains a comprehensive and concise definitions of all of the pertinent terminology.
[539] See, for example, s. 8, 'Minimum terms and conditions of a research agreement'
[540] Administrative Order no. 96-20 (n535 above), s. 8.1(14)
[541] Administrative Order no. 96-20 (n535 above), s.14
[542] Glowka, n528 above, at 250. Examples include the National Parks Act 1991 of Nigeria; and Title 36(2.5) of the US Code of Federal Regulations
[543] Laws of Sarawak, Forest Ordinance 1958, as amended
[544] Andean Community, Decision No. 391 Establishing the Common Regime on Access to Genetic Resources, 1996

negotiation of the Convention.[545] As such, the implementation (or pending implementation) of these national regimes in the time period immediately around the adoption of the CBD is somewhat misleading, as the fact of their implementation is not, in itself, evidence of the successful promotion of ABS values by the CBD.

It is a relatively common argument that the imposition of access regulation may serve to stifle innovations in biotechnology; however, from the perspective of research and development, the implementation of clearly drafted access regulation is actually advantageous as it provides legal certainty concerning the status of the resources accessed. This serves to protect the party conducting research and development involving genetic resources from a state with access regulation from subsequent difficulties should the research result in a commercialised product. This point will be returned to in chapter seven.[546]

What the examples considered serve to demonstrate is that what is missing from the realization of the ABS values encapsulated in article 15 is balance. The notion of benefit sharing is only vaguely defined by the CBD. While it is possible to leave the concept of equitable benefits open to negotiation on a case by case basis, relying upon MAT as the sole means of implementing benefit sharing creates serious practical considerations. The key substantive issue is whether there is sufficient scope in a state party's national legal framework to support benefit sharing. Potential benefit sharing issues include: whether the holder(s) of a genetic resource have legal personality, whether the benefits in question fit within the scope of contractual obligations as defined in that jurisdiction; and the availability and ability of the resource holders to enforce benefit sharing obligations, among others. Linked with this, is the concern as to whether the holders of genetic resources are able to effectively negotiate a fair and equitable access and benefit sharing agreement. This raises questions regarding both legal and scientific capability. Thus, relying upon the concept of MAT alone as a means of ensuring benefit sharing seems

[545] R. Jayakumar Nayar and David Mohan Ong, 'Developing Countries, 'Development' and the Conservation of Biological Diversity' in Bowman and Redgewell (eds) n495 above, at 238-241
[546] See, section 7.3.1 below

unlikely to produce fair and equitable benefit sharing without a thoroughly detailed national ABS regime. The examples above demonstrate that this was rarely the case. Not only that, but the absence of an adequate compliance mechanism at the international level means that even where a comprehensive national ABS regime has been developed (such as that of the Philippines) it will lack teeth if states parties are unable to effectively hold other states parties responsible for upholding the benefit sharing obligations of either the state itself or legal personalities within its jurisdiction. This point is returned to in chapter six.[547]

5.2.3.2 Access to traditional knowledge

The CBD does not contain a provision which exclusively treats access to associated traditional knowledge. Rather, TK is addressed as an element of *in situ* conservation. Article 8(J) provides that contracting parties are to respect, preserve and maintain and promote the wider application of the knowledge, innovations and practices of indigenous and local communities relevant to the conservation and sustainable use of biological diversity, with the approval and involvement of the holders of the knowledge, innovations and practices in question. The provision is limited subject to national legislation and by the general caveat of 'as far as possible and as appropriate.' Contracting parties are also to 'encourage' the equal sharing of benefits arising out of the knowledge in question. On its own, article 8(j) does little more than express an ideal that states parties approach the issue of access to TK and the distribution of the benefits arising from the access and utilization of TK with some degree of fairness towards the holders of the knowledge in question. As such, while the CBD does pay due notice to TK, and in doing so cements it as an ABS issue to be considered by the international community, any actual ABS developments are solely within the discretion of states parties. This is likely a result of the incredibly diverse and undocumented nature of much traditional knowledge, laws and practices. It is also attributable to the fact that issues concerning access to TK do not

[547] See, section 6.3.3. below

arise in all contracting parties. However, this ambiguity is of little utility to either the holders of or to potential end users of TK.

It is clear from the fact that TK is not addressed in a separate provision that it is not a primary concern of the CBD. Nonetheless, the issue of associated TK has not remained static within the framework of the Convention. Aside from being developed under the subsequent Nagoya Protocol, it is also the subject of continued study and scrutiny within the ambit of the CBD itself. The fourth meeting of the COP established a Working Group on Article 8(j) (traditional knowledge) in 1998 (WG8J).[548] The COP adopted a programme of work for the Working Group at its fifth meeting.[549] This included, *inter alia*, the implementation of participatory measures needed to ensure the full participation of indigenous and local communities;[550] the need for case studies to be developed in conjunction with indigenous and local communities in order to create a 'meaningful assessment' of existing legal and other relevant methods for the protection of the knowledge, innovations and practices of indigenous and local communities;[551] and to explore the possibility of the development of legal and other forms of protection for TK.[552]

While article 8(j) does not provide any kind of structured obligation for states parties where the relationship between indigenous and local communities, forms of indigenous knowledge and biodiversity are concerned, through the Working Group it has provided a platform for elevating the concerns to the international level. While progress may be slow on this front, it is arguably more valuable that such a forum exists for a debate that includes the interested parties, as opposed to the imposition of a binding but otherwise unhelpful treaty provision. The Working Group has experienced success in addressing some of the issues within its mandate; the most pertinent example is the development in 2015 of: 'Draft Voluntary Guidelines for the development of mechanisms, legislation, or other appropriate initiatives to ensure the [free,] prior informed consent [or

[548] Decision IV/4, UNEP/CBD/COP/4/7, 15th May 1998
[549] Decision V/16, UNEP/CBD/COP/5/23
[550] ibid, at para. 5
[551] n548 above, at para. 13
[552] n548 above, at para. 1(a)

approval and involvement] of indigenous peoples and local communities for accessing their knowledge, innovations and practices, the fair and equitable sharing of benefits arising from their use and the application of such knowledge, innovations and practices relevant for the conservation and sustainable use of biological diversity and for reporting and preventing unlawful appropriation of traditional knowledge' ('draft guidelines').[553] While the draft guidelines have not yet been formally adopted, they are debatably already of value, as they not only demonstrate areas in which a consensus has been achieved, but also they provide useful guidance for outside parties seeking to access TK, especially where the national ABS regime may be under developed.

5.2.4 Intellectual Property and the Convention on Biological Diversity

The Convention on Biological Diversity was negotiated in the UNEP forum at the same time as the negotiations were taking place in the GATT that would lead to the Agreement on Trade Related Aspects of Intellectual Property (TRIPS). Although the issue of intellectual property protection was fiercely debated during the negotiation of the CBD,[554] the debate was largely centred upon what would become article 16, which concerns access to and transfer of technology. Article 16 provides for the facilitated access to biotechnology as a means of achieving the development of objectives of the Convention. As such, the debate focused upon the extent of protection afforded IPRs in technology transfer. The question of IP protection for genetic resources or products derived thereof is not addressed by article 15. This can partly be attributed to the era in which the negotiation of the Convention took place; as during the late 1980s and early 1990s the potential of biotechnology was not yet fully understood. It can also be attributed to UNEP not being perceived as an appropriate forum for the discussion of IP concerns when other more appropriate forums, such as the World Intellectual Property Organization (WIPO), GATT, and UPOV existed. Another factor is that the issue of IP protection for genetic resources or products derived thereof can be argued to be within an individual state's

[553] UNEP/CBD/WG8J/REC/9/1, 7th November 2015
[554] Ian Walden, 'Intellectual Property Rights and Biodiversity' in Bowman and Redgwell (eds), n495 above, at 172

sovereignty over their resources, and as such did not require addressing by the Convention as the issue was discretionary. Thus, the CBD does not explicitly or adequately confront the relationship between IP and genetic resources. Given the fact that article 27.3(B) TRIPS requires its member states to make available IP protection for plant-based innovations, the failure to address the relationship between genetic resources in a substantive way in the CBD is firmly to the detriment of the holders of genetic resources. However, the issue of IP in the context of ABS would later be addressed in the development of the Bonn Guidelines and the Nagoya Protocol, and is considered in section 5.3.3 below.

5.2.5 Summary: Convention on Biological Diversity

The primary achievement of the Convention on Biological Diversity was the introduction of basic principles relating to the conservation and use of the natural world in to international law. This includes the principles of access and benefit sharing. However, as the provisions are relatively dilute, their effect is ultimately at the discretion of states parties. As a result, it does not offer much certainty for stakeholders or users of genetic resources and is therefore of limited use. The area in which this deficit is particularly evident is the failure to adequately address the relationship between genetic resources and IP rights. Nonetheless, the CBD has succeeded in creating both a framework and a forum for these issues to be discussed and developed. As can be seen from the first part of the chapter, this was a major achievement at the time. The results of this accomplishment are considered in section 5.3 next.

5.3 The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization

5.3.1.1 Negotiation History of the Nagoya Protocol

In 2002, the attendees of the World Summit on Sustainable Development in Johannesburg agreed to begin negotiations on an international benefit-sharing regime.[555] At the following Conference of the Parties to the CBD in 2004, the Ad Hoc Working Group on Access and Benefit Sharing (Working Group, or WGABS) was given the mandate to

[555] UN, *Report of the World Summit on Sustainable Development: Johannesburg, South Africa, 26 August-4 September 2002* (United Nations, New York, 2002) at paras. 44(n), 44(o)

collaborate with the 'Ad Hoc Open ended Inter-sessional Working Group on Article 8(j) and related provisions' to elaborate and negotiate a new international access and benefit sharing (ABS), with the aim of adopting instrument(s) to effectively implement articles 15 and 8(j), in addition to complying with the three central aims of the Convention.[556] The mandate of the Working Group required that indigenous and local communities, NGOs, intergovernmental organizations and industrial, scientific and academic institutions be invited to participate in the debate.[557] The Decision included an Annex which contained detailed terms of reference, including the process, nature, scope and elements of such a regime.[558]

The Working Group met eleven times between 2005 and 2010. The introduction of a draft Protocol text at the Fourth Meeting in January 2006[559] served to highlight the divergence between industrialised states on one side and the group of Like Minded Mega Biodiverse states and the G77 on the other. The first group questioned the necessity and scope of a legally binding regime, as the draft text did not adequately reflect their views. Collectively, the industrialised states were concerned that the scope of the subject matter that might be included in the protocol was too broad.[560] Several also expressed the strongly held view that a legally binding regime would be too restrictive, as it could potentially prevent bio-prospecting altogether. In the words of the Australian APEC[561] Study Centre, such a regime would constitute 'onerous regulation'.[562] Such regulation would lead to a reduction in the commercial benefits arising out of the exploitation of genetic resources, and this in turn would lead to fewer benefits being shared with providing states.

Furthermore, the opinion was raised that some of the proposals for the regime which would create a right for governments to have a say in how genetic resources or

[556] CBD, 'Working Group on Access & Benefit Sharing' available at: https://www.cbd.int/abs/wgabs/ (accessed: 15th July 2020)
[557] Decision D, UNEP/CBD/COP/DEC/VII/19, 13th April 2004
[558] ibid
[559] UNEP/CBD/COP/8/6
[560] UNEP/CBD/WG-ABS/4/2
[561] Asia Pacific Economic Cooperation
[562] UNEP/CBD/WG-ABS/4/2, at p. 3

products derived from genetic resources, including patented products or products are otherwise the subject of IP protection, are to be used would undermine intellectual property law, and what they considered to be its role in managing access to genetic resources.[563]

The second group considered the draft text to be an adequate starting point for the elaboration of a comprehensive regime that would include, *inter alia*: capacity building; compliance; transfer of technology; access to justice; ensuring that genetic resources and associated traditional knowledge are accessed on the basis of Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT); the effective participation of local and indigenous communities; disclosure requirements for intellectual property protection; and operate as effective guidance for national legislation.[564]

The Working Group continued to address the nature, objective and scope of an international regime through its fifth, sixth and seventh meetings and COP-9, as well as at Expert Meetings between COPs 9 and 10. At the eighth meeting of the Working Group, all of the debate on the content and nature of the regime was developed into a single negotiating text which incorporated all of the possible elements and the views of all of the parties, referred to as the 'Montreal Annex'. The draft text was over 57 pages in length and contained over 3400 squared brackets,[565] representing issues that had been raised but not yet agreed upon.[566] The overwhelming and divergent nature of the combined document led many negotiators to doubt whether it would be possible to reach an agreement on the basis of this text.[567]

[563] ibid, at 2-3
[564] Soledad Aguilar, Xenya Cherny, Stefan Jungcurt, Elisa Morgera and Elsa Tsioumani, 'Summary of the Fourth Meeting of the Working Group on Access and Benefit Sharing of the Convention on Biological Diversity: 30 January-3 February 2006' (2006) 9(344) IISD Earth Negotiations Bulletin at 8
[565] Linda Wallbott, Franziska Wolff and Justyna Pożarowska, 'The negotiations of the Nagoya Protocol: Issues, coalitions and process' in Sebastian Oberthür & G. Kristin Rosendal (eds.) *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol* (Oxon, Routledge, 2014) at 46
[566] Richard E. Saunier & Richard A. Meganck, *Dictionary and Introduction to Global Environmental Governance* (London, Earthscan, 2007) at 237
[567] Matthias Buck & Clare Hamilton, 'The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization' (2011) 20(1) Review of European Community and International Environmental Law 47 at 50

In order to push the negotiations forward, a draft text of the Protocol was prepared by the co-chairs of the Working Group. This was accepted as the basis for negotiations from the ninth meeting in Cali, Colombia, in place of the Montreal Annex.[568] However, despite significant progress, the Working Group failed to finalise the text of the Protocol. In light of the approaching deadline for adoption at COP-10, a second session was convened. Many of the key issues remained contentious until the last minute. The issues included the economic scope of the Protocol: whether it would support ABS frameworks for just naturally occurring gene sequences or whether it would include naturally occurring compounds that result from the metabolic process of cells; the geographical scope of the Protocol; the status of non-commercial research under the Protocol; the scope obligations of parties to provide access to genetic resources over which they have sovereign rights; the relationship between the Nagoya Protocol and other international instruments; the extent to which the Protocol would enable originating states to challenge the misuse of genetic resources and breaches of relevant contracts in other states' jurisdictions; whether the Protocol would apply to genetic resources and TK accessed before the Protocol entered into force: access to *ex situ* collections of genetic resources; whether the Protocol would address access and benefit sharing for associated traditional knowledge in a manner equal to ABS for genetic resources; and how the Protocol would complement states' general obligation to combat biopiracy.[569] A bargain between the user and provider countries of genetic resources was only possible as the result of the intervention of the Japanese COP presidency.[570]

The compromise text of the Protocol was adopted on 20 October 2010 and was open for signature until 1 February 2012; during which time it was signed by 92 states parties. It entered into force on 12 October 2014, ninety days after the deposit of its

[568] CBD, 'History: Negotiations of an International Regime on ABS' available at https://www.cbd.int/abs/background/ (accessed: 15th July 2020)
[569] Buck & Hamilton, n567 above, at 50-51. Also at issue was the application of the Protocol to pathogens of public concern to the health of human beings, plants and animals.
[570] Elsa Tsioumani, 'Access and Benefit Sharing- The Nagoya Protocol' (2010) 40(6) Environmental Law and Policy 288 at 288-289

fiftieth instrument of ratification. Currently, there are 124 states parties to the Protocol.[571] Its membership is substantially smaller than that of the Convention on Biological Diversity, a fact that can at least in part be attributed to the many compromises made on polarising issues contained in the final draft of the Protocol.

5.3.1.2 The objective and scope of the Nagoya Protocol

The objective of the Protocol is stated as being the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including appropriate access to genetic resources, with the aim of contributing to the conservation of biological diversity and the sustainable use of its components.[572] The primary objective of the Protocol is identical to the third objective of the CBD, which is complemented by the supplementary goals of biodiversity conservation and the sustainable use of resources, which reflect the first and second goals of the Convention. Thus, the Protocol posits ABS as a specific tool for achieving all of the goals of the Convention.

It is noteworthy that associated traditional knowledge (TK) is not referenced in the objectives of the Protocol, either in terms of access to TK or the redistribution of benefits arising from its use, despite it being the subject of several substantial provisions of the Protocol, including article 3 concerning its scope.[573]

The Protocol builds upon the principles of the CBD by providing a flexible framework, which attempts to accommodate the concerns of both user and provider states, in line with their development capacities. It is intended to encourage partnerships between national and local authorities, local and indigenous communities, and the private sector.[574] Thus, the access and benefit sharing regime envisioned by the Protocol operates

[571] CBD, 'Parties to the Nagoya Protocol' available at https://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml (accessed: 15th July 2020)
[572] NP, art. 1
[573] Thomas Greiber, Sonia Peña Moreno, Mattias Åhrén, Jimena Nieto Carrasco, Evanson Chege Kamau, Jorge Cabrera Medaglia, Maria Julia Oliva and Frederic Perron-Welch with Natasha Ali and China Williams, *An Explanatory Guide to the Nagoya Protocol on Access and Benefit-Sharing* (Gland, IUCN, 2012), at 57
[574] Elisa Morgera, Matthias Buck & Elsa Tsioumani, 'Introduction' in Elisa Morgera, Matthias Buck & Elsa Tsioumani (eds), *The 2010 Nagoya Protocol on Access and Benefit-sharing in Perspective: Implications for International Law and Implementation Challenges* (Leiden, Koninklijke Brill NV/Martinus Nijhoff, 2013) at 1

primarily bilaterally, on a contractual basis between the user and the owner of the genetic resources in question, subject to Mutually Agreed Terms.[575]

The scope of the Protocol is stated as being the utilization of genetic resources and associated TK within the purview of article 15 of the CBD and the benefits arising from those resources and/or knowledge.[576] Article 3 does not provide a list of genetic resources that is either included or excluded from the scope of the Protocol, as this could not be agreed upon during the negotiation process.[577] Instead, article 2 defines the 'utilization of genetic resources' to mean conducting research and development on the genetic and/or biochemical composition of genetic resources.[578] This includes biotechnology[579] and extends to naturally occurring derivative compounds, even where they do not contain functional units of heredity.[580]

5.3.2.1 Access to genetic resources under the Nagoya Protocol

Access to genetic resources is outlined in article 6, which builds upon articles 15(1) and 15(3) of the CBD. The term 'access to genetic resources' is not defined by the Protocol, however access may be considered to constitute the beginning of the conduct aimed at research and development of genetic resources acquired in another state party. Elisa Morgera et al. suggest that there are a number of activities in the jurisdiction of the Party providing genetic resources that constitute 'access' in practice. They include: collecting wild biological material, obtaining samples from gene banks, research institutions or the private sector, and potentially, accessing digital information about the composition of genetic resources. Given the relative simplicity of defining access based on scientific and research and development practice, the inclusion of a definition of 'access'

[575] NP, art. 6.3(f)
[576] NP, art. 3
[577] Greiber et al., n573 above, at 25
[578] NP, art. 2(c)
[579] NP, art. 2(d)
[580] NP, art. 2(e)

in domestic ABS frameworks would lend legal certainty and clarity among states parties, as well as facilitate compliance monitoring.[581]

Article 6.1 reaffirms state parties' sovereignty over their genetic resources. This limits the scope of the Protocol to genetic resources directly within the state's control or privately controlled genetic resources within a state's jurisdiction, such as national gene banks. As such, the collections of international gene banks are excluded.[582]

Article 6.1 qualifies that access to genetic resources for the purpose of their utilization must be on the basis of Prior Informed Consent (PIC), unless the provider country determines otherwise. There are two consequences of this provision. The first is that as a result of their sovereign rights over their genetic resources, it continues to remain within states parties' discretion whether or not they choose to implement a national ABS framework. Thus, states which are primarily the recipients of genetic material may choose not to develop an ABS regime that would otherwise serve little purpose. In such cases, states are only obliged to establish compliance control.[583] In contrast with a national ABS framework for genetic resources, the obligatory compliance control requirements necessitate a national framework regulating the utilization of imported genetic resources, which serves to support the ABS regime of the state providing the genetic resources in question.[584]

The second consequence of article 6.1 is that subjecting access to genetic resources to the requirement of PIC may create a loophole concerning the legitimate access of genetic resources. Neither the CBD nor the Nagoya Protocol mandate that states parties introduce a law concerning PIC; they merely require that where genetic resources are accessed for utilization that such access is subject to the domestic PIC requirements of

[581] Elisa Morgera, Mattias Buck & Elsa Tsioumani, *Unravelling the Nagoya Protocol: A Commentary on the Nagoya Protocol on Access and Benefit Sharing to the Convention on Biological Diversity* (Leiden, Matinus Nijhoff, 2014) at 140-141
[582] Germplasm held by international gene banks may be accessible under the Multilateral System of the ITPGRFA, see section 4.2 above
[583] Gerd Winter, 'Points to consider for national legislation on access to genetic resources and benefit sharing' in Evanson Chege Kamau, Gerd Winter & Peter-Tobias Stroll (eds.), *Research and Development on Genetic Resources: Public Domain Approaches in Implementing the Nagoya Protocol* (London, Routledge, 2015) at 308
[584] see, section 5.3.4.1 below

the state providing the genetic resources. Essentially, this means that the existence of domestic arrangements concerning PIC is a pre-requisite for provider countries PIC.[585] Accordingly, the lack of a domestic regime can be interpreted as waiving the obligation for PIC. Resolving this ambiguity is likely to be of little difficulty for states that are primarily recipients of genetic resources. However, it is a more serious issue for developing states that are predominantly the providers of genetic resources, as it appears to equate the lack of a domestic regime for PIC with legitimate free access to a state party's genetic resources.[586] There remains some academic disagreement as to the effect of a lack of domestic PIC requirement upon the benefit sharing obligations attached to access to genetic resources.

Gurdial Singh Nijar argues that this approach could be viewed as condoning biopiracy[587] and that this is particularly problematic given the historic difficulties experienced by many developing and provider states in ABS regimes in compliance with their obligations under the CBD. He suggests that rather than affirming and building upon the rights secured in the CBD, the imposition of detailed conditions for access imposed by the Protocol has in fact, limited the sovereign rights of states over their genetic resources, without any real, corresponding developments concerning benefit sharing.

Morgera et al. agree that this provision is a source of difficulty, especially when read in conjunction with article 6.3, which requires states parties requiring PIC to take necessary legislative, administrative or policy measures to implement the minimum standards outlined in article 6.3.[588] Consequently, article 6.3 can be interpreted to mean that the requirement for PIC (or lack thereof) must be explicitly laid out in the domestic ABS framework. If this is the case, it then raises the issue as to whether responsibility for compliance with PIC resides with the user, if there is no indication from the state party in

[585] Gurdial Singh Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: An Analysis* (CEBLAW, Kuala Lumpur, 2011(a)) at 16
[586] ibid, at 16
[587] ibid
[588] Morgera, Buck & Tsioumani (2014), n581 above, at 141

question, or whether the obligation ultimately lies with states parties to ensure that their position regarding PIC is clear.

The precise nature of the requirement for PIC is perhaps best understood in the context of a more nuanced reading of the wording of the exception in article 6.1:

> 'access to genetic resources *shall* be subject to prior informed consent….unless otherwise determined by that Party' [emphasis added]

The use of the imperative 'shall' in conjunction with the caveat 'unless otherwise determined by that Party' suggests that the requirement for PIC effectively functions as an 'opt out'. In other words, it should be presumed that PIC is required[589] unless there is clear evidence that a state party has chosen to waive the requirement.[590] It is therefore clear that there is a need to distinguish between provider states that have made a deliberate and obvious choice to exclude the requirement for PIC[591] and provider states, which have not yet implemented national ABS frameworks. This view is supported by the work of the Ad Hoc Intergovernmental Committee for the Nagoya Protocol.[592] Thus, a cautious approach is advised for users of genetic resources where PIC requirements are unclear in a particular state.

Article 6.2 addresses the intra-state component of PIC by requiring states parties to take appropriate measures 'with the aim of ensuring' that the PIC or the 'approval and involvement of local and indigenous communities' for access to genetic resources where they have an established right to grant access to those resources. This represents a considerable development from the CBD, as its treatment of access to genetic resources does not touch upon the rights of indigenous and local communities over genetic resources.[593] Furthermore, the CBD provision dealing specifically with local and indigenous

[589] Morgera, Buck & Tsioumani (2014), n581 above, at 141
[590] ibid, at 142
[591] Winter highlights the examples of the Norwegian Nature Diversity Act, s.57 and the Swiss Bundegesetzüber den Natur- und Heimatschutz, as amended on 21 March 2014, s. 23q as examples of legislative measures taken by developed states to limit the scope of their domestic ABS regime. See, Winter, n583 above, at 308
[592] UNEP/CBD/ICNP/2/7, para. 19(d)
[593] CBD, art. 15

knowledge, innovations and practices[594] is limited to 'promoting' and 'encouraging' the approval and involvement of the communities in question. It is therefore clear that Nagoya has played an important role in the cementing of indigenous rights in international law.[595] However, the impact of article 6.2 is limited by the fact that the requirement for the PIC of indigenous and local communities is reliant upon 'an established right' over the resources in question. Thus, article 6.2 does not provide the foundation for the rights of local and indigenous communities over genetic resources where such rights do not already exist in domestic law. Nonetheless the situation concerning the rights of local and indigenous communities is arguably somewhat ambiguous, as Federico Lenzerini purports that indigenous peoples have emerged as a distinct subject of international law.[596] As such, the issue of the recognition of indigenous sovereignty over territory and resources within the scope of the Nagoya Protocol is perhaps more complex than it initially appears. If indigenous communities are *de facto* subjects of international law, then the drafting of the Protocol is inadequate. It is logical to extend that as distinct sovereign subjects of international law, that communities' customary rights over resources should be equally as valid as relying upon an established right arising in domestic regime. Accordingly, the implementation of this apparently straightforward provision in the Protocol appears to demand that states parties address the relationship between domestic rights and customary indigenous rights over resources.

In the same vein, article 6.2 is supplemented by article 6.3(f) which requires states parties to set out criteria and/or processes for obtaining the PIC or approval and involvement of local communities, where appropriate. Thus, there exists an impetus for states parties to address the formal relationship between the state and local and indigenous communities in either extant or new ABS frameworks if they have not already done so. However, this again is limited by the caveat of 'appropriateness'. It can therefore be argued that, if a local or indigenous community does not possess the established right

[594] CBD, art. 8(j)
[595] Buck & Hamilton, n567 above, at 52
[596] Federico Lenzerini, 'Sovereignty Revisited: International Law and Parallel Sovereignty of Indigenous Peoples' (2007) 42 Texas International Law Journal 155 at 179-181

over genetic resources mentioned in art. 6.2, then it is not appropriate to elaborate criteria or processes for obtaining the communities PIC or approval and involvement.

Article 6.3 lays out the requirements that should form part of a domestic ABS framework for regulating and determining access to genetic resources as envisaged by article 6.1. Paragraphs (a)-(g) of article 6.3 provide a list of measures to be implemented through legislative, administrative or policy means, as appropriate. Details of the necessary components of domestic access frameworks were included in the Protocol to provide legal certainty, as the implementation of the much more loosely framed ABS obligations under the CBD had resulted in 'over-bureaucratic and intransparent access procedures'.[597] This was particularly true in the case of traditional provider states that had enacted restrictive ABS laws as a reaction to users of genetic resources taking advantage of the right of access under article 15.1 CBD, without fulfilling their benefits sharing obligations under article 15.2 CBD.[598]

States parties that demand PIC are required to, *inter alia,* provide legal certainty, clarity and transparency in their domestic ABS regimes;[599] to provide fair and non-arbitrary rules and procedures on access to genetic resources;[600] information on how to apply for PIC;[601] and the availability at the time of access of a permit indicating the grant of PIC and the establishment of mutually agreed terms.[602] Additionally, states parties requiring PIC must implement clear rules and procedures for establishing MAT.[603] Thus, the purpose of article 6.3 is the establishment of guiding legal principles rather than mandating specific access requirements. This can be attributed to the fact that the development of a domestic regime for access to genetic resources is voluntary under the Nagoya Protocol. Therefore,

[597] Evanson Chege Kamau, Bevis Fedder and Gerd Winter, 'The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is new and what are the implications for provider and user countries and the scientific community?' (2010) 6(3) Law Environment and Development Journal 248 at 250
[598] Greiber et al., n573 above, at 101
[599] NP, art. 6.3(a)
[600] NP, art. 6.3(b)
[601] NP, art. 6.3(c)
[602] NP, art. 6.3(e)
[603] NP, art. 6.3(g). Domestic rules concerning PIC should contain, *inter alia*: a dispute settlement clause; terms on benefit sharing, including in relation to intellectual property rights; terms of subsequent third party use; and terms of changes of intent.

the measures listed in article 6.3 are intended to balance the concerns of both users and providers of genetic resources, whilst allowing states parties sufficient flexibility to implement their domestic ABS regime according to their national needs.

5.3.2.2 Access to associated traditional knowledge

Access to TK associated with genetic resources is addressed separately in article 7. It obliges states parties to take measures, as appropriate and in accordance with domestic law, 'with the aim of ensuring' that the PIC or approval and involvement of the local and indigenous communities in which the knowledge originates is obtained, on the basis of mutually agreed terms. The national implementation of ABS regimes should not preclude the exchange and use of genetic resources and traditional knowledge within and between indigenous and local communities for their own benefit and where it is customary practice.[604] Alongside article 5.5 (concerning benefit sharing), the provision represents a significant advancement from the treatment of associated traditional knowledge in the CBD. Article 15 CBD, the main ABS provision, is restricted to access to genetic resources and does not touch upon associated TK.[605] Similarly, article 8(j) CBD, the main provision concerning TK is focused on state parties respecting, promoting and maintaining TK. While article 8(j) CBD does contain the language of ABS: states parties should 'promote their wider application with the approval and involvement of the holders … and encourage the sharing of benefits arising from the utilization', it is expressed in purely aspirational terms. Article 7 of the Protocol however, is successful in building upon the rights of indigenous communities over their traditional knowledge as recognised in the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP).[606] Article 31.1 UNDRIP recognises the right of indigenous peoples to *inter alia,* 'maintain, control, protect and develop' their traditional knowledge, including manifestations of their sciences, technologies and cultures, which encompasses genetic resources, seeds and knowledge of the properties of fauna and flora. Additionally, it recognises the right of indigenous peoples

[604] Winter, n583 above, at 313
[605] Explanatory guide, at 129
[606] UNDRIP, art. 31(1)

to 'maintain, control, protect and develop' their intellectual property over their cultural heritage and traditional knowledge. Accordingly, article 7 of the Protocol concretes these rights of indigenous people over associated TK by elaborating the specific requirement for PIC in cases of access to traditional knowledge associated with genetic resources on the basis of MAT and extends the right through the inclusion of local communities in the provision.[607]

Nonetheless, the Protocol's treatment of associated TK is somewhat more cautious than its treatment of genetic resources. While article 7 undoubtedly represents progress, its effects are somewhat limited by heavy use of qualifiers in the provision. Specifically, the insertion of 'shall take measures, as appropriate' and 'with the aim of ensuring' renders states parties' obligations rather dilute. Furthermore, its potency is reduced by the inclusion of redundant language: the notion of the 'approval and involvement' of indigenous and local communities is particularly unhelpful, as it does not appear to include anything that is not evident within the concept of PIC.[608]

5.3.3 Benefit sharing

There are two forms of distribution of benefits arising from the sustainable use of biodiversity envisaged under the Nagoya Protocol. The first of which is direct benefit sharing, on a bilateral contractual basis, which is elaborated in article 5 of the Protocol. The second is indirect benefit sharing, which is outlined in article 10, concerning the Global Multilateral Benefit Sharing Mechanism.

5.3.3.1 Direct benefit sharing

Article 5.1 of the Protocol provides that the benefits of the utilization of genetic resources and their subsequent use and commercialisation are to be shared in a fair and equitable way with the provider of the genetic resources, whether that be the country of origin of the resources or a party that has acquired the genetic resources in accordance with the Protocol. This largely reflects articles 15.3 and 15.7 CBD; however, it is notable

[607] Morgera, Buck & Tsioumani (2014), n581 above, at 171-172
[608] Greiber et al., n573 above, at 110-111

that the Protocol employs the term 'genetic resources' rather than the 'genetic material' referred to in the CBD. This is of value, as combined with the inclusion of the term 'utilization' in reference to genetic resources, it extends the provision to include derivatives.[609] The inclusion of derivatives serves to bring all biochemical material related to genetic resources within the scope of the Protocol, rather than being restricted to 'functional units of heredity', as is the case of the CBD.[610] The significance of this wider approach is that the ABS regime encompasses a broader range of industry uses of biochemical material derived from genetic resources but which do not involve functioning units of heredity. Indeed, Nijar argues that without the inclusion of derivatives, the development of the Nagoya ABS regime might have been emptied of its value.[611]

In the same vein as domestic access provisions, states parties may implement their benefit sharing obligations through legislative, administrative or policy measures, as appropriate.[612] The sharing of benefits is to be on the basis of MAT,[613] as is required for the grant of PIC.[614] MAT can be understood to mean that the users and providers of genetic resources or associated TK have jointly agreed upon the conditions, obligations, procedures, types, timing, distribution and mechanisms of benefit sharing.[615] While MAT is closely linked with PIC and the wording of the Protocol appears to assume that they will be negotiated simultaneously, this is not necessarily true as it is possible that MAT may need to be negotiated or renegotiated in the light of subsequent new forms of utilization, development or commercialisation.[616]

States parties are also obliged to take measures with the aim of ensuring that the benefits arising from the utilization of genetic resources originating from local and indigenous communities are shared in a fair and equitable way with those communities,

[609] Nijar (2011a), n585 above, at 29
[610] CBD, art. 2; art. 15
[611] ibid, at 14
[612] NP, art. 5.3
[613] NP, art. 5.1
[614] NP, art. 6.3(e)
[615] Greiber et al., n573 above, at 90
[616] ibid, at 86

again on the basis of mutually agreed terms.[617] This obligation is, in the same vein as article 6.2 concerning PIC, subject to the caveat of such local and indigenous communities having 'established rights' over the resources in question in domestic law.

Thus, the Protocol breaks new ground by attempting to address the intra-state component of benefit sharing. It is important to note however, that article 5.2 only extends local and indigenous communities benefit sharing rights arising from the utilization of genetic resources; this does not extend to 'subsequent applications and commercialisations' in the same manner as article 5.1. A literal reading of article 5 could be interpreted as depriving local and indigenous of the benefits arising from any subsequent applications and commercialisations other than the initial utilization for which permission for access was sought.[618] Given that the benefit sharing arising out of genetic resources generally and those controlled by local and indigenous communities are addressed separately in the Protocol, this interpretation may well be correct. However, the benefits sharing obligations addressed in article 5.2 can be considered to constitute a subset of the benefit sharing obligations in article 5.1.[619] The intra-state benefit sharing component elaborated in article 5.2 is complementary to, and forms part of the same benefit sharing system as the inter-state component outlined in article 5.1. The successful balancing of inter- and intra-state benefit sharing will largely depend upon how this relationship is addressed in domestic ABS frameworks.

Additionally, article 5.5 requires states parties to implement appropriate legislative, administrative or policy measures so that the benefits arising out of associated traditional knowledge are also shared in a fair and equitable way with the communities that hold the knowledge in question, again on the basis of MAT.[620]

[617] NP, art. 5.2
[618] Morgera, Buck &Tsioumani (2014), n581 above, at 127
[619] ibid
[620] NP, art. 5.5

Possible benefits are elaborated in Annex I to the Protocol, and include monetary and non-monetary benefits.[621] This broadly reflects the list contained within Annex II of the Bonn Guidelines.[622] Potential monetary benefits include forms of direct financial compensation;[623] financial contribution towards research and biodiversity conservation;[624] and most pertinently, the joint ownership of relevant intellectual property rights.[625] Non-monetary benefits include, *inter alia*: the sharing of and participation in research and development;[626] scientific collaboration;[627] admittance to *ex situ* collections of genetic resources;[628] institutional, human and material capacity building;[629] access to scientific information relevant to the conservation and sustainable use of biodiversity;[630] 'food and livelihood security benefits';[631] and again, the joint ownership of relevant intellectual property rights.[632]

For the purposes of the present analysis, it is the opportunity for the joint ownership of intellectual property rights, as a potential monetary or non-monetary benefit, that is of greatest interest. Despite the emphasis that was placed on IP based concerns during the negotiation of the Protocol, its presence in Annex I is one of very few appearances in the entire text.[633][634] To date, this option has received little academic commentary. Indeed, even the comprehensive Explanatory Guide to the Nagoya Protocol produced by Greiber et al. only touches upon the potential for joint ownership of intellectual property rights as a means of monetizing benefits in the case that a product derived from either genetic

[621] NP, art. 5.4
[622] Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (Bonn, 2002)
[623] NP, Annex I, arts. 1.(a)-(e) and art. 1(g). Direct financial benefits include: access fees for samples collected; upfront or milestone payments; royalties or license fees for commercialisation; salaries and preferential terms where mutually agreed upon.
[624] NP, Annex I, arts. 1(f) and (h)-(i). Conservation and research benefits include: special fees to be paid into a trust fund in support of the conservation and sustainable use of biodiversity; research funding and joint ventures.
[625] NP, Annex I, art. 1(j)
[626] NP, Annex I, art. 2(a), 2(c)
[627] NP, Annex I, art. 2(b)
[628] NP, Annex I, art. 2(e)
[629] NP, Annex I, art. 2(h)-(i)
[630] NP, Annex I, art. 2(k)
[631] NP, Annex I, art. 2(o)
[632] NP, Annex I, art. 2(q)
[633] Morgera, Buck & Tsioumani (2014), n581 above, at 134
[634] Aside from Annex 1(j) and 2(q) the only other reference made to intellectual property concerns is made in article 6.3(g)(ii), which refers to intellectual property rights as being a potential means of benefits sharing to be incorporated into MAT.

resources or associated TK is commercialised, or as a possible feature of an agreement for a joint venture in research and development.[635] Equally, treatment of the non-monetary capacity of possible joint ownership of IPRs is simply suggested as a means of recognising and promoting local expertise, knowledge and institutions.[636]

Nonetheless, the World Intellectual Property Organisation (WIPO) has highlighted a number of key issues that arise out of the potential joint ownership of IPRs.[637] WIPO suggests that joint ownership of IPRs may be a preferable mechanism for benefit sharing as it provides a means of ensuring that the provider of genetic resources or associated TK retains a stake in the outcome of the access.[638] However, WIPO also notes that it is important to recognise situations in which joint ownership of intellectual property rights are not the best means of benefit sharing, such as where the access provider is a government agency, public institution or other authority or a community organisation.[639]

There are a number of practical considerations which need to be explicitly addressed, either at the original point of access, or failing that, as a part of the renegotiation of MAT. Firstly, the possibility of joint ownership of an IPR needs to be available within the domestic law of the state in which the material originates.[640] Second, it must be borne in mind that ownership of IPRs is accompanied by the costs and responsibility for securing, maintaining and enforcing the rights.[641] As such, poorly implemented joint ownership of IPRs could be to the detriment of resource holders. Third, it is incorrect to assume that joint ownership of an IPR automatically equates to equal benefits, particularly if monetary benefits arise as part of a licensing agreement or other commercial endeavours undertaken by one owning party. Thus, an agreement containing

[635] Greiber et al., n573 above, at 267
[636] ibid, at 268
[637] WIPO, 'Draft Intellectual Property Guidelines for Access to Genetic Resources and Equitable Sharing of the Benefits Arising from their Utilization' 4 February 2013, available at http://www.wipo.int/export/sites/www/tk/en/resources/pdf/redrafted_guidelines.pdf (accessed: 15 July 2020) It is important to note that WIPO emphasises these guidelines are strictly advisory in nature.
[638] ibid, at 19
[639] WIPO, n637 above, at 20
[640] WIPO, 'Report on Practical Workshop on Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions/Folklore' (17-20 August 2015) available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_iptk_wdh_15/wipo_iptk_wdh_15_report.pdf (accessed: 15th July 2020) at 30
[641] WIPO, n637 above, at 20

a provision for joint ownership of IPRS requires a comprehensive assessment of the full benefits of the IPR in question, including distribution and apportionment.[642]

In the specific case of plant varieties, WIPO suggests that there are six IP centred concerns which need to be addressed as part of an access and benefit sharing agreement. It is pertinent to briefly consider them, as they serve to help illustrate the extent to which intellectual property concerns might form part of ABS agreements and which in turn, should help us identify the role of intellectual property protection in this field.

The first point of concern is to establish whether access to genetic resources or associated TK is likely to result in the development of new plant varieties through breeding or other research activities.[643] The second is identifying what form of IP protection might be available for this newly developed variety.[644] This will vary dependent upon how a state party has opted to implement their obligation under article 27.3(b) TRIPS. The specific form of IP protection available for a newly developed plant variety in a providing state may affect utility of joint ownership of IPR as a benefit sharing mechanism. For example, the owners of the resources in question may not be capable of being recognised as an IPR holder. Third, parties should agree upon the circumstances in which IP protection should be sought for a new plant variety developed from accessed genetic resources. Fourth, the issue of ownership of the IPR must be comprehensively addressed, including how this may vary in different territories.[645] This can also be linked with the second point, as the availability of different models of intellectual property protection for plant varieties may in turn shape decisions concerning IP ownership. For example, if a plant variety has been co-developed utilizing genetic resources originating from a local community or indigenous group, it may not be possible within some states domestic framework to recognise such a group as the owner of an IPR. As such, the issue as to in which states the developers are likely to want to pursue IP protection needs to be carefully thought

[642] WIPO, n637 above, at 21
[643] WIPO, n637 above, at 31
[644] ibid
[645] ibid

through at the outset, as 'joint ownership of IP protection' may not in fact be based upon equal ownership, but rather on a combination of joint and single ownership of IPRs, as appropriate. This leads directly to the fifth point for consideration, which is how the IPR for the plant variety will be exploited in the various territories and by whom. Thus, there is a need to consider the role of licensing in the original access agreement. Finally, the apportionment of benefits arising from the commercial exploitation needs to be considered and balanced against any other benefits arising out of the original access agreement that the owners of the genetic resources in question may continue to receive, regardless as to whether an IPR has been acquired or exploited. Thus, it is difficult to accurately characterise the role of IPRs as a benefit sharing mechanism within the Nagoya Framework as both the nature of its use and the extent to which it is employed will be widely variable subject to individual access and benefit sharing agreements. Nonetheless, specific provision has been made by the Democratic Republic of Congo for the joint commercial venture and co-ownership of intellectual property rights involving both biological resources and traditional knowledge[646] as a part of its wider part of its TK protection and governance strategy.[647] However, it does not build upon the specifics of such arrangements.

The range of possible benefits outlined in Annex I is in line with the flexible approach to ABS implementations envisaged in the Protocol and the bespoke nature of individual ABS agreements. However, the broad ranging list of possible benefits contrasts considerably with the relatively specific criteria for access to genetic resources. This makes it easy to criticise the ABS approach taken in the Protocol for being weighted in favour of ensuring access to genetic resources and associated TK, rather than guaranteeing certain benefits for the holders of genetic resources. Ultimately, the determination of available benefits is dependent upon the resources available to the user. As this is established by individual benefit sharing agreements, the success of article 5 depends upon fair and

[646] Law no.14/003 of 11 February 2014 Relative to the Conservation of Nature, art. 62
[647] Freedom-Kai Phillips, 'Intellectual Property Rights in Traditional Knowledge: Enabler of Sustainable Development' (2016) 32(83) Utrecht Journal of International and European Law 1 at 12

balanced contractual negotiations between holders and the users of genetic resources and associated TK.

5.3.3.2 Indirect Benefit Sharing: The Global Multilateral Benefit Sharing Mechanism

Article 10 sets out the future task for states parties to consider the need for, and modalities of, a global multilateral benefit sharing mechanism (GMBSM). While the concept of a GMBSM was discussed during the negotiation of the Protocol, it was a casualty of both the time constraints for reaching a final agreement and a lack of consensus, and therefore the task of evaluating the necessity and features of such a mechanism was entrusted to future debates.

The idea of a multilateral benefit sharing mechanism is hinted at in the CBD, with the financial mechanism under the Convention potentially acting as benefit sharing instrument.[648] Interestingly, article 10 refers to a 'mechanism' rather than a fund; this may be a result of an intention to include both monetary and non-monetary benefits.[649] Such an approach would be in line with that taken in the rest of the Protocol. However, article 10 is silent on the institutional and technical aspects of a GMSBM, as the issues could not be resolved during the negotiation of the Protocol.[650]

Article 10 sets out two key situations in the context of which the necessity of a GMBSM should be considered. The first is for the distribution of benefits arising from genetic resources or traditional knowledge arising in transboundary situations. The second is where it is not possible to grant or obtain PIC. This then raises the question as to what situations in which it is not possible to grant or obtain PIC are envisaged by the Protocol. The application of the Protocol is restricted to genetic resources within the scope of article 15 of the CBD. Article 15.3 limits the application of the Convention to genetic resources

[648] Greiber et al., n573 above, at 127
[649] Morgera, Buck & Tsioumani (2014), n581 above, at 203-204
[650] CBD, 'Global Multilateral Benefit Sharing Mechanism' available at https://www.cbd.int/abs/art10.shtml (accessed: 15th July 2020)

which are provided by Parties which are countries of origin[651] or countries providing genetic resources[652] in accordance with article 2.

Therefore, any GMBSM cannot include pre-CBD collections of genetic resources or genetic resources or associated TK that has been illegally obtained. It is also necessary to consider the relationship between the mechanism and *ex situ* collections of genetic resources, since many of these collections contain unique germplasm that is also available from provider countries.[653] Until the issue of *ex situ* collections is adequately addressed, there exists a potential loophole that will allow users of genetic resources to circumvent benefit sharing obligations. In the case of agriculture, the need to clarify the relationship between *ex situ* collections of genetic resources and the GMBSM is somewhat mitigated by the existence of the Multilateral System of the ITPGRFA, because the focus of the system is germplasm (of Annex I crops and other voluntarily included species) included in *ex situ* collections, gene banks and other international institutions.[654]

While article 10 leaves open to debate the necessity and format of a GMBSM, it somewhat curiously pre-emptively states how and with whom the benefits arising are to be shared.[655] The benefits arising from the utilisation of genetic resources and TK that are accessed through the mechanism are to be used to support the conservation of biological diversity and the sustainable use of its components globally. This implies, where the envisaged transboundary situation exists, that benefits will not be redistributed to the states parties or local communities from which the genetic resources or knowledge originated.

[651] CBD, art. 2 states that: '"Country of origin of genetic resources" means the country which possesses those resources in *in situ* conditions.'
[652] CBD, art. 2 states that: '"Countries providing genetic resources" means the country supplying genetic resources collected from *in situ* sources, including populations of both wild and domesticated species, or taken from *ex situ* sources, which may or may not have originated in that country.'
[653] Gurdial Singh Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries* (Geneva, South Centre, 2011(b)) at 33
[654] ITPGRFA, art. 11(2)
[655] Nijar (2011b), n653 above, at 32

An interesting point of note is that article 10 refers to 'benefits shared by users' of genetic resources rather than states parties or user countries.[656] This implies that article 10 is intended to stimulate voluntary benefit sharing beyond specific obligations.

The GMBSM has been considered on several occasions since the adoption of the Protocol. An initial consultation took place in 2012,[657] which attempted to identify the necessity for such a mechanism and to clarify the scope of its application. A core aspect of the discussion was establishing the relationship between bilateral benefit sharing under the protocol and the multilateral global mechanism. While the bilateral contract-based benefit sharing outlined in article 5 is obviously the primary ABS mechanism envisaged under the protocol, it remains to be determined how the multilateral system might 'fill in the gaps'.

Interestingly, among the submissions made by states parties was a list of technical questions which the submitting party considered needed to be resolved before the modalities of a GMBSM could be arrived at.[658] The issues raised in the list serve to pinpoint several likely potential situations relevant to agricultural development; the resolution of which appears necessary in order to determine what role the GMBSM is to fulfil. Among the issues highlighted were: how to address TK originating from more than one community; what is to happen in a situation in which the centre of diversity for a genetic resources is distinct from the centre of origin; what is to happen when a user cannot access a resource *in situ* but has access to the resource *ex situ*; how to distribute benefits where associated TK has been acquired through a publicly available text but the genetic resources have been obtained from a landrace; and how domesticated varieties will be addressed under the mechanism.

This initial synthesis of the relevant issues was followed by the decision at the subsequent COP-11 to undertake a broad ranging consultation with states parties, other

[656] Morgera, Buck & Tsioumani (2014), n581 above, at 204
[657] 2nd Meeting of the Open-ended Ad Hoc International Committee for the Nagoya Protocol and the Fair and Equitable Sharing of Benefits arising from their Utilization (ICNP-2), 2-6 July 2012
[658] UNEP/CBD/ICNP/2/7.11

governments, international organisations, local and indigenous communities and other interested stakeholders on article 10.[659] Subsequently, the Meeting of the Parties (MOP) commissioned a study analysing, *inter alia,* experiences gained implementing the Protocol thus far; case studies relating to *in situ* and *ex situ* genetic resources; traditional knowledge associated with genetic resources and transboundary situations.[660] The study was undertaken by the Expert Group Meeting on Article 10.[661] Among the view expressed was that the bilateral approach to ABS was the most appropriate, as it is respectful to states' sovereign rights over their genetic resources and as such, should be utilised wherever possible. Consequently, the application of any multilateral system would be narrow.[662]

Nonetheless, the Group considered it necessary in order to proceed with the examination of article 10 to identify situations in which it may not be possible to obtain PIC, and whether, in those situations a potential GMBSM would be the most appropriate tool for the distribution of the benefits arising from the genetic resources or TK in question. Alongside which, it considered the function of a GMBSM in the context of transboundary situations.

Interestingly, the Group noted that in the case of *ex situ* collections, that many institutions had developed codes of conduct and best practices related to ABS. It found that collections were often unwilling to share material where it was not possible to establish the original source. Of particular note is the fact that many end users were unwilling to utilise genetic resources because in this case it may lead to legal uncertainty.[663] Indeed, they suggested that it should be possible to develop the implementation of the Protocol in such a way that that it could steer potential users away from genetic where PIC is unavailable, or where possible, redirect users to the country of origin.

[659] UNEP/CBD/COP/DEC/XI/1.B
[660] ICNP 3 Recommendation 3/3 'The need and modalities of a global multilateral benefit sharing mechanism'
[661] Expert Group Meeting on Article 10 of the Nagoya Protocol on Access and Benefit-sharing, 1-3 February 2016, Montreal, Canada.
[662] UNEP/CBD/ABS/A10/EM/2016/1/4 at para. 20
[663] ibid, at para. 23

While it is logical to redirect end users to the country of origin where feasible, from the perspective of end users, it would be useful to develop an alternative means of establishing legal certainty for genetic resources where the origin of the material is uncertain. Recalling that the purpose of the Protocol is the fair and equitable sharing of the benefits arising from the utilisation of genetic resources, thereby contributing to the conservation and sustainable use of biological diversity, it is necessary to recognise that it is only through the utilization of genetic resources that potential benefits arise. Whilst it would unquestionably be preferable for PIC to be granted by the state or community of origin, the realisation of a mechanism that would allow end users to access genetic resources held in *ex situ* collections with legal certainty could be advantageous to research and development, as well as generating benefits that could support biodiversity conservation globally, if it were tied to compulsory benefit sharing.[664]

Concerning transboundary co-operation, the expert group was of the opinion that article 11[665] should be sufficient to manage situations in which genetic resources or associated TK were found *in situ* in more than one state. Additionally, based on what evidence was available, regional approaches appeared to be successful in handling transboundary situations.[666]

The position of the Expert Group was definitive that where the grant of PIC were not possible because the states party in question had not yet developed procedures, then the GMBSM should not fulfil this role. Rather, this should be addressed by means of human and institutional capacity building in line with article 22 of the Protocol.[667] Similarly, in

[664] See, NP. art. 10
[665] Article 11 of the Nagoya Protocol concerns Transboundary Cooperation. It reads:
1. In instances where the same genetic resources are found *in situ* within the territory of more than one Party, those Parties shall endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concern, where applicable, with a view to implementing this Protocol.
2. Where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties, those Parties shall endeavour to co-operate, as appropriate, with the involvement of the indigenous and local parties concerned, with a view to implementing this Protocol.

[666] UNEP/CBD/ABS/A10/EM/2016/1/4 at para. 33
[667] UNEP/CBD/ABS/A10/EM/2016/1/4 at para. 29

several different situations[668] where it was not possible to grant PIC for TK associated with genetic resources, the Expert Group felt that a participation and capacity building approach would be preferable to the automatic application of a GMBSM. This is because a capacity building approach would allow for the participation of the local and indigenous communities in question and serve to help them engage with the ABS process.[669]

Overall, the study and the synthesis of views of the parties highlighted the need for further information and study.[670] This is true with regard to both the need for a GMBSM and the need to collect information concerning ABS practices. What is clear is that any potential need for a GMBSM should be interpreted relatively restrictively,[671] particularly in the light of its outcomes outlined above. The issue of the necessity and modalities of the GMBSM has been left for further consideration by the Subsidiary Body for Implementation.[672]

The position advocated by the Expert Group is entirely logical, as minimising the role of any potential GMBSM in favour of a capacity building approach should encourage the full and functional development of domestic ABS systems and consequently contribute to the widespread realisation of the spirit of the Protocol. Nonetheless, however limited the role of the GMBSM may be, it does still appear that its inclusion within the Nagoya Framework would be of value. The drawback of relying largely upon a capacity building approach through the adoption of domestic ABS systems is that it is a long-term solution. Determining definitively the role of the GMBSM will lead to enhanced legal certainty both for states parties in developing their ABS requirements and for users of genetic resources and associated TK. While no aspect of international law can be claimed to be swift, the introduction of a GMBSM, however restrictively interpreted, should serve to ensure that

[668] The situations considered included: (a) a lack of capacity to grant PIC; (b) where it was not clear who had the authority to grant PIC; and (c) when community protocols included procedures for access although no national PIC requirement had been established.
[669] UNEP/CBD/ABS/A10/EM/2016/1/4 at para. 31
[670] UNEP/CBD/ABS/A10/EM/2016/1/4 at para. 41(b)
[671] UNEP/CBD/ABS/A10/EM/2016/1/4 at para. 41(a)
[672] CBD/NP/MOP/DEC/2/10.

some of the benefits arising from the utilization of genetic and associated TK are appropriately redirected.

5.3.4.1 Compliance

Under article 15.1 of the Nagoya Protocol, states parties are required to adopt 'appropriate, effective and proportionate' legislative, administrative or policy measures to ensure that genetic resources used within its jurisdiction have been accessed in accordance with PIC and on the basis of mutually agreed terms as is required by the domestic ABS framework of the other party. Thus, responsibility falls to the user state, rather than the state in which the genetic resources was accessed, to ensure compliance. The wording of this provision closely reflects that of article 6.1 (concerning access to genetic resources). This emphasises the close relationship between access standards and national implementation measures.[673] The approach taken in article 16.1 concerning compliance with ABS for associated TK effectively mirrors that of article 15.1, save the somewhat superfluous addition of local and indigenous communities 'approval and involvement'. Both article 15.1 and article 16.1 concern compliance with ABS requirements at the time of access to the genetic resources and associated TK in question.[674]

However, the onus on ensuring that TK is accessed in accordance with the domestic ABS framework is potentially more onerous, as proving the legal status of TK accessed is likely to be more problematic. Firstly, because the definition of associated traditional knowledge will be derived from the domestic ABS regime, not the Protocol and therefore will be variable depending upon in which state party the knowledge originated. Secondly, in the case of TK, grappling with the domestic ABS system of the state of origin is likely to be more complex as it may involve interacting with customary law systems.[675] The involvement of customary law systems can be problematic on two fronts: the first is

[673] Buck & Hamilton, n567 above, at 52
[674] Both article 15.1 and article 16.1 are expressed in terms of 'have been accessed'; i.e. PIC and MAT were in place at the time of access to the GR and TK in question, as opposed to non-compliance, which is dealt with in article 17 (below).
[675] Buck & Hamilton, n567 above, at 55-56

intrinsic to the nature of customary law systems and the second is the interaction between the customary law system and the wider state framework in which it is located.

The notion of customary and traditional legal systems in a domestic or regional context[676] escapes precise definition, but can be summarised as encompassing the laws, practices and customs intrinsic to the life of indigenous peoples and local communities which govern the behaviour and relationships and are viewed within the community as having a binding quality.[677] These may be express or implicit; they may be codified, however they are often held and transmitted orally.[678] Customary law systems are of direct relevance to traditional knowledge as TK is developed, maintained and disseminated within traditional communities. Accordingly, in the context of compliance with ABS requirements, this raises the issue as to how these systems are recognised and addressed by the domestic regime of state(s) in which the TRK in question is situated.

One possible approach is that which has been taken by the Philippines. The application of customary law systems is formally incorporated into the state's constitutional framework. This was first achieved through the recognition of the economic, social and cultural rights of indigenous cultural communities in the Constitution, which also provides for the potential recognition of 'the applicability of customary laws governing property rights or relations in determining the extent of ancestral domain.'[679] This provision was subsequently augmented by the Indigenous Peoples' Rights Act 1997[680] (IPRA) which recognises the rights of indigenous peoples and communities to, *inter alia*, the right to ancestral lands.[681] Within indigenous ancestral domains and land, indigenous peoples and communities are recognised as having the right to self-governance;[682] and

[676] As distinct from customary international law, which has a more precise meaning and refers to the rules, customs and practices governing relations between states.
[677] WIPO, 'Customary law, traditional knowledge and intellectual property: An outline of the issues' (2013) available at: http://www.wipo.int/export/sites/www/tk/en/resources/pdf/overview_customary_law.pdf (accessed: 15th July 2020) at 2, 11
[678] ibid
[679] The Constitution of the Philippines, 2 February 1987, article XII section 5
[680] Republic Act no. 8371
[681] IPRA, ss. 4-12
[682] IPRA, s. 13

the right to their own justice system.[683] The IPRA also formally recognises the indigenous concept of ownership, which incorporates the notion that their ancestral domains and the resources found therein form the basis of their cultural integrity; the essence of which is that property is held privately but communal to the group.[684] This extends to traditional resource rights.[685]

Most relevant in the context of the Nagoya Protocol, are the right to protect their culture, traditions, institutions;[686] the right to protect community intellectual rights;[687] and the right to indigenous knowledge systems and to develop their own sciences and technologies, which grants indigenous peoples 'full ownership and control end protection of their cultural and intellectual rights.'[688] Recognised indigenous communities have the right to develop 'special measures to control, develop and protect' their sciences and technologies, which includes genetic resources, which encompasses seeds and other derivatives and knowledge of flora and fauna. This sits alongside the requirement for the free and prior informed consent of such communities in accordance with the applicable customary laws in the case of access to biological resources and indigenous knowledge.[689] Thus, the IPRA provides explicit evidence of formal interaction between customary law systems and domestic legislation and offers a clear model for compliance with arts. 15.1 and 16.1 NP. However, there is no provision concerning TK in the Intellectual Property Code of the Philippines.[690][691] As such, it is arguably limited in its utility for potential end users as it does not contain any explanation as to how to make the provision operational.[692] This highlights the difficulty in achieving compliance with arts. 15.1 and 16.1 that is practically viable for end users.

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[683] IPRA, s. 15
[684] IPRA, s.5
[685] ibid
[686] IPRA, s. 29
[687] IPRA, s. 32
[688] IPRA, s. 34
[689] IPRA, s. 35
[690] Christopher E. Cruz, 'Intellectual Property of Indigenous Peoples (IP of IP): Challenges of Protecting Traditional Knowledge in the Philippines' 10th De La Salle Arts Congress, 16 February 2017, available at: https://www.dlsu.edu.ph/wp-content/uploads/pdf/conferences/arts-congress-proceedings/2017/paper-7-abstract.pdf (accessed: 15th July 2020) at 14
[691] Republic Act no. 8293
[692] Cruz, n690 above, at 14

The Philippines is not the only example of the recognition of customary systems being formally recognised in national law; similar mechanisms are in the process of being developed by a number of African states.[693] However, a question that arises from the example of the Philippines is whether it is possible to recognise the role of customary law systems within a national ABS regime without the wider domestic recognition of the rights of indigenous peoples and local communities, as is the case in this example.

Both articles 15.2 and 16.2 require states parties to take appropriate and effective and proportionate measures to address situations of non-compliance. Equally, both articles 15.3 and 16.3 call for states parties to cooperate in cases of alleged violation of articles 15.1 and 16.1, respectively.

5.3.4.2 Compliance monitoring

The inclusion of compliance measuring mechanisms in the Nagoya Protocol represents a considerable advancement of the global ABS framework, as the Convention on Biological Diversity does not contain specific measures intended to monitor compliance.[694] While the Bonn Guidelines include references to monitoring and reporting and some means for verification[695] they do not elaborate on specific compliance monitoring tools.[696]

Article 17 sets out a non-exhaustive list of tools to aid monitoring compliance with the Protocol. The two main tools elaborated in article 17 are: the use of checkpoints to monitor ABS compliance,[697] and internationally recognised certificates of compliance.[698] The aim of these tools is to facilitate transparency in implementing the Protocol. Interestingly, the title of the provision is 'monitoring compliance with the utilization of genetic resources' and as such, states parties do not appear to be obliged to implement compliance monitoring mechanisms with regard to associated TK, as this is not addressed

[693] WIPO, n677 above, at 14
[694] Morgera, Buck &Tsioumani (2014) n581 above, at 273
[695] Bonn Guidelines, paras. 55-58
[696] Morgera, Buck & Tsioumani (2014) n581 above, at 273
[697] NP, arts. 17(1)
[698] NP, arts. 17(2)-17(4)

in article 17 or elsewhere in the Protocol. Consequently, the provisions of the Nagoya Protocol pertaining to associated TK are fundamentally weaker than those concerning genetic resources.

5.3.4.3 Checkpoints

The primary compliance monitoring tool introduced by article 17 is the use of Checkpoints. States parties are to designate one or more checkpoints. The purpose of the checkpoint(s) is to collect or receive information relevant to PIC, the source of the genetic resources in question, the establishment of MAT, and the utilization of genetic resources, where appropriate.[699]

Article 17 does not list or designate specific agencies or institutions to act as a checkpoint. It merely indicates that checkpoints should be 'effective' and have functions relevant to collecting and receiving the information outlined in art. 17.1(a).[700] The issue as to whether to include a list of possible checkpoint authorities was debated during the negotiation of the Protocol. Among the proposed options were customs checkpoints, patent offices, market approval offices, research funding agencies and indigenous and local community representatives.[701] However, all of these options were eventually omitted from the final draft as a number of states categorically refused to support the inclusion of patent offices and alongside this, any suggestion of compulsory disclosure requirements in patent applications. This was consistent with their position in the WTO to oppose the amendment of art. 27.3(b) TRIPS to eventually include a mandatory disclosure provision.[702] As such, article 17 refers only to 'designated checkpoints'.

In support of the mandatory checkpoint requirement, states parties are to require users of genetic resources to provide the information specified in article 17.1(a)(i) to the designated checkpoint.[703] The inclusion of this provision is somewhat obvious in order for

[699] NP, art. 17.1(a)(i)
[700] Art. 17.1(a)(iv) suggests that 'relevant functions' includes 'functions relevant to the utilization of genetic resources, or the collection of relevant information at, *inter alia*, any stage of research, development, innovation, pre-commercialization or commercialization.'
[701] Greiber et al. n573 above, at 174
[702] Buck & Hamilton, n567 above, at 53
[703] NP, art. 17.1(a)(ii)

the checkpoint to function. It is potentially restricted by the appearance of the qualifier 'as appropriate'. Whilst the inclusion does serve to provide flexibility, it can also serve to mitigate the strength of the checkpoint mechanism, as it makes it possible for states parties to limit the information required by the checkpoint.[704] As a result, the importance of the role of the checkpoints can be significantly reduced. Additionally, states parties are obliged to 'take appropriate, effective and proportional measures to address situations of non-compliance'.[705] This again, has the potential to be interpreted in a manner that limits the efficacy of the checkpoint system. In such a case, it would fall to the state of origin to raise a complaint concerning the user state's compliance.[706]

5.3.4.4 Internationally recognised certificates of compliance

The second specific compliance monitoring tool introduced by the Protocol is internationally recognised certificates of compliance. The term is introduced in article 17.1(a)(iii) as a potential source of information evidencing compliance with PIC to be produced to national competent authorities and the Clearing House Mechanism.[707] However the meaning of the term is not defined in article 2, nor does the Protocol provide a procedure for the issuance of an internationally recognised certificate of compliance, nor does it state what entities are responsible for granting such certificates.[708] Nonetheless articles 6.3 and 13.2 indicate that the original domestic permit for access constitutes an internationally recognised certificate of compliance, provided that it contains the minimum information outlined in article 17.4, provided that information is not confidential. This includes: details of the authority issuing the domestic access permit; the date of issuance of the permit; details of the provider of the genetic resources; a unique identifier of the certificate; the person or entity to whom prior informed consent was granted; details of the subjectmatter or genetic resources covered by the certificate; confirmation that mutually agreed terms were established; confirmation that prior informed consent was

[704] Greiber et al. n573 above, at 177
[705] NP, art. 17.1(a)(ii)
[706] NP, art. 30
[707] See section 4.5
[708] Greiber et al., n573 above, at 180

obtained; and indication as to whether the proposed use of the material is for commercial and/or non-commercial use. Of particular note are the requirements that the permit confirm the establishment of MAT[709] and PIC.[710]

5.3.4.5 The ABS Clearing-House Mechanism

Article 14.1 of the Protocol establishes the ABS clearing-house mechanism as part of the clearing-house mechanism envisaged under article 18.3 CBD. Its purpose is to facilitate the implementation of the Protocol by improving transparency and enhancing legal clarity.[711] The ABS clearing-house mechanism is intended to serve as a platform for sharing information related to access and benefit sharing, in particular, the information supplied by Parties regarding their implementation of the Protocol. The sharing of information relating to ABS implementation should serve not only as a means of monitoring states parties' compliance with their ABS obligations but should also serve to assist parties in their implementation of ABS obligations.[712] Equally, the availability of information concerning states parties ABS requirements should simplify the process of acquiring PIC for the potential users of genetic resources and associated TK. Thus, the clearing-house mechanism is intended to support the realisation of the sustainable use of biological diversity.

States parties are to make available information concerning the legislative, administrative and policy measures pertaining to ABS;[713] information on the national focal point and nationally competent authorities[714] and permits granted at the time of access to genetic resources or associated TK as evidence of PIC and MAT.[715] The list is non-exhaustive; however, states parties are not required to produce confidential information. States parties may opt to include, on a voluntary basis, additional information concerning: the relevant and competent authorities of local and indigenous communities where

[709] NP, art. 17.4(g)
[710] NP, art. 17.4(h)
[711] CBD, 'The ABS Clearing House' available at https://www.cbd.int/abs/theabsch.shtml (accessed: 15th July 2020)
[712] Greiber et al. n573 above, at 150
[713] NP, art. 14.2(a)
[714] NP, art. 14.2(b)
[715] NP, art. 14.2(C)

appropriate;[716] model contractual clauses;[717] methods and tools developed to monitor genetic resources;[718] and codes of conduct or best practices.[719] The modalities of the clearing-house mechanism were not agreed upon by the final draft of the Protocol; instead responsibility for its format and implementation was deferred to the MOP.[720] This decision was made in the light of experiences from the CBD clearing-house and the Biosafety clearing-house established under the Cartagena Protocol on Biosafety;[721] which suggested that those mechanisms had been haphazardly developed and consequently underutilised.[722] Thus it was agreed that the Nagoya clearing-house should be implemented in a phased manner, which would allow its functions and activities to be built up in response to identified demands.[723]

The pilot phase of the clearing-house was implemented shortly prior to the adoption of the Protocol,[724] with the aim of it being fully operational by the time the Protocol entered force.[725] Since its introduction, the clearing-house has gradually received submissions from contracting parties. Most interestingly, the mechanism has also attracted submissions from non-parties to the Protocol.[726] For example, a considerable number of non-parties (including non-signatories) have registered designated National ABS Focal Points.[727] The significance of designating a competent authority should not be underestimated as the identification of an easy to locate national ABS contact point is essential from a research perspective.[728]

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[716] NP, art. 14.3(a)
[717] NP, art. 14.3(b)
[718] NP, art. 14.3(c)
[719] NP, art. 14.3(d)
[720] NP, art. 14.4
[721] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 29 January 2000
[722] Morgera, Buck & Tsioumani (2014) n581 above, at 239
[723] ICNP 1 Recommendation 1/1 'Modalities of the Access and Benefit-Sharing Clearing House'
[724] ibid
[725] ICNP 3 Recommendation 3/4 'Modalities of Operation of the Access and Benefit Sharing Clearing House'
[726] See, for example, CBD, 'ABS National Focal Point' available at https://absch.cbd.int/search/nationalRecords?schema=focalPoint (accessed: 10th July 2020)
[727] The list of non-party-non-signatories include: Afghanistan, Azerbaijan, Bahrain, Bangladesh, Barbados, Bosnia and Herzegovina, Canada, Chile, Cook Islands, Democratic People's Republic of Korea, Dominica, Equatorial Guinea, Estonia, Haiti, Iran, Iraq, Israel, Jamaica, Kiribati, Latvia, Libya, Malaysia, Maldives, Montenegro, Nepal, New Zealand, Oman, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Saudi Arabia, Singapore, Sri Lanka, The Former Yugoslav Republic of Macedonia, Timor-Leste, Turkey, Tuvalu, USA, Uzbekistan, and Venezuela.
[728] Susette Biber-Klemm & Sylvia I. Martinez, 'Experiences in accessing biological resources for non-commercial research: results of an informal survey in Switzerland' in Kamau, Winter & Stroll, n597 above, at 179

However, states parties' submissions continue to be limited in several key areas. This includes: the designation of national checkpoints; at the time of writing, only 45 states have submitted information concerning their national checkpoint to the clearing house mechanism.[729] Similarly, information pertaining to internationally recognised certificates of compliance has only been supplied by a handful of states parties;[730] and information concerning national websites and databases has only been published by 30 states.[731] This is somewhat disappointing given that the clearing-house mechanism is intended to be one of the key methods of facilitating ABS under the Protocol. Similarly, at the time of the introduction of the clearing-house mechanism, there existed relatively few domestic, regional or institution based access and benefit sharing databases.[732] In order for the clearing-house mechanism to be successful, it is dependent upon the active participation of states parties.[733] This includes both the development of domestic and regional databases on ABS requirements and the submission of relevant information to the clearing-house. The availability of information through the clearing-house mechanism, should in turn, promote the fair access to genetic resources.

5.3.5 Access and Benefit Sharing under the Nagoya Protocol and the International Treaty for Plant Genetic Resources for Food and Agriculture

The Nagoya Protocol applies to genetic resources and traditional knowledge within the scope of article 15 of the CBD;[734] thus it effectively applies to all types of genetic resources and all potential uses. However, genetic resources are frequently the subject of specialist access regimes.[735] In the case of underutilised crop varieties and agriculture

[729] CBD, 'The Access and Benefit-Sharing Clearing-House: Checkpoints' available at https://absch.cbd.int/search/nationalRecords?schema=absCheckpoint (accessed: 15th July 2020)
[730] Thus far, 10 states parties have submitted 113 records of internationally recognised certificates of compliance, with India having submitted 86 of these. See, CBD, 'Internationally recognised certificates of compliance' available at https://absch.cbd.int/search/nationalRecords?schema=absPermit (accessed: 15th July 2020)
[731] CBD, 'National Websites and Databases' available at https://absch.cbd.int/search/nationalRecords?schema=database (accessed: 15th July 2020)
[732] UNEP/CBD/ABS/EM-CH/1/2 at III. 15 states parties had national ABS databases when the Protocol was completed, 14 of which were developed states. At the regional level, the European Union maintained an Access and Benefit Sharing Portal; the African Regional Intellectual Property Organisation had its Swakopmund Protocol on the Protection of Traditional Knowledge and Folklore (available at: https://wipolex.wipo.int/en/text/201022 (accessed: 5th May 2021)) alongside the combined decisions of the Andean Community of Nations.
[733] Greiber et al. n573 above, at 150
[734] NP, art. 3
[735] For example, genetic material collected in Antarctica is subject of the Antarctic Treaty System.

generally, the specialist ABS regime in question is the Multilateral System of the ITPGRFA. For the purpose of the present analysis, it is pertinent to characterise the relationship between the regimes. As the later of the two regimes, it is the Nagoya Protocol that expressly addresses the relationship between them.

The preamble to the Protocol 'acknowledges the fundamental role' of the ITPGRFA with regard to genetic resources for agriculture and the importance of PGRFA for achieving food security and poverty alleviation. Article 8(c) requires states parties to 'consider the importance of genetic resources for food and agriculture and their special role for food security'. There are two noteworthy features of article 8(c). The first is that it does not make direct reference to the ITPGRFA or its Multilateral System. The second is that while article 8(c) clearly affords an exemption for PGRFA,[736] the choice of language of the provision is not particularly strong: 'consider the importance' does not require any specific action.[737] Claudio Chiarolla et al. point out that on the face of the provision, states parties are equally free not to exclude PGRFA from their normal ABS requirements. However, in combination with the preambular paragraph identifying the special role of PGRFA, it would be insupportable not to distinguish between PGRFA and other genetic resources.[738] There is therefore a need to balance domestic ABS regimes so that specialist measures are not used to circumvent benefit sharing obligations.[739]

Resolving the overlap between the regimes is simplified in a significant number of cases, as the divergence in membership between the ITPGRFA and the Nagoya Protocol automatically simplifies the relationship between the two ABS regimes. At the time of writing there are 124 states parties to the Nagoya Protocol[740] and 147 states parties to the ITPGRFA.[741] Thus, where a state is only party to one regime, that regime will

[736] Claudio Chiarolla, Selim Louafi, Marie Schloen, 'An Analysis of the Relationship between the Nagoya Protocol and Instruments related to Genetic Resources for Food and Agriculture and Farmers' Rights' in Morgera, Buck and Tsioumani (eds) (2013), n574 above, at 100
[737] Greiber et al., n573 above, at 123
[738] ibid, at 101
[739] ibid
[740] Out of 126 ratifications. See, 'Parties to the Nagoya Protocol' available at: https://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml (accessed: 15th July 2020)
[741] FAO, 'International Treaty on Plant Genetic Resources for Food and Agriculture', available at: http://www.fao.org/fileadmin/user_upload/legal/docs/033s-e.pdf (accessed: 15th July 2020)

necessarily apply to plant genetic resources, and vice versa. Notably, a number of megadiverse[742] countries and members of the group of Like Minded Megadiverse countries fall into this category.[743]

Nonetheless, for the majority of states parties the issue requires resolution. Concerning the relationship between the Protocol and its relationship with other international agreements, article 4.4 states that where a specialised ABS instrument applies, the Protocol does not apply for parties to that instrument with regard to the specific genetic resources covered by that instrument for the specialised purpose of the instrument, provided its aims do not run counter to the Protocol or the CBD. Thus, the ITPGFRA has precedence as a specialist instrument. However, the effect of this provision is to frame the exception so that even where a specialist regime exists, it does not necessarily apply to a specific usage of genetic resources.

Therefore, in order to accurately frame the application of the Nagoya Protocol to PGRFA, it is necessary to consider the application of the Multilateral System (MLS).[744] The MLS under the ITPGRFA includes the genetic resources of the 64 Annex I crops and the genetic resources of any voluntarily included non-Annex I crops that are in the public domain and are held by local, national or international gene banks under the direct control of contracting parties. Thus, where a state is party to both regimes, the Nagoya ABS will continue to apply to genetic resources outside the public domain, such as those in private *in situ* or *ex situ* collections, non-Annex I crops that have not been included in the multilateral system or those held by local or indigenous communities. Accordingly, the

[742] The term 'megadiverse' was coined by NGO Conservation International in 1988. The concept refers to countries have both a high number of total species and that possess high degree of endemism at the species and higher taxonomic levels. In order to qualify as megadiverse, a state must have: at least 5000 endemic species of plants; and have marine ecosystems within its borders. Other secondary criteria, such as animal and invertebrate endemism and ecosystem diversity are also factored into the assessment. There is no legal significance attached to the designation itself. Rather, it serves to denote the fact that a relatively small number of countries bear a disproportionately large social and political responsibility for conservation and biodiversity management. The terminology was adopted by Mexico when it formed the group of Like-Minded Megadiverse Countries in 2002. See: UNEP, 'Megadiverse countries', available at: https://www.biodiversitya-z.org/content/megadiverse-countries (accessed: 9 May 2021)

[743] Of the 17 countries identified as being megadiverse by Conservation International, five (the United States, Australia, Columbia, Brazil and Papua New Guinea) have not yet ratified the Nagoya Protocol. Similarly, of the 20 members of the group of LMMD states, five (Brazil, Columbia, Costa Rica, Iran, and Venezuela) have not yet ratified the Protocol.

[744] See Section 4.2 above

Protocol continues to be of potential relevance to the research and development concerning underutilised crop varieties. However, the applicability of the Protocol may be limited by the domestic implementation of access and benefit sharing requirements by a state party.

Aside from its application to genetic resources, the benefit sharing regime under the Protocol also incorporates associated traditional agricultural knowledge. Although the ITPGRFA recognises the contribution of local and indigenous communities to the conservation and development of PGRFA,[745] it does not provide for benefit sharing on the basis of access to TK. It seems reasonable to assert therefore, that the ABS provisions of the Protocol apply to access to traditional agricultural knowledge regardless of whether a state is party to the ITPGRFA or if the TK in question pertains to an Annex I crop, provided that the domestic implementation of article 5.5 and article 7 permits it.

5.3.6 Summary

At this stage in its implementation, it is difficult to attempt to assess the impact of the Nagoya Protocol. This is in part, a result of the Protocol's reliance upon domestic implementation of the ABS provisions. As the development of states parties' domestic ABS frameworks is slow, finding tangible evidence of the effect of the Protocol continues to be problematic. It is also difficult to assess because of the use of heavily qualified provisions throughout the text of the Protocol. Whilst these serve to add flexibility for states in choosing how to implement the Protocol, they also introduce ambiguity. Furthermore, several key aspects of the Protocol have been deferred for future debate and possible implementation. This further complicates any evaluation of the Protocol's success.

The complete success of the Protocol would depend upon universal implementation, or as near as possible. As it stands, this is a considerable distance from being achieved. This is unsurprising given the widespread and varying points of dissatisfaction with

[745] ITPGRFA, art. 9.1

compromises made in order to produce the final text of the Protocol, as discussed in section 5.3.1.1. Indeed, given the level of high level of discontent with the Protocol, the current level of membership may be viewed as a success.

From a strictly legal perspective, it is certain that the Protocol represents progress from the ABS principles outlined in the Convention on Biological Diversity. However, the discrepancies between the obligations of states parties concerning genetic resources and those concerning TK are a source of concern, particularly in the agricultural sphere. Although the negotiation of an international legal instrument(s) intended to ensure the effective protection of TK, traditional cultural expressions (TCE) and genetic resources continues within the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore,[746] it has not yet produced an agreement concerning the sharing of benefits arising from the use of traditional knowledge.[747] To that end, the inclusion of traditional knowledge within the Nagoya ABS regime represents an important milestone, at least for the contracting parties. This is because plant genetic resources for food and agriculture and associated TK are particularly interrelated, especially in the case of farmers' varieties and landrace crops.

When evaluating the Nagoya ABS regime, it is important to consider it from all standpoints. When considering the perspective of end users, we must not only consider the positions voiced by predominantly user states, but also of the actual end users, whether they be institutions or communities. The primary ABS mechanism under the Protocol is bilateral, contract-based benefit sharing. As such, the success of the Protocol rests not only on states parties' implementation of their obligations but fundamentally on the success of those ABS contracts. Consequently, Nagoya's success also rests in the commercial contract sphere.[748] Achieving the goal of fair and equitable benefit sharing

[746] WIPO, 'Matters concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore' (Fifty-fifth Session, October 4-15, 2015) available at: http://www.wipo.int/export/sites/www/tk/en/igc/pdf/igc_mandate_1617.pdf (accessed: 15th July 2020)
[747] WIPO, 'The Protection of Traditional Knowledge: Draft Articles' WIPO/GRTKF/IC/34/5, available at: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=368218 (accessed: 15th July 2020)
[748] Morten Walløe Tvedt, 'Into ABS Implementation: Challenges and Opportunities for the Nagoya Protocol' 30th September 2014, Biores vol. 8(8) available at: https://www.ictsd.org/bridges-news/biores/news/into-abs-implementation-challenges-and-opportunities-for-the-nagoya (accessed: 15th July 2020)

therefore relies upon the balance between negotiation and enforcement of contractual obligations; both of which require certainty as to the relevant states' parties ABS requirements. This is where the underdeveloped content of the Protocol falls short. Combined with the disorganised implementation of ABS requirements at the national level, this creates uncertainty for both users and providers. Furthermore, without clarity as to who or what groups hold rights over resources at the domestic level, potential users are likely to find themselves unable to appropriately negotiate access in the first place. While the final text of the Protocol is far from perfect, the possibility does exist for the ABS principles and mechanisms it establishes to operate effectively. However, this will rely upon states parties explicitly addressing their stance on access to genetic resources and traditional knowledge, whether this is a comprehensive approach or by waiving access requirements.[749] It is only then that it will be possible to approach practical issues such as whether the holders of genetic resources or associated TK are able to effectively negotiate benefit sharing agreements.

[749] See, Winter, n583 above

Chapter 6: Intellectual property protection for plant-based innovations and access and benefit sharing in Malaysia

6.1 Introduction

In the previous chapters, we have considered the scope of the international norms pertaining to plant-based innovations. We have scrutinised the extent of the obligation contained within article 27.3(b) of the Agreement on Trade-Related Aspect of Intellectual Property (TRIPS) to provide intellectual property (IP) protection for plant-based innovations; and critiqued the *de facto* standard IP right for plant varieties provided by the Conventions of the International Union for the Protection of New Varieties of Plants (UPOV). We have also considered the access and benefit sharing (ABS) obligations arising out of the Convention on Biological Diversity (CBD), its Nagoya Protocol and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) in the context of facilitating the development of new subsistence crop varieties.

The purpose of this chapter is to build upon the analysis of these international norms and to provide a commentary on the relevant legislative framework pertaining to intellectual property protection for plant-based innovations and access and benefits sharing in Malaysia. It will consider how the international norms have been translated into the national and state level frameworks. This will form the first half of the case study and provide the foundation for the specific examples considered in chapter seven.

6.1.1 Background: Malaysia

Situated just north of the equator, Malaysia comprises of 330,803 square kilometres of land located across two major landmasses, the Malay Peninsular and the island of Borneo, in addition to numerous small islands in the South China Sea. As of 2018, it is home to approximately 32.6 million people.[750] Malaysia is one of the twelve

[750] Department of Statistics Malaysia, 'Population & Demography' available at: https://www.dosm.gov.my/v1/index.php?r=column/ctwoByCat&parent_id=115&menu_id=L0pheU43NWJwRWVSZklWdzQ4TlhUUT09 (accessed: 15 July 2020)

mega biodiverse countries in the world.[751] As such, it contains one of the highest concentrations of genetic wealth on earth. In Asia, it is second only to its neighbour Indonesia.[752] Malaysia also possesses high diversity between ecosystems.[753] At present, there is no comprehensive checklist of the flora of Malaysia, however it is estimated that it is home to at least 15,000 plant species [754] with an estimated 8,300 species in peninsular Malaysia and between 8,000 and 15,000 species in the states of Sabah and Sarawak.

In terms of agricultural biodiversity, it has experienced the same expansion and contraction that has taken place all over the world. The gradual improvement of crop species through cultivation lead to the availability of a large number of varieties; however, the introduction of modern, high yielding varieties has caused a sharp decline in the number of varieties available for cultivation. For example, the majority of rice cultivation in Malaysia is now produced from just three varieties. Consequently, where traditional varieties have not been collected and stored in seed banks many have been lost.

Malaysia continues to be highly dependent upon imports of both food and seeds,[755] and is a net importer of food. The need to improve national food security and self-sufficiency was highlighted during the economic crisis of 2008 when food prices reached an all-time peak.[756] Indeed, the National Food Policy 2011-2020 suggests that in order to address the challenges of increased food demand, the increased cost of agricultural inputs and the challenges arising out of climate change,[757] aspects of food and nutritional security should be emphasised in food production.[758] The Policy also recognises that there is a need to emphasise the development of sustainable agricultural practices[759] and that the

[751] Mohamad Bin Osman & A. H. Zakri, 'Malaysia's Approach to Access and Benefit Sharing' in Lyle Glowka, Balakrishna Pisupati & Sanjiv da Silva (eds), *Access to Genetic Resources and Traditional Knowledge: Lessons from South and South East Asia* (Colombo, IUCN, 2001) at 52
[752] Ministry of Natural Resources and Environment, *Biodiversity in Malaysia* (2006) at 2
[753] ibid, at 3, 4
[754] L. G. Saw and R. C. K. Cheung, 'The Flora of Malaysia Projects' (2015) Rodriguésia 16(4) These figures are currently subject to a comprehensive long term review.
[755] Rozan Abu Dardak, 'Impacts of National Agrofood Policy towards Agricultural Sector in Malaysia' (MARDI) available at: http://ap.fftc.agnet.org/files/ap_policy/853/853_1.pdf (accessed: 15th July 2020)
[756] Ministry of Agriculture and Agro-based Industries Malaysia, *Dasar Agromakanan Negara 2011-2020* (National Food Policy) (Putrajaya, Malaysia, 15th December 2011) at 2
[757] ibid, at v
[758] n756 above, at vi (translated: 'pengetahuan dan inovasi kepelbagaian etnik')
[759] n756 above, at vi

development of the agricultural sector should draw on the strength of the countries biodiversity and the 'innovation of its ethnic diversity'.[760]

There is little demographic data available on farming in Malaysia.[761] From the information available, we know that farming in Malaysia is broadly split between large scale commercial plantations, often in excess of 500ha and dedicated to the production of commodity crops; and small scale farmers, with holdings in the range of 1-2ha.[762] The majority of plant breeding activities in Malaysia are undertaken by agricultural research institutions, state agencies, public universities and private companies.[763] Plant-based innovation also takes place as a part of on farm practices;[764] indeed, the possibility of farm based developments is recognised by the Protection of New Varieties of Plants Act 2004 (PNVP).[765] This is where there exists potential for underutilised crop species to be of value in Malaysia: they have the opportunity to supplement existing agricultural practices, either as commodity crops in commercial production, or as a part of subsistence farming by small scale farmers.

6.2 Implementation of article 27.3(b) TRIPS in Malaysia

Malaysia has been a member of the World Trade Organisation (WTO) since its inception in 1995; as such, it is required to implement the minimum standards of IP protection mandated by the TRIPS Agreement. In order to comply with its obligations arising out of article 27.3(b) TRIPS, the Protection of New Varieties of Plants Act was passed in 2004. Indeed, Malaysia has cited TRIPS obligations as the primary reason for enacting PVP legislation.[766] This provides a *sui generis* plant variety protection regime for

[760] ibid, at vi
[761] Indeed, the researchers developing Bambara in Malaysia are currently undertaking field based sociological research in order to better understand farming demographics in Malaysia, and in turn, how they can best support small scale farmers.
[762] Baki Hj. Bakar, Azirah Hashim, Che Wan Jasimah Mohamed Radzi & Peter Songa, 'The New Malaysian Agro-Food Policy: Food Security and Food Safety Issues' (3rd Conference on Global Environmental Change and Food Security, Marrakesh, November 2012) at 2
[763] Gurdial Singh Nijar, *Malaysia's Implementation of the Multilateral System of Access and Benefit-sharing* (Rome, Bioversity International, 2012) at 17
[764] Participant comment, Interview January 2020
[765] s. 14(2)
[766] Graham Dutfield and Uma Suthersanen, *Global Intellectual Property Law* (Cheltenham, Edward Elgar, 2008) at 38

plant-based innovations. Malaysia has opted not to make patent protection available for plant varieties.[767]

Malaysia is not yet a member of the International Union for the Protection of New Varieties of Plants (UPOV); however, it has applied to join the Union.[768] In addition, as discussed in section 2.4, TRIPS plus obligations have the potential to impact upon Malaysia's freedom to implement article 27.3(b), including by mandating UPOV membership. Therefore, its relationship to the UPOV system will be considered in section 6.2.6, before considering the implications of TRIPS plus trade agreements.

6.2.1 Intellectual Property Protection for Plant-Based Innovations in Malaysia: Protection of New Varieties of Plants Act 2004

Prior to the introduction of the Protection of New Varieties of Plants Act in 2004,[769] protection for plant-based innovations in Malaysia was limited to an informal system of plant breeder variety registration, under which the Department of Agriculture registered new varieties of fruits for certification purposes.[770]

The PNVP Act encompasses all plants but excludes micro-organisms. The objective of the PNVP Act is to provide for the protection of the rights of breeders of new varieties of plants, while recognising and protecting the contributions of farmers, local communities and indigenous peoples to existing plant varieties and to encourage the investment in and development of new varieties in both the public and private sectors.[771] According to the Department of Agriculture (DOA), the introduction of plant variety protection (PVP) legislation is expected to put Malaysian growers in a better position by making new and improved plant varieties more accessible, as the expansion of plant breeders' rights to include harvested material had caused practical difficulties for Malaysian breeders and growers.[772]

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[767] s. 13(1)(b) Patents Act 1983
[768] UPOV, 'Status in relation to the International Union for the Protection of New Varieties of Plants (UPOV)' as of 2 May 2019, available at: https://www.upov.int/export/sites/upov/members/en/pdf/status.pdf (accessed: 15th July 2020)
[769] Act 634
[770] Ida Madieha bt. Abdul Ghani Azmi, 'The Protection of Plant Varieties in Malaysia' (2004) 7(6) Journal of World Intellectual Property 877 at 877. The system of variety registration was in place from the 1930s.
[771] ibid
[772] DOA, 'Plant Variety Protection Malaysia', available at: http://pvpbkkt.doa.gov.my/ (accessed: 15th July 2020)

The PNVP Act technically came into force on 1st July 2004, however the Act was not effective until the supplementary Protection of New Varieties of Plants Regulations entered into force until 20th October 2008. The Malaysian PVP office did not begin to receive applications for registration until 1st November 2008. Since then, there has been a gradual uptake of PVP in Malaysia.[773] This delay is unsurprising, as the passing of the Act is just one aspect of implementing PVP: the legislation also needs to be supported by a corresponding regulatory framework, as well as appropriate institutions and expertise. This is a common challenge shared by states with young and nascent systems of PVP.

The PNVP Act is a sincere attempt to balance the interests of various stakeholders. Indeed, the drafting of the act was conducted by the relevant government ministries and agencies in conjunction with non-governmental organisations, including Third World Network.[774][775] The PNVP Act is largely based upon the UPOV 1978 model. To that end, the main model of PVP that it contains is reflective of the international standard. Plant variety protection is available for varieties that fulfil the criteria of new, distinct, uniform and stable.[776] However, plant variety protection is also available for varieties that have been bred, discovered or developed by farmers, local communities or indigenous people where the variety can fulfil the criteria of being new, distinct and identifiable.[777] Thus, the PNVP Act appears to contain two standards for the grant of PVP, dependent upon the applicant. It is noteworthy that these are two separate standards for obtaining the same plant breeders' right, rather than there being two different rights available; one for farmers, local communities and indigenous people, and one for all other plant breeders. The only other notable distinction between the two is that the plant breeders' right available under s. 14(2) is for a shorter period.[778] The implications of this are considered in chapter seven.

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[773] See, section 7.3.2.3, below
[774] Azmi, n770 above, at 878
[775] Third World Network is an independent, non-profit, international research and advocacy organisation based in Penang, Malaysia involved in issues relating to development, environment and the sustainable distribution of resources. See, https://www.twn.my/ (accessed: 15 July 2020)
[776] PNVP, s. 14(1)
[777] PNVP, s. 14(2)
[778] PNVP, s. 32(1)(b). PVP for varieties that are distinct and identifiable is available for a period of 15 years from the date of application for registration, as opposed to 20 years for varieties that are distinct, uniform and stable.

6.2.2 Scope of plant variety protection under the PNVP Act

Provided a variety meets the requirements of either s. 14(1) or s. 14(2) for the registration of a plant variety under the PNVP Act and the grant of a plant variety protection, s. 30(1) of the PNVP Act entitles the holder of a breeders' right to carry out the following acts on a commercial basis with respect to the registered variety:

(a) Producing or reproducing;

(b) Conditioning for the purposes of sale;

(c) Offering for sale;

(d) Marketing, inclusive of selling;

(e) Exporting;

(f) Importing;

(g) Stocking the material for the purposes mentioned in paragraphs (a)-(f)

S. 30(2) extends the plant breeders' right to include: any propagating material or harvested material of the registered variety, entire plants or parts thereof where the propagating material of the plant variety has been obtained through unauthorized means from a registered variety; plant varieties which are essentially derived from the registered variety, if the registered plant variety is not essentially derived from another variety; plant varieties which are not distinguishable from the registered variety; the production of other plant varieties which require the repeated use of the registered variety. This is reflective of the rights granted to a breeder under the UPOV Convention. It is notable that the scope of a breeder's right includes essentially derived varieties[779] as this is not present in the 1978 Enactment upon which Malaysian PVP was based. This offers stronger protection to breeders as it prevents the commercial exploitation of minor variations[780] upon a registered variety without the consent of the original breeder. This can be argued to be encouraging the development and registration of plant varieties by offering stronger

[779] PNVP, s. 30(2)(c). A variety is essentially derived if it is predominantly derived from the registered variety, or from a variety that is itself predominantly derived from an initial variety and clearly maintains the characteristics of the original variety. The essentially derived variety should be clearly distinguishable from the initial variety, but maintains the same expression of essential characteristics that result from the genotype of the original variety. See, PNVP, s. 2

[780] The degree to which a variation is minor will be dependent upon the plant species in question.

protection for innovators. However, given the availability of protection for traditional and farmers' varieties under s. 14(2), the inclusion of the concept of essentially derived varieties may also serve to afford greater protection for traditional and farmers' varieties from appropriation, provided the owners of the variety in question have taken the opportunity to register it. Thus, the inclusion of essentially derived varieties provides an additional means of ensuring that the contributions of small farmers, local communities and indigenous people are respected. In this way, it may also represent a useful tool for addressing bio piracy concerns. To that end, the inclusion of essentially derived varieties supports the aims of the PNVP Act.

6.2.3 Limitations of Plant Variety Protection

The Act contains a number of exceptions to a plant breeders' right. These can be split into two categories: exceptions that apply to PVP generally, and exceptions that apply specifically to small farmers. General limitations include acts done privately and on a non-commercial basis;[781] acts done for experimental purposes;[782] acts done for the purposes of breeding other plant varieties; and acts that fall within the scope of the exclusive rights of the breeder[783] in respect of those other varieties, except where the other varieties are considered to be essentially derived varieties.[784] These three general exceptions reflect the compulsory exceptions included in the 1991 UPOV Enactment.[785] The balancing act achieved by these provisions serves to support plant-based innovations by protecting breeders' rights over their innovations while ensuring adequate material for further development. This should meet the needs of both public and private commercial breeders.

Limitations which apply specifically to small farmers include: acts of propagation of registered varieties done by small holders on their own holdings;[786] the exchange of 'reasonable' amounts of propagating material between small farmers;[787] and the sale of farm-saved seed where the small farmer cannot make use of the farm-saved seed on his

[781] PNVP, s. 31(1)(a)
[782] PNVP, s. 31(1)(b)
[783] Exclusive rights of the breeder as outlined in PNVP, s.30(1)(a)-(g) and discussed in section 6.2.2 above
[784] PNVP, s. 31(1)(c)
[785] UPOV 1991, art. 15(1)
[786] PNVP, s. 31(1)(d)
[787] PNVP, s. 31(1)(e)

own holding due to an emergency, natural disaster or other factors beyond their control, provided that the amount sold is no more than what they can use on their own holding.[788] The term 'reasonable' is not defined by the Act or the Administrative Guidelines (AG); however given the restriction on the amount of seed that small farmers are permitted to sell is limited to the amount they are able to use on their own holdings, it seems plausible to suggest that this is likely the upper limit of what might be considered to be reasonable for the purposes of exchange between farmers.

The inclusion of these exceptions appears to fit within the optional UPOV exemption for farmers to save the seed of protected varieties for propagating purposes on their own holdings or seed that they have obtained by planting on their own holdings.[789] It demonstrates a balancing of national interests in the drafting of the legislation, as it achieves an equilibrium between providing and upholding breeders' rights and policy considerations such as access to planting material and serving food security concerns. However, the Administrative Guidelines define a small farmer as one whose holdings do not exceed 0.2 hectares.[790] According to the limited demographic data available on farmers in Malaysia,[791] the average size of a small farm is between 1 and 2 hectares. Thus, based on this information, the exemption for small farmers in Malaysia appears to be quite strictly limited. During the drafting of the Regulations, the size of holdings of a small farmer was proposed to be 1.2 hectares. Again, based on limited demographic data, this would encompass a large number of small farmers in Malaysia. As it stands, it appears that the size of a small farmer is perhaps intended to reflect individuals growing for their own purposes and is therefore calculated to permit seed saving and exchange for individuals who use their holdings to grow food for personal consumption or who engage in plant breeding activities as a hobby, although whether it has been decided on this basis is not clear. Thus, the implementation of the PNVP appears to place greater emphasis on

[788] PNVP, s. 31(1)(f)
[789] UPOV 1991, art. 15(2)
[790] AG, s. 14
[791] Baki Hj. Bakar, Azirah Hashim, Che Wan Jasimah Mohamed Radzi & Peter Songan, 'The New Malaysian National Agro-Food Policy: Food security and food safety issues' (3rd International Conference on Global Environmental Change and Food Security, Marrakesh, November 2012) available at: https://www.researchgate.net/publication/280495910_The_New_Malaysian_National_Agro-Food_Policy_Food_Security_and_Food_Safety_Issues (accessed: 15th July 2020)

plant breeders' rights, by excluding small farmers from the privileges and flexibilities that have been carved out for them in the PNVP Act. However, it is important to note that there is a considerable lack of demographic and sociological data on small farmers and farming in Malaysia,[792] therefore it is very difficult how appropriate or successful this development of the PNVP Act might be.

6.2.4 Plant variety protection under s. 14(1)

Any individual plant breeder, company, or government or statutory body may apply for PVP under article 14(1).[793] Plant variety protection is available for varieties meeting the criteria of new, distinct, uniform and stable (DUS). A plant variety is deemed to be novel if it has not been sold or otherwise disposed of on a commercial basis with the breeder's consent either within one year of the filing date in Malaysia.[794] A plant variety is regarded as uniform where it is suitably uniform in its relevant characteristics.[795] A variety is considered to be distinct if it is clearly distinguishable from any other plant variety, the existence of which is common knowledge on the date of filing the application for PVP.[796] Finally, a plant variety is deemed to be stable if its relevant characteristics remain unchanged after repeated propagation.[797] Thus, the criteria for a plant breeder's right under article 14(1) track UPOV standards. The successful applicant will be granted PVP for a period of 20 years from the date of filing.[798]

The basis for determining whether a variety fulfils the DUS criteria is the DUS Test Guidelines; the availability of DUS test guidelines directly corresponds to the availability of PVP for a given species or genera. These are produced by the Plant Variety Protection Office. The process of developing DUS test guidelines is outlined below. Thus, to the extent that DUS guidelines are available, the PVP provided by s.14(1) reflects the

[792] The absence of accurate social and demographic data on farming and farmers in Malaysia has been confirmed by a number of sources. One organization that commented (Crops for the Future) was in the process of undertaking their own small scale, local study in order to begin the process of better understanding local farmers' practices and needs.
[793] PNVP, s. 13(1)
[794] PNVP, s. 14(3)(a)(i)
[795] PNVP, s. 14(3)(c)
[796] PNVP, s. 14(3)(b)
[797] PNVP, s. 14(3)(d)
[798] PNVP, s. 32(1)(a). In the case of trees and vines, the Board may grant a PVP with a duration of 25 years (s. 32(2))

international standard for plant variety protection. As such, it should meet the needs of commercial breeders; its suitability for different types of plant breeders is considered in chapter seven.

6.2.4.1 DUS Test guidelines

The process of developing DUS test guidelines in Malaysia broadly follows the same process as the development of UPOV test guidelines.[799] Test guidelines are developed by a technical committee of plant experts. These experts may consist of plantation workers, crop scientists, other agricultural researchers, and officers from the relevant agricultural departments, depending upon the type of plant under scrutiny. The technical committee will meet several times during the development of the test guidelines; these meetings will take place on site in farms, plantations or orchards where samples of the species are being grown. The purpose of the meeting is to determine the appropriate DUS characteristics for a given plant species as well as the method and duration of testing. The development of test guidelines takes on average around two to three years; this is dictated by the type of plant. Sometimes existing test guidelines either produced by UPOV or by other countries are used as a basis for the development of the Malaysian guidelines. This can potentially reduce the amount of time it takes to produce the guidelines to around one year. Finally, the test guidelines are trialled to ensure that they are an accurate and useful tool for assessing the relevant aspects of a plant variety.

6.2.5 Plant variety protection under s. 14(2)

An alternative standard for plant variety protection is available under s. 14(2) of the PNVP Act. This is sometimes referred to as protection for traditional or farmers' varieties. The availability of the alternative standard for PVP is a result of the advocacy of various members of the drafting committee to recognise the role of indigenous peoples and small farmers in the development of local agriculture.[800] It also reflects the

[799] Description of the development of DUS Guidelines is compiled from several descriptions provided by the PVPO and crop scientists with relevant experience.
[800] Personal communication, Department of Agriculture, (January 2019)

contributions that farmers historically have made to the agricultural industry in Malaysia; this express recognition and protection fulfils one of the policy objectives of the Act. [801]

The alternative PVP is available to farmers, local communities and indigenous peoples.[802] The definition of 'farmer' under the act is interesting, as it includes not only individuals who cultivate crops themselves or by directly supervising others but also anyone who preserves, jointly or severally a traditional variety of crops or who adds value to the traditional variety through their selection and identification of their useful purposes. This might suggest that the category is intended to be constructed more broadly than what is normally understood to mean. This would allow for a wider group of potential applicants to protect their local and traditional varieties, which would be in line with the aim of the PNVP Act to recognise and protect the contributions of farmers, local communities and indigenous people. 'Indigenous people' are considered to be those who fall within the terms of 'aborigine' or 'native' as defined by Federal Constitution (FC).[803] 'Local communities' is defined as a group of individuals that have settled together and who continuously inherit a production process or culture, or that live together under an eco-cultural system. Accordingly, the term 'indigenous' is linked with the heritage of the applicant whereas both 'farmer' and 'local community' are centred upon a positive link to the genetic resources at issue.

Thus, it is available to a limited class of applicants. Where the applicant is a local community or indigenous people, the authority that represents the local community or indigenous people is responsible for submitting the application.[804] In the same vein as s. 14(1), a plant variety is considered new if it has not been made available for sale or otherwise disposed of in Malaysia for one year before the application,[805] or for most plant varieties, for four years before the date of filing in other countries.[806] Equally, the criterion of 'distinct' is considered to be where a new variety is clearly distinguishable from existing

[801] Azmi, n770 above, at 878
[802] PNVP, s. 14(2)
[803] 'Aborigine' means an aborigine of Peninsular Malaysia (FC, art. 160(2)). The term 'Native' refers to individuals in either the states of Sabah or Sarawak, who belongs to one of a closed list of indigenous ethnic groups (FC, arts. 161(6), 161(7))
[804] PNVP, s. 13(3)
[805] PNVP, s. 14(3)(a)(i)
[806] PNVP, s. 14(3)(a)(ii). A period of up to six years is permissible in the case of trees and vines.

varieties, the existence of which is common knowledge.[807] Based upon these requirements, it is clear that alternative PVP in Malaysia is intended to the recipient of the same plant breeder's rights as commercially developed varieties. This approach differs from that taken in other states which have adopted a unique *sui generis* system of plant variety protection which also recognises existing traditional and farmer's varieties. For example, the approach adopted in India[808] provides for two different alternative *sui generis* IP rights over traditional or farmers' varieties: protection for extant varieties and protection for farmers' varieties. Protection for extant varieties provides registration for varieties that meet the DUS criteria but are not new.[809][810] It does not grant the applicant an IPR over the extant variety but assigns the rights to the extant variety to the Indian government. Equally, protection for farmers' varieties allows for the registration of varieties about which there is common knowledge among farmers or communities.[811] Applicant varieties are also required to meet a modified version of the DUS criteria.[812] Rather than operating as an intellectual property right in the strict sense, it provides for the registration of farmers' varieties and the right for the registered owners of the variety to claim compensation for the use of their varieties. Like the alternative plant variety protection encapsulated in s. 14(2), the aim of these provisions is to recognise the contributions of farmers, local communities and indigenous people. There are other states besides India which have adopted a similar approach.[813] The significance of this is that the Malaysian regime appears to provide a unique opportunity for the developers of farmers and traditional varieties by offering them the same intellectual property right as commercial breeders.

Under the PNVP Act, a variety is identifiable if it can be distinguished from any other plant in the same grouping by the expression of one or more characteristics which

[807] PNVP, s. 14(3)(b)
[808] Protection of Plant Varieties and Farmers' Rights Act, No.53 of 2001 (PPVFRA)
[809] PPVFRA, s. 2(j)
[810] Protection of Plant Varieties and Farmers' Rights (Criteria for DUS Registration) Regulations 2009, available at https://wipolex.wipo.int/en/text/200387 (accessed: 15th July 2020) s.4
[811] PPVFRA, s. 2(l)
[812] PPVFRA, s. 5
[813] A similar example is Thailand, which provides for the registration of Local and Domestic Varieties, and General Domestic and Wild Varieties. See, Plant Variety Protection Act, B. E. 2542 (1999)

is identifiable within individual plants and across the grouping;[814] and characteristic can be identified by anyone skilled in the relevant art.[815] The criterion of 'identifiable' is not subject to established test guidelines in the same manner as the Uniformity and Stability criteria; rather it is informed by the process of variety development reported by local farmers. The inclusion of the Identifiable criterion is intended to support the possibility of applications for PVP from the identified individuals or groups who have considerable agricultural knowledge but do not have formal education or scientific knowledge about plant breeding. In the process of drafting the PNVP Act, the committee examined the process by which local and indigenous farmers developed plant varieties. They found that the breeding process undertaken by local farmers and indigenous peoples generally followed a cycle of discovery, selection, repeated breeding to encourage the desired characteristics, which in turn produces some degree of uniformity and stability, although this may not be akin to the standards of uniformity and stability demanded by the DUS test guidelines. [816] This is at least in part because of the influence of environmental factors upon the uniformity and stability. Thus, the concept of identifiable functions more or less as the measure of distinctiveness: it is the measure by which a person skilled in the relevant art[817] is able to assess that the relevant characteristic of an applicant variety is present across the sample group.

The other way in which the alternative PVP under s. 14(2) differs from standard PVP under s. 14(1) is that it expands the scope of activities involved in producing a registerable variety. Farmers, local communities and indigenous people may apply for PVP for a variety which they have 'bred, discovered or developed'.[818] This is distinct from s.14(1) which does not refer to the process by which the new variety has been attained. However, given the fact that PVP under s. 14(1) is reflective of the international or UPOV standard, it is not unreasonable to suggest that it is implicit that the production of the new variety is through traditional plant breeding techniques. The term 'discovered or

[814] PNVP, s. 14(3)(e)(i)
[815] PNVP, s. 14(3)(e)(ii)
[816] Personal communication, Department of Agriculture, (January 2019)
[817] PNVP, s. 14(3)(e)(i), s. 21
[818] PNVP, s. 14(2)

developed' is somewhat interestingly defined as 'activities which lead to the desired phenotypic expression and affect the crop genotype and which may or may not entail the deliberate or artificial creation of genetic variability'.[819] This suggests that the alternative PVP is intended to capture plant varieties which are created through means other than formal or scientific breeding processes and thus make protection available for traditional or farmers' varieties.

The references to the phenotype and the genotype of the variety are particularly interesting. The term 'genotype' refers to the complete hereditary information of an organism.[820] The term 'phenotype' refers to the sum total of an organism's observable characteristics (including its morphology) as a consequence of the interaction between its genotype and its environment.[821] This suggests that the provision is intended to encapsulate a more flexible standard than that espoused in s. 14(1), as it appears to contain an allowance for the effect of the local environment on the physical manifestation of a traditional or farmers' variety. The relevance of this is that while traditional or farmers' varieties are highly likely to have been selectively bred for identifiable traits, those traits may also be influenced by the local environment in which they are cultivated. Therefore, they may not be likely to produce the same traits in a uniform or stable manner if cultivated elsewhere. This is reflected in the Administrative Guidelines,[822] which sets out the testing process for traditional or farmers' varieties. The Administrative Guidelines require the inspection of a minimum of five plants possessing the same characteristics.[823] This testing can take place either on site (i.e. at the applicant or breeders' premises) or at a DUS testing station; whereas the testing of an applicant variety under s. 14(1) requires both on site testing and testing at a DUS testing station. This arguably factors in any environmental or ecological influences into the variety testing process. Therefore,

[819] PNVP, s. 2
[820] 'genotype' Oxford English Dictionary Online, available at: https://www.oed.com/view/Entry/77623?rskey=GWHgvw&result=2&isAdvanced=false#eid (accessed: 15th July 2020)
[821] 'phenotype' Oxford English Dictionary online, available at: https://www.oed.com/view/Entry/142359?rskey=DzHmaR&result=1&isAdvanced=false#eid (accessed 15th July 2020)
[822] DOA, 'Administrative Guidelines on the Application and Registration of New Varieties of Plants' (2008) available at: http://pvpbkkt.doa.gov.my/ (accessed: 15th July 2020)
[823] ibid, at 11.3

divergences in phenotype caused by the influence of a variety's local environment should not impede registration under s. 14(2). The effect of this is that it should make it easier for farmers and local communities to register their varieties.

The phrase 'bred, discovered or developed' is also used in the definition of a plant breeder in the 1991 UPOV Enactment.[824] Interestingly, this definition is not present in the 1978 UPOV Enactment upon which the Malaysian PVP law was based.[825] UPOV has provided explanatory guidance as to the meaning of 'discovered and developed' within the UPOV system. It distinguishes the notion of 'discovery' from 'development': it suggests that discovery may refer to the initial step in breeding a variety, and that development is the necessary quality to make a variety eligible for a plant breeders' right.[826] In effect, they are both requirements of the plant breeding process. The special relevance of the inclusion of the concept of discoveries to the UPOV system is that it is one of the key conceptual differences between patent protection and *sui generis* systems of protection for plant varieties. Patent protection requires an inventive step; whereas *sui generis* plant variety protection was originally devised to encourage all forms of plant improvement, which includes discoveries.[827] This is because it is possible for a natural variation to be the source of a new plant variety as well as deliberate work on the part of the breeder. The term was reintroduced in the 1991 Enactment, as it was felt that it was necessary to recognise the role discoveries (i.e. natural variations) play in plant variety development. It was, however, emphasised that both discovery and development are required in order to produce a registerable variety.[828] The curiosity here is that in the PNVP act this phrase has been used for alternative PVP under s. 14(2) but not for standard PVP. This suggests that the meaning of the term 'discovered and developed' has been constructed somewhat

[824] UPOV 1991, art. 1(iv)
[825] According to UPOV, the word 'discoveries' is omitted from the 1978 Enactment as the possibility of natural mutation being the source of initial variation is implicit in article 6(1)(a), which suggests that the origin of a potentially registerable variety may be natural or artificial. Similarly, the 1978 Enactment does not define 'breeder' or 'breeding'. See, n826 below, at paras. 11-13
[826] UPOV, 'Explanatory guidelines on the definition of breeder under the 1991 UPOV Convention' 24th October 2013, available at: https://www.upov.int/edocs/mdocs/upov/en/caj_67/upov_exn_brd_draft_6.pdf (accessed: 15th July 2020)
[827] UPOV Council, 'The notion of breeder and common knowledge' 19th Extraordinary Session, Geneva, 19th April 2002, at paras. 5-10
[828] ibid, at paras. 16-17

differently under the PVP than under UPOV. It is possible to interpret this drafting as an indication that conventional PVP is intended to serve the results of formal breeding activities and that the inclusion of 'discovered and developed' under s. 14(2) encapsulates a more flexible approach to the development of traditional and farmers' varieties. It also seems likely that it may be intended to provide a certain degree of flexibility, as PVP for traditional or farmers' varieties under s. 14(2) requires applicant varieties to be new, whereas other models for the registration of local, traditional or farmers' varieties do not include a novelty requirement.[829] Thus, the inclusion of 'discovered and developed' in s. 14(2) may serve to soften the novelty requirement for traditional and farmers' varieties.

6.2.6 The Protection of New Varieties of Plants Act: Compatibility with UPOV

As is noted in section 6.1.1 above, although Malaysia is not a member of UPOV, it has applied to join the Union. It has been suggested by Ida Azmi that the Protection of New Varieties of Plants Act is 90% UPOV compliant.[830] However, if this is the case, the remaining 10% appears to be something of a sticking point. The Malaysian Act was drafted based upon the 1978 UPOV Enactment, as opposed to the 1991 UPOV Enactment. [831] However, since the 1991 Enactment came into force on 24th April 1998 it is no longer possible to accede to the 1978 Enactment. Nonetheless, the PNVP Act contains a number of the key features of the 1991 Enactment, most notably the inclusion of essentially derived varieties. The issues concerning UPOV compatibility can be broadly placed into two categories: those concerning technical compliance with UPOV standards and the availability of PVP for traditional and farmers' varieties under s. 14(2).

Concerning technical compliance, Malaysia has attended UPOV meetings as an observer and has received UPOV technical assistance since the Act was in the process of being drafted.[832] Such assistance has been focused on achieving compliance with the standards required by the 1991 Enactment, as it is only possible to accede to the UPOV

[829] See, section 5.3.2.1 above, for discussion of protection of Extant and Farmers' varieties in India. See also, registration of Local and Domestic varieties, and General Domestic and Wild varieties in Thailand, n813 above.
[830] Azmi, n770 above, at 878
[831] Suzi Fadhilah Ismail, 'Intellectual property protection for agricultural biotechnological inventions: a case of Malaysia' (PhD Thesis, University of Nottingham, 2011)
[832] UPOV Gazette no. 96, UPOV/PUB/438/96 at para. 52

system if the Council has reviewed the conformity of the laws of the applicant state and its view is positive.[833][834] Some of this guidance can be considered to be mere procedural requirements. For example, the original UPOV Council advice on the PNVP highlighted the fact that it failed to include the required list of at least 15 genera or species of plants to be protected,[835] which could be achieved in line with national needs and priorities. Indeed, since the Act came into operation, the PVP Office has implemented DUS guidelines for 24 crop species,[836] effectively making protection available the under the Act.[837] The species for which protection was introduced clearly reflect Malaysia's existing agricultural priorities: they include financially lucrative crops such as ornamental flowers and popular fruits; industrial crops such as oil palm and commodity crops, such as rice.

However, other elements of the guidance and suggestions provided by the UPOV Council pertain to more fundamental changes to the Act, and as a result are more difficult to reconcile with the fact that the PNVP Act is an attempt to design a PVP system that caters to Malaysia's unique set of needs. Of particular note is its objection to s. 15, concerning prohibition of the registration and grant of a breeders' right. The UPOV Council has suggested that the restriction of the grant of a PBR where it may affect public order or morality, or where there are reasonable grounds to believe that the cultivation, production or use of the plant variety may produce a negative impact on the environment, is an additional restriction on the grant of a breeders' right, beyond those permitted by UPOV (which only allows for a breeder's right to be denied where the variety does not meet the DUS criteria). The Council suggested that this provision should be deleted and perhaps replaced by separate legislation, which would apply to commercialised varieties regardless of whether they were registered.[838]

[833] UPOV 1991, article 34(3)
[834] It is to be recalled that the UPOV system provides a model system for plant variety protection rather than a directly applicable regime.
[835] UPOV Council, *Twenty-Second Extraordinary Session; Geneva, April 8 2005* at para. 7
[836] The species for which PVP is currently available in Malaysia are: Durian, Papaya, Guava, Mango, Pineapple, Rambutan, Pitaya, Dabai, Nangka, Chilli, Dendrobium, Chrysanthemum, Lily, Mokara, Vanda, Paddy, Acacia, Teak, Cocoa, Oil Palm, Pepper, Rubber, Kelapa, Sweet Potato (Accurate as of June 2020)
[837] PVPO, 'DUS Test Guidelines' available at: http://pvpbkkt.doa.gov.my (accessed: 15th July 2020)
[838] n835 above, at para. 15

The UPOV Council's critique of the alternative plant variety protection regime set out in s. 14(2) suggests that in its view, the alternative PVP should be set out in a separate part of the Act and clearly identified as a different PVP regime as it pertains to a restricted group of applicants and has a different subject matter and conditions for protection and has a different duration.[839] This can be viewed in two separate ways. The first is that the notion of a plant breeder's right or plant variety protection should be reserved for traditionally styled plant variety protection (which the right outlined in s.14(1) can be said to be) and correspondingly, a right that is designed around manifestly different qualities does belong in a separately identifiable regime. It is also arguable that this approach also makes practical sense for end users.

On the other hand, it can be argued that the suggestion that the alternative form of plant variety protection should not be recognised as the same plant breeders' right is contradictory to the stated aims of the PNVP Act, and undermines the purpose of offering alternative PVP, particularly if protection for traditional and farmers' varieties is intended to be the same IPR that is available for commercial plant breeders, as opposed to a different or equivalent right.

6.2.7 TRIPS Plus and Plant Variety Protection in Malaysia

As we have seen in this chapter so far, Malaysia has adopted an interesting, hybrid *sui generis* approach to it implementation of article 27.3(b); although this remains in its infancy and the possibility remains that it may be reconceived in the near future. It has also been observed that, at present, Malaysia's relationship to the UPOV Conventions continues to be open but with significant obstacles to its potential accession to the Union. The situation as it currently stands is underdeveloped, however, there is sufficient flexibility in the existing legislative, administrative and regulatory framework for it to be moulded to national plant breeding and food security needs.

However, there is a spectre looming over the current status quo. The spectre in question is the possibility of Malaysia adopting a TRIPS Plus trade agreement which will

[839] n835 above, at paras. 10-11

oblige Malaysia to become party to the 1991 UPOV Enactment. This has been a very realistic prospect for some time: as outlined in section 2.4 above, the now defunct Trans-Pacific Partnership (TPP), which Malaysia had signed,[840] but not ratified, would have required it to implement UPOV 1991 standards within three years.[841] Similarly, its successor, the Comprehensive and Progressive Trans-Pacific Partnership (CPTPP), to which Malaysia is also signatory,[842] but has not yet ratified, also imposes the same obligation.[843]

At the time of writing, the future of the CPTPP, and therefore the obligation to implement UPOV 1991 in Malaysia is uncertain.[844] Dependent upon the political success of this TRIPS Plus agreement, there are two possible outcomes. The first, is that should it elect to ratify the CPTPP, is that Malaysia will be obliged to implement UPOV 1991. As discussed in section 6.2.6 above, achieving UPOV compliance is dependent upon significant modification of the existing Malaysian formulation of plant variety protection, including the removal of the alternative form of PVP contained in s. 14(2) of the Protection of New Varieties of Plants Act. Therefore, the new Malaysian plant variety law will be strictly limited in its ability to implement unique *sui generis* solutions for plant variety protection. The utility of the revised plant variety law will also be limited to the suitability of UPOV style PVP for supporting developments in underutilised crop varieties and addressing food security concerns, which was considered in chapter three, and will be returned to in chapter seven.

Alternatively, if the ratification of the CPTPP does not come to fruition in Malaysia, then it will be free to either continue with the current PNVP Act as it stands or revise it in a way that reflects what it perceives to be its needs and priorities.

Thus, it may prove to be the case that the form of revisions to the PNVP Act will not be dictated by their suitability for domestic plant breeders and national food security concerns, but as a consequence of wider trade ambitions.

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[840] Malaysia signed the TPP on 4th February 2016
[841] TPP, article 18.7.2(d)
[842] The CPTPP was signed on 8th March 2018; it entered into force on 30th December 2018, 60 days after the ratification of the agreement by 50% of the signatories.
[843] CPTPP, article 18.7.2(d)
[844] Due to the historic change in the Malaysian government in early 2019, Malaysia's subscription to the CPTPP is under review and no date has been set for ratification. See, Ministry of International Trade and Industry, https://fta.miti.gov.my/index.php/pages/view/71 (accessed: 15th July 2020)

6.2.8 Possible reform of the Protection of New Varieties of Plants Act

At the time of writing, the possibility of reforming the PNVP Act is being deliberated by Parliament and the relevant government agencies in Malaysia. There are a number of reasons why reform is being considered. The first is the overhanging threat of an international trade agreement that will necessitate PVP reform in order to bring it into line with UPOV standards, as considered in section 6.2.6 above. At the same time, there are those who believe that the Malaysian framework should align itself more completely with UPOV, notwithstanding any trade-based obligations. Of particular relevance is Malaysia's membership of the East Asian Plant Variety Protection forum (EAPVP); an organisation established to encourage information exchange and compliance with UPOV 1991 among East Asian nations.[845]

Also relevant is the fact that despite the national seed sector in Malaysia being relatively nascent, the uptake of PVP since the introduction of the PNVP act to has been slow. On the other hand, it is neither proper nor useful to lay all of the blame for the limited uptake of PVP at the foot of the legislative framework, as lack of relevant expertise, high turnover of staff, budgetary constraints and administrative delays in granting PVP have all been cited as factors that have impeded its success so far.[846]

At present, reform of the Act is likely although it is very difficult to speculate upon when this might take place given how long it normally takes for new legislation to be developed and enacted in Malaysia. The recent flip-flopping of the Malaysian government[847] is also likely to be a factor in when or if this might be achieved. Reform of the PNVP Act does not necessarily require Malaysia to abandon its alternative plant variety protection, although it may need to be considerably repackaged in order for its existence alongside traditional PVP to be acceptable to the UPOV Council.

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[845] EAPVP is composed of the ten member states of the Association of South East Asian Nations, plus China, Japan and Korea.
[846] DOA, 'Malaysia's implementing of EAPVP 10 year strategic plan'; Personal communication, Department of Agriculture (February 2019)
[847] Johnathon Head, 'How Malaysia's government collapsed in two years' BBC News, available at: https://www.bbc.com/news/world-asia-51716474 (accessed: 15th July 2020)

6.3 Access and Benefit Sharing in Malaysia

6.3.1 Malaysia and the Convention on Biological Diversity

Malaysia signed the Convention on Biological Diversity at the Rio Earth Summit[848] and subsequently ratified the treaty on 24th June 1994. This brought into effect the obligations of the CBD, including *inter alia* the requirement to create conditions to facilitate access to genetic resources on the basis of mutually agreed terms (MAT) and subject to Prior Informed Consent (PIC), and to encourage the equitable sharing of the benefits arising from the use of genetic resources[849] and associated traditional knowledge.[850]

In response, Malaysia established a National Committee on Biological Diversity charged with the development of appropriate ABS principles and producing a draft bill, which was completed in 1999.[851] The draft bill was scheduled to go through the national consultation process between 2000 and 2001 and for subsequent approval by parliament. However, its progress with national consultation proved to be much slower than anticipated. Delays in the consultation of the ABS bill can also be attributed to the fact that the Ministry of Science, Technology and Environment prioritised enacting the draft bill on Biosafety[852] over the ABS bill. As a result, the ABS bill lost momentum. It continued to face a number of serious conceptual difficulties, including addressing the challenge of dividing ownership and management of resources between state and federal governments.[853] Issues pertaining to indigenous and community held resources, knowledge and innovations; and controversy over a proposed *sui generis* system of community intellectual property rights also remained unresolved.[854]

As a result of the difficulty resolving these issues, the original national ABS bill never passed. There were some piecemeal measures in place to regulate access to biological resources in peninsular Malaysia, predating the CBD, although these served

[848] United Nations Conference on Environment and Development, 3 to 14 June 1992
[849] CBD, art. 15
[850] CBD, art. 8(j)
[851] Santiago Carrizosa, 'Scenarios of Policymaking Progress' in Santiago Carrizosa, Stephen B. Brush, Brian D. Wright & Patrick E. McGuire (eds.) *Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity* (IUCN, Gland, 2004) at 57
[852] as required by the Cartagena Protocol on Biosafety to the Convention on Biological Diversity
[853] Mohamad Osman, 'Malaysia: Recent Initiatives to Develop Access and Benefit-Sharing Regulations' in Carrizosa, Brush, Wright & McGuire (eds.) n851 above, at 245-246
[854] Carrizosa, n851 above, at 58

more of the function of monitoring access to genetic resources rather than acting as required permission.[855] Crucially, these measures lacked the necessary benefit sharing component. However, the east Malaysian states of Sabah and Sarawak, which are home to a greater proportion of the nation's biodiversity, took the initiative to develop their own state level ABS regimes, centred on state biodiversity centres in order to conserve the states' genetic resources.[856]

Due to the soft nature of the provisions of the Biodiversity Convention, Malaysia remained in compliance with its obligations under the CBD even in the absence of a national ABS framework. However, the delays in implementing a national legislative framework regulating access to biological diversity demonstrates the difficulty of balancing such complex interrelated concerns, even in a mega biodiverse state with a desire to protect its resources. This situation was potentially beneficial to developers, as there were no issues accessing biological resources for experimentation and development. However, it left both state and privately owned biological resources open to bio piracy and appropriation of associated traditional knowledge.

6.3.2 Malaysia and the Nagoya Protocol

The early stages of Malaysia's relationship with the Nagoya Protocol were not particularly easy. Malaysia participated in the negotiation of the Protocol as a part of the group of Like Minded Megadiverse Countries (LMMC) and the group of Like Minded Asia Pacific Countries (LM APAC). As is noted in chapter five, the late stages of drafting the Protocol were polarised between a group of parties including Japan, the EU, Brazil, Namibia and Norway, which produced and presented their own, complete draft of the protocol behind closed doors, from which Malaysia was excluded.[857] When the final compromise

[855] A scheme was administered by the Economic Planning Unit, which required foreign prospectors to acquire a permit. Such a permit did not mitigate the need to acquire relevant permits at the state level. In Peninsular Malaysia, prospecting in the forest also required a licence under the National Forestry Act 1984 (Act no. 313). The export of biological resources is governed by the Customs Act 1967 (Act 235)

[856] The majority of state held collections of germ plasm are in Sabah or Sarawak. State authorities with *ex situ* germplasm collections are: Sabah Parks; Department of Agriculture, Sabah; Department of Forestry, Sabah; Department of Agriculture, Sarawak; Department of Forestry, Sarawak; Sarawak Botanical Garden; and the Sarawak Biodiversity Centre. The only exceptions are the Penang Botanical Garden and the Kedah Regional Development Authority.

[857] This approach to achieving a draft protocol was heavily criticised by the LMMC, including the Malaysian delegation registered their protest with the manner in which the negotiations had been conducted. Nijar, n763 above, at 5

text of the Protocol was presented on a 'take it or leave it basis', it received protestations from the Malaysian delegation as it did not consider the text to represent a balanced protocol.

It was unsurprising then, that Malaysia did not choose to adopt the final text of the Protocol at Nagoya. It did however later opt to sign the Protocol on 5th November 2018 before acceding to the Protocol on 3rd February 2019, as a means of fulfilling its ABS obligations under the Convention on Biological Diversity. One of the fundamental concerns espoused by the delegations of developing states during the negotiation of the Protocol was that should key issues not be adequately addressed, they would be left in a worse position than they had been under the CBD alone.[858] This is a significant factor that contributed to Malaysia's slow adoption of the Nagoya Protocol, and is reflected by the prolonged negotiation of a national ABS framework under the CBD, as discussed above.

The reason why states and biologically rich states in particular, would likely find themselves worse off under the Protocol is that the CBD requires that parties wishing to access a biological resource to obtain the consent of the contracting party in which that resource is located, unless that obligation has been waived by the contracting party concerned.[859] The CBD does not require the enactment of a domestic law; whereas the Nagoya Protocol appears to require the enactment of a relevant law as a precondition for the consent of the country in question.[860] This has been viewed by developing states as onerous as it presents the choice between implementing an ABS regime and ceding sovereignty over its genetic resources. This also creates pressure on both time and resources to craft an appropriate national ABS framework.[861] Given this, it is entirely understandable that states, including Malaysia, have been reluctant to adopt the Protocol until adequate domestic ABS measures are in place. This is evidenced by the fact that Malaysia did not adopt the Protocol until a year after the Access to Biological Resources

[858] The Malaysian Minister of Natural Resources and Environment, Douglas Unggah emphasised that LMMC states should not rush to adopt a weak protocol, as it would be detrimental to the long term interests of the group and would undermine progress already achieved with ABS issues. See, Nijar, n763 above, at 10
[859] CBD, art. 15.5
[860] Gurdial Singh Nijar, 'The Nagoya Protocol on Access and Benefit Sharing: Analysis and Implementation options for Developing Countries' March 2011, CEBLAW, at 2
[861] ibid

and Benefit Sharing Act was in place: otherwise, up until that point it would have only been possible to require consent for access to genetic resources in the states of Sabah and Sarawak, which had already implemented state level ABS regulation.

6.3.3 Access to Biological Resources and Benefit Sharing Act 2017

The Access to Biological Resources and Benefit Sharing Act 2017 (ABRBS) entered into force on 17th October 2017. The act applies nationally across the countries 13 states and three federal territories and operates in conjunction with the existing state level access and benefit sharing solutions. It concerns all genetic and biological resources which are not the subject of another specialised instrument to which Malaysia is party. Thus, the Act does not apply to the genetic resources which fall within the multilateral system of the ITPGRFA, or PGRFA that are within the state's control and in the public domain. This means that the gene banks of the Malaysian Agricultural Research and Development Institute (MARDI) and the Department of Agriculture fall outside of the scope of the ABRBS Act.

The ABRBS Act introduces a tiered scheme of competent authorities responsible for access to biological resources in Malaysia. It introduces a national competent authority responsible for coordinating the implementation and enforcement of the ABS requirements of the Act.[862] Its role includes, *inter alia,* coordinating the implementation and enforcement of the Act and implementing and fulfilling the requirements under any treaty, agreement, convention or protocol relation to access and benefit sharing to which Malaysia is party.[863] This is supported by competent authority in each state or federal territory which has jurisdiction over all matters relating to the biological resources in its territory.[864] The competent authorities are responsible for dealing with all applications relating to access for biological resources and associated traditional knowledge.[865] Thus, responsibility for access and benefit sharing resides primarily at the state level.

[862] The national competent authority consists of the Secretary General of the Ministry Natural Resources and the Environment, now the Ministry for Natural Resources and the Environment was restructured into the Ministry of Water, Land and Natural Resources (KATS); and their chosen appointees (ABRBS, s. 7(2))
[863] ABRBS, s. 8
[864] The Ministry of Federal Territories is the competent authority for the federal territories of Kuala Lumpur, Labuan and Putrajaya.
[865] ABRBS, s. 10(1)(a). The competent authorities are set out in schedule one of the ABRBS Act.

This approach reflects the tiered, federal political structure in Malaysia and creates appropriate leeway for the competent authorities to tailor how they implement their ABS obligations to local needs and requirements. It also allows the ABS framework to retain some flexibility, which is useful given the difficulties experienced in the earlier attempts to create such a framework. However, the success of this approach relies upon equal uptake at the local level. This includes the establishment of regulations governing access and benefit sharing, as well as the existence of appropriate local institutions and expertise. As we will explore in this chapter, the uptake of this has been asymmetrical among the states and federal territories. Although a certain degree of asymmetry is fitting, given the variation in biodiversity between the states, failure to address this may create uncertainty for end users and result in a lack of benefit sharing with the holders of biological resources.

6.3.3.1 Biological Resources and Traditional Knowledge

As is stated explicitly in the title of the Act, access and benefit sharing is concerned with biological resources, rather than genetic resources as expressed in the Nagoya Protocol. Both the terms 'biological resources'[866] and 'genetic resources' are used in the Convention on Biological Diversity; however, so far as utilization, the third aim of the Convention is concerned, this is limited to genetic resources.[867] The definition of biological resource adopted in the s.4 of the ABRBS Act includes: genetic resources, organisms, microorganisms, derivatives and parts of thereof; populations and any other biotic components of ecosystems with actual or potential use or value for humanity; and any information relating to these. The ABRBS Act does not explicitly define traditional knowledge; however, s.4 refers to traditional knowledge as being a resource that originates in indigenous and local communities. This generally reflects the approach taken in the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP). While s. 31 UNDRIP does provide examples of what may constitute traditional knowledge, the emphasis is on the link between the originators of the knowledge, rather than the

[866] The CBD defines biological resources as including 'genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use for humanity, art. 2
[867] CBD, art. 1

substance of the knowledge itself.[868] Therefore, the provisions relating to TK relate to closed groups.

Given how 'biological resources' has been constructed under the ABRBS Act, its scope Act is potentially much broader than that of either the CBD or the Nagoya Protocol. Under the Act, genetic resources are one possible manifestation of a biological resource. There are two particular points of interest in the definitions here: the first is the explicit inclusion of derivatives, which was a point of contention during the negotiation of the protocol. The second is the inclusion of information relating to biological resources. This is particularly interesting as it appears that it may extend the application of the ABS principles established by the Act to include knowledge associated with biological resources other than traditional knowledge. There are two possible implications of this: the first is that the definition is intended to capture knowledge relating to a biological resource that does not originate from a group identifiable as a local community or an indigenous people within the operational definitions in Malaysia.[869] This might include knowledge held by individuals who fall outside the defined groups.

Alternatively, the inclusion of the term 'any information relating to' biological resources in the definition of biological resources may effectively subject a new type of knowledge to the requirements of the ABS regime, as arguably, research data relating to biological resources may come within the scope of information relating to biological resources and therefore fall within the definition of biological resource. The effect of this is that the scope of the ABRBS Act is much wider than that provided for by the Nagoya Protocol. This represents a significant success of the Act, as it clearly integrates Malaysia's national focus of a broad interpretation of ABS obligations into its solution. Thus, the construction of 'biological resources' creates considerable flexibility in the interpretation of the Act, which may go beyond the extent intended by the drafters. The extent to which

[868] Article 31 UNDRIP outlines the rights to maintain, control, protect and develop inter alia, their traditional knowledge, including manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines and knowledge of the properties of flora and fauna.
[869] Indigenous communities are defined by the Act as persons recognised by the Aboriginal Peoples Act 1954 (in Peninsular Malaysia) or natives as defined by Clause (6) of Article 161A of the Federal Constitution (in Sabah and Sarawak) (s.4). Local communities are defined as a group of individuals who have settled together and either under an eco-cultural system or that continuously inherit production processes (s.4)

this flexibility actually exists can only be determined through use based evidence, and the Act and its implementation are relatively nascent. This issue will be returned to in chapter seven.

6.3.3.2 Access to Biological Resources and Traditional Knowledge

Access to biological resources under the ABRBS Act is defined as the taking of a biological resource from its natural habitat or other place where it is kept, grown or found[870] for the purpose of research and development.[871] It also includes situations where the competent authority deems there to be a reasonable prospect that a resource accessed will be subject to research and development.[872] This introduces a safeguard, to ensure that the Malaysia's biological resources are not subject to biopiracy. The act does not apply to biological resources that have been cultivated or tended for any purposes other than research and development.[873] Notably, it also excludes the use and exchange of biological resources by indigenous and local communities in and among themselves in the exercise of traditional and customary practices.[874]

Interestingly, the Act cites adverse impact upon food security as a reason for refusing access to biological resources.[875] It is not clear what type of situation access to biological resources might have such an impact, however the inclusion of this provision in the Act is consistent with Malaysia's national agricultural priorities.

The Act distinguishes between applicants who wish to apply for access to biological resources for commercial research and those who wish to apply for non-commercial research purposes. Applicants who wish to apply for access for commercial or potentially commercial purposes are required to establish a benefit sharing agreement with the resource provider, on the basis of MAT and PIC, before permission for access will be granted by the relevant competent authority.[876] Once a permit has been granted under s. 13(1) of the Act, no change in use of the biological resources is allowed. If the permit

[870] The provision also includes commercially available biological resources – 'in the market'
[871] ABRBS, s. 5(1)
[872] ABRBS, s. 5(1)
[873] ABRBS, s. S.5(2)(c)
[874] ABRBS, s.5(2)(g)
[875] ABRBS, s. 12(2)(i)
[876] ABRBS, s. 12(2)(a)-(b), s. 22(1)-(2)

holder wishes to change their use of a biological resource, they are required to make a new application and reacquire permission from the competent authority.[877] The Act does not specify exactly what constitutes a change in use. The significance of this is it will be necessary for permit holders to continue to reflect upon and evaluate whether their research is likely to have a commercial application throughout the research process.

Applicants who wish to apply for access for non-commercial research can apply to the relevant competent authority, provided that: the applicant themselves is a non-profit organisation based or registered in Malaysia; local researchers are involved in the activity; and that a programme for capacity building is included in the activity.[878] The necessary condition of the involvement of Malaysian researchers and/or organisations demonstrates the emphasis placed on developing Malaysia's own ability to benefit from its genetic wealth. Provided that these conditions are met, non-commercial access to biological resources or associated TK does not trigger automatic benefit sharing obligations under the Act, although indirect benefits will be achieved through the capacity building requirements. Applicants who can satisfy the competent authority that the application is not for commercial purposes and that they have acquired PIC, should be able to access genetic resources. Finally, no permission is required for non-commercial research carried out in Malaysia by, or on behalf of a public higher education institution, public research institution or government agency.[879] This again reflects the priority placed upon Malaysia developing its own exploitation of its genetic resources. The relevance of the distinction access for commercial and non-commercial purposes is considered in section 7.3.1 below.

6.3.3.3 Prior informed consent

Access to biological resources is subject to the requirement of prior informed consent. However, the PIC requirement is limited to relevant indigenous and local communities, where the biological resource in question occurs on land to which the indigenous or local communities have a right established in law, or traditional knowledge

[877] ABRBS, s. 13(2)
[878] ABRBS, s. 15(2)
[879] ABRBS, s. 18(a)

that is held by a local or indigenous community.[880] Beyond this, the Act does not impose a PIC requirement. Both article 6.1 of the Nagoya Protocol and article 15.5 of the CBD refer to the 'prior informed consent of the party providing such resources….unless otherwise determined by that party'.

The Act does not set a standard or procedure for acquiring PIC, although it does dictate who is capable of giving informed consent.[881] PIC must also be acquired in accordance with the customary laws and practices, protocols or procedures of the appropriate local or indigenous community.[882]

The significance of this for agricultural development is that a plant variety which is not the subject of PVP will be brought within the scope of the ABRBS whereas a plant variety that has been granted PVP is not. This creates a situation in which there is the potential for the same plant variety to be treated very differently under the regime dependent upon whether it is the subject of PVP. Where it is not the subject to a breeders' right, access to the biological resource will be controlled by the relevant competent authority (in conjunction with the appropriate local or indigenous communities, where relevant); whereas there is no such regulation of access to a variety which has been granted PVP. It is worth remembering that a variety being the subject of PVP is not a requirement in order to sell that variety. It is also relevant that plant variety protection continues to only be available for a limited number of genera in Malaysia. Thus, it is possible for developed plant varieties to fall within the scope of the ABS regime. Therefore, it is possible that non-PVP varieties may be better off, in terms of benefit sharing, than PVP protected varieties, as the former requires some form of benefit sharing at the point of access.

[880] ABRBS, s. 23(1)
[881] ABRBS, s. 23
[882] ABRBS, s. 23 (1)-(2)

6.3.3.4 Exception for protected plant varieties

The access provisions of the Act do not apply to the taking of a biological resource for which plant variety protection has been granted and subsists under the protection of new varieties of plants act.[883] This approach is also consistent with the Nagoya Protocol, as it requires states parties that require PIC for access to genetic resources to provide for legal certainty, clarity and transparency in their domestic ABS regime;[884] the Protocol does not require states parties to automatically allow the genetic resources within their control to be accessed through the ABS regime. It also treats plant varieties that are the subject of PVP as privately controlled inventions, rather than genetic resources. This approach makes sense: the exclusion of protected plant varieties from the access requirements is in line with the UPOV exceptions to a breeders' right, allowing for acts done privately and for non-commercial purposes, experimental purposes or for the purpose of breeding other varieties, which is reflected in the PNVP Act.[885]

6.3.3.5 Benefits available under the ABRBS Act

Under the act, any applicant for permission to access a biological resource or associated TK (for commercial or potentially commercial purposes) must enter into a benefit sharing agreement with the resource provider;[886] this is to be on the basis of MAT and provide for fair and equitable benefit sharing.[887] This provision echoes article 5.1 of the Nagoya Protocol.

The Act prescribes that any monetary benefits paid under benefit sharing arrangements are to be deposited into a fund established by the state or federal government.[888] If the Federal Government or State Authority is not the resource provider, they may require the applicant to pay a percentage of any monetary benefits arising under

[883] ABRBS, s. S.5(2)(h)(ii)
[884] NP, art. 6.3(a)
[885] UPOV 1991, art. 15(1); PNVP, s. 31(1)
[886] ABRBS, s.22(1)
[887] ABRBS, s.22(2)
[888] ABRBS, s.22(4)

the benefit sharing agreement.[889] Any payment made is to be used towards the conservation of biodiversity and the sustainable use of its components.[890]

The Act does not automatically prescribe monetary benefits; it merely sets out the format where financial benefits are the agreed method of benefit sharing. Beyond this, the Act does not describe or prescribe any other means of direct benefit sharing. It does not restrict the sharing of other benefits (such as those outlined in Annex I of the Nagoya Protocol) as a part benefit sharing arrangements; it merely means that determining where non-monetary benefits are appropriate is left to either be prescribed by state level ABS frameworks or to be agreed on a case by case basis in individual benefit sharing arrangements. In the latter case, this means that reaching a fair benefit sharing arrangement will be dependent upon the negotiation skills of the parties to the agreement. In most cases, one of the parties will be the competent authority for the state in which the biological resource is found, and thus be in a relatively strong negotiating position, given the role of the competent authorities in granting permission for access to biological resources. The scope of redistribution of benefits will be considered in section 7.3.1 below.

6.3.3.6 Intellectual property protection under the ABRBS

s. 31 of the Access to Biological Resources and Benefit Sharing Act requires anyone applying for a patent in relation to a biological product or traditional knowledge, whether in Malaysia or another state, to notify the National Competent Authority within thirty days of the application. Failure to do so is an offence subject to imprisonment or a fine.[891] The provision does not contain any reference to applications for plant variety protection.[892] The natural inference from this is that it is not legally necessary for those developing commercial plant varieties from biological resources accessed in Malaysia to notify the National Competent Authority of their application, either in Malaysia or overseas. This

[889] ABRBS, s.22(3)
[890] ABRBS, s.22(5)
[891] Under s. 31(2), Individuals found to have contravened s.31(1) is liable for a fine not exceeding 100,000 ringgit or a term of imprisonment not exceeding seven years or both; corporations responsible for contravening s.31(1) are liable for a fine not exceeding 500,000 ringgit.
[892] The only reference made to plant variety protection is in s.5, which concerns access to biological resources

appears to create a gap in the regulation of access to and the monitoring of the use of Malaysia's biological resources.

There are a number of possible explanations for this: it may be because of the fact that the development of the PVP system in Malaysia has been a slow journey,[893] and that its national seed market is juvenile. Consequently, it is possible that the view has been taken that applications for PVP using biological material accessed in Malaysia would be quite limited, if any might be made at all. However, this does not mitigate the fact that it is possible under the Act for plant variety protection to be acquired for a commercial plant variety developed using biological material acquired in Malaysia anywhere else in the world, without notifying the National Competent Authority. Another possible explanation is that as a matter of priority, the drafters of the Act considered that the research and development using biological resources and TK in activities other than traditional plant breeding, such as pharmaceutical development, to be of greater concern for the holders of biological resources than traditional plant breeding. This viewpoint may have some merit, as the ABS experiences in Malaysia have demonstrated that there is considerable interest in commercialising non-agricultural innovations based upon Malaysian biological resources. However, this explanation only stretches so far, as the commercial production of non-agricultural products derived from Malaysian biological resources may require the upscaling in production of the biological resources from which they are derived. This in in turn will likely require the plants from which those resources are derived to be developed in the same manner as industrial crops, which are often the subject of PVP.

A further possible reason for the emphasis on patent applications over other forms of IP protection is that the standard of an inventive step required to acquire patent protection for genetic material varies significantly among states. Thus, even though it may not be possible to acquire patent protection for certain biological inventions in Malaysia, it may be possible elsewhere. If nothing else, the requirement to notify should

[893] See section 6.2.1 above

provide the relevant authorities with information as to how Malaysian biological resources are being utilised, and where, beyond that supplied in the original access agreement.

It is arguable that the effect of this gap is limited, as the successful acquisition of an IPR for an invention involving biological resources or traditional knowledge sourced in Malaysia does not trigger any additional benefit sharing obligation under the Act, beyond those specified in the original access license. Furthermore, dependent upon how access agreements are framed in the individual states and federal territories, the obligation to notify upon application for plant variety protection may be imposed anyway.

Indeed, s. 31 appears to be something of an odd provision, as while it requires applicants for patent protection to notify the National Competent Authority, it does not go any further. It is neither a provision relating to access or benefit sharing; it is merely an additional requirement for those who are developing biological resources or traditional knowledge to undertake in order to maintain compliance with the law. For context, the Nagoya Protocol refers to the distribution of intellectual property rights as a component of clear and mutually agreed terms for access to genetic resources;[894] on paper, s.31 appears to be somewhat at odds with this.

6.3.4 Access to Biological resources and benefit sharing in Sabah

Access to genetic resources and traditional knowledge in Sabah is regulated by the Sabah Biodiversity Enactment 2000 (SBE).[895] The Enactment establishes the Sabah Biodiversity Centre, which is responsible for, *inter alia*, managing and sustaining the utilisation of the biodiversity of the state[896] and establishing a system for the protection of biological resources so that indigenous and local communities shall be recognised as the legitimate creators users and custodians of traditional knowledge.[897] In also established the Sabah Biodiversity Council, whose functions include the regulation the access to

[894] NP, art. 6.3(g)
[895] No. 7 of 2000
[896] SBE, art. 9(1)(b)
[897] SBE, art. 9(1)(j)

biological resources of the state, including the removal of biodiversity from the state[898] and to approve and issue access licenses for access to genetic resources.[899]

An application for access to genetic resources is required for anyone wishing to conduct research in the state, regardless of whether they wish to collect biological material.[900] Applicants are also obliged to name a local Malaysian institution as a collaborator in the research as a condition for an access license.[901] The intention of this provision is that local institutions remain involved in research pertaining to biological resources originating in Sabah, and this stand to benefit from the research.

Under the Enactment, the conditions for access are not subject to explicit benefit sharing obligations. Applicants are required to provide details of any benefits, including economic, technical, social, scientific, environmental or other which the state or affected communities may receive as a product of the intended research and any proposed benefit sharing arrangements in their application for access to the Sabah's biological resources.[902] It seems implied therefore that benefit sharing is a necessary condition for access to the state's biological resources. Thus, while the Sabah Biodiversity Enactment established a gatekeeping mechanism to protect the local and state interests in their biodiversity, it stops short of implementing a prescriptive benefit sharing requirement.

The Enactment does not touch upon the issue of the commercialisation of developments based upon biological resources accessed in the state: commercialisation is defined within the scope of 'access' to biological resources,[903] although applicants wishing to commercialise any information or developments resulting from an access activity are required to declare this on applying for a license.[904] Nor does it make any reference to the issue of intellectual property rights over innovations developed from biological material accessed in the state. It is interesting to note that in avoiding these issues, the approach taken in Sabah circumvents a number of the issues which impeded the development of a

[898] SBE, art. 8(2)
[899] SBE, art. 8(1)
[900] SBE, art. 16; this includes biological resources located on reserves, native customary lands or any sites over which indigenous and local communities exercise community-based or customary rights.
[901] SBE, art. 23
[902] SBE, art. 17(1)(b)(viii)
[903] SBE, art. 2
[904] SBE, art. 17(1)(b)(ii)

national ABS framework under the CBD. To that end, it provided a useful, intermediate solution which allowed the competent authority to serve as gatekeeper to the state's biological resources and to implement benefit sharing arrangements of a discretionary basis. The issue that arises as a result of only defining benefit sharing obligations as part of the access license is that it does not provide a guarantee of any benefits arising out of subsequent research activities or commercialisation, including the grant of IPRs if this is not anticipated by the terms of the original access licence. Equally, access to biological resources under the Enactment does not explicitly operate on the basis of prior informed consent or mutually agreed terms. Although concerning, this can be somewhat reconciled by the fact that access to biological resources is subject to the terms and conditions agreed by the competent authority. This approach is in line with the MAT requirement contained in article 15.4 of the CBD. Similarly, it can be argued that the terms and conditions for access can be viewed as the PIC of the contracting party, as is required by the CBD.[905] Although this does not necessarily equate to the PIC of the owners of the biological resources in question, this can be explained by the fact that this is a more recent development and is not referred to in the CBD. However, in the absence of a national ABS framework, the protection afforded to Sabah's biological resources by the Sabah Biodiversity Enactment is a noteworthy contribution to the regulation of access to genetic resources. From the perspective of developing genetic resources, it serves to clarify researchers' obligations in establishing consent for access to biological resources, although its failure to address IP concerns is potentially problematic. This issue is considered further in section 7.3.1 below.

6.3.5 Access to biological resources and benefit sharing in Sarawak

The other Malaysian state to implement its own ABS regime is Sarawak. It first passed the Sarawak Biodiversity Centre Ordinance (SBO) in 1997 and the Sarawak Biodiversity Regulations (SBR) in 1998. As of 2016, the Biodiversity Regulations have

[905] CBD, art. 15.5

been amended to incorporate the ABS standards of the Nagoya Protocol.[906] Sarawak opted to create a responsible body, the Biodiversity Council, to *inter alia,* regulate and control public access to the state's biological diversity.[907] It also created the Sarawak Biodiversity Centre which acts not only as a gatekeeper to Sarawak's biological resources, but also takes a proactive approach to investigating and documenting the biological diversity and associated traditional knowledge of the state.[908]

Sarawak has opted to implement a more detailed legislative regime than in Sabah or under the ABRBS Act. In terms of access to biological resources, the basic requirements are fairly standard[909] and reflective of the international norms. However, the Sarawak scheme possesses a number of noteworthy features. First is the fact that permission is also subject to the requirement that applicants submit both a sample of the material that they have collected and a copy of the data, reports or manuscripts that have resulted therefrom.[910] This is a rather clever inclusion that allows the Biodiversity Centre's documentation project to be a passive beneficiary in any access agreement.

Second, it is mandatory for a fair and equitable benefit sharing agreement to already be in place before a permit will be granted in cases where there is a likelihood of commercial use or the acquisition of intellectual property rights.[911] This strong, clear and defined link serves to secure the interests of local stakeholders, especially given that the formation of the benefit sharing agreement is to take place prior to access. It is also valuable for the consumers of biological resources to have their obligations dictated in such clear terms.

Where this also involves the traditional knowledge associated with the biological resources in question, it is necessary to acquire the prior, informed consent of the natives[912] in which that knowledge is vested, and that they be made beneficiaries to the

[906] Concerning benefit sharing, the latest version of the regulations has explicitly includes the same monetary and non-monetary benefits as are set out in Annex I to the Nagoya Protocol.
[907] SBO, s. 6
[908] SBO, s.6. The centre currently operates five research programmes in support of its aims.
[909] SBR, s. 3-18
[910] SBR 6.2(f)
[911] SBR s. 14(1)
[912] Term used in the regulations

benefit sharing agreement.[913] Interestingly, the 2014 amendment to the Biodiversity Ordinance made the Biodiversity Council legally responsible for ensuring that such an agreement is concluded.[914] This additional measure is a firm manifestation of the states' commitment to ABS principle and serves as an additional safeguard for local and indigenous interests. Furthermore, there is an assumption that, unless agreed otherwise, research and development that has the potential to result in commercial gain or intellectual property rights will take place in a Sarawak laboratory, institution or hospital unless specifically agreed with the Biodiversity Council.[915]

The regulations also provide for community agreement where the resource at issue is their property.[916] In addition, they set out detailed requirement for PIC, including *inter alia,* a minimum time period for considering the access request;[917] that the relevant community understand the request;[918] and that local cultural norms, customary rules and protocols are observed.[919] The burden for ensuring that these requirements are observed is on the applicant.[920] The level of detail of the requirements for PIC is evidence of the proactive approach to ABS taken by the Sarawak government, and again, the plain and clear manner in which the requirements for access is set out in the regulations should serve not only the holders of biological resources and associated TK but also potential users.

The regulations are explicit on the point of ownership of intellectual property: no one may claim IPRs over developments based upon biological material accessed in Sarawak unless entitled to do so under a pre-existing benefit sharing agreement;[921] and then only with permission.[922] They also establish right of the Sarawak government, as well

[913] SBR 14.1
[914] SBO, 6(bb)
[915] SBR 13(a)
[916] SBR s. 14.4
[917] SBR s. 22.1(b)
[918] ibid
[919] SBR s. 22.1(d)
[920] SBR s.22(2)
[921] SBR, s. 17.1; s. 33.1
[922] SBR, s. 33.2

as the originators of the biological resources in question to benefit from any intellectual property rights or licensing agreements.[923] This will be returned to in chapter seven.

6.4 Summary

The legislative framework pertaining to plant-based innovations in Malaysia contains some unique features which may serve to support development. Intellectual property protection for plant-based innovations remains a separate, but interrelated concern to access to genetic resources and associated traditional knowledge. While the future of the PNVP Act is uncertain at the moment, what can be said in the meantime is that it provides an interesting, hybrid system of plant variety protection. The PNVP Act can be described as a hybrid approach, because it contains PVP that looks very much like the international standard (UPOV) alongside a unique *sui generis* approach. On paper at least, these look like they should be able to fulfil a spectrum of plant breeders needs, including small and local breeders. However, some evidence, such as the slow uptake, suggests that this might not be the case. This will be considered in more depth in chapter seven. With the overhanging threat of TRIPS plus agreement and with it, inevitable membership to UPOV 1991 the question remains as to whether any future revisions to or replacement of the PNVP Act will still permit this degree of flexibility, or multiple types of plant variety protection to exist side by side and the answer is decidedly uncertain.

Concerning Malaysia's ABS framework, the recent Access to Biological Resources and Benefit Sharing Act appears promising. It has fleshed out the ABS principle set out in the Nagoya Protocol in a manner that appears to have set the foundation for future ABS success. It remains to be seen whether the seemingly wider flexibilities built into the ABRBS Act will actually prove to be so in practice. Sarawak in particular, has managed to achieve a level of clarity in its ABS framework that should support the holders of genetic resources, the state government and end users at the same time. However, this may in part be due to the fact that it predates the ABRBS Act considerably, and the regime has been gradually strengthened over a number of updates. In order for the ABRBS Act to be

[923] SBR, s.14.2(c)

truly successful, it needs to be more thoroughly and consistently implemented throughout Malaysia. It will also need to receive adequate administrative and institutional support.

Chapter 7 – Case study: developing the Bambara groundnut in Malaysia

7.1 Introduction

The purpose of this chapter is to return to the original research question: what role can intellectual property protection play in the development of underutilised crops? This is realised by examining the legal frameworks considered thus far in the context of the development of underutilised crops and food security. This is achieved through a case study focused upon the development of underutilised crops in Malaysia, and how those activities intersect with the legal framework. The case study is informed by qualitative research. This consisted of semi-structured interviews with stakeholders in underutilised crops and subsequent correspondence with participants. Participants included crop scientists;[924] food product development and quality professionals;[925] experts in the field of intellectual property protection and access and benefit sharing in Malaysia; and officials from the Malaysian Plant Variety Protection Office.[926]

The qualitative aspect serves to ground the analysis in the reality of developing underutilised crop varieties. As is noted in the first chapter, this discussion is primarily focused on a single underutilised crop species, the Bambara groundnut. Bambara is an effective lens through which to conduct the analysis, as it has potential for both subsistence and for commercial usage and therefore allows us to explore the range of related IP and ABS issues more fully.

In the ideal version of this exercise, it would be possible to discuss the pertinent IP and ABS concerns using one example from start to finish, i.e., with one crop species. However, due to a range of factors, this has not been possible in this case. Therefore, in order to fully explore the range of issues it has been necessary to draw upon a range of

[924] The term 'crop scientists' is used as an umbrella term here to encompass various crop related roles, including agronomists, crop geneticists, agricultural management experts, and crop technicians, among others.
[925] The term 'food development product development and quality professionals' refers to individuals whose roles is focused on post-harvest management and products developed from underutilised crops. They form the link between the crops and the consumer and are necessary for the process of developing the Bambara groundnut as a possible means of addressing food security concerns.
[926] Interview participants have not been identified as a condition of participation. Interview data has been used to compile the description of the crop development process. It has also informed the theme and direction of this research. Significant comments from interviews have been referenced as such.

examples. This is achieved through a mixture of ethnographic descriptive text,[927] drawn from a range of sources, with particular reference to qualitative interview data. The case study is structured as follows: the first part will contain the descriptive text which will highlight IP and ABS concerns. This will be followed by a summary of the key IP and ABS concerns which will map out the discussion in the second part of the chapter.

7.2.1 The role of the Bambara groundnut in Malaysia

As is described in the first chapter,[928] the Bambara groundnut is a highly nutritious, widely cultivated underutilised crop species, which is drought tolerant and is suitable for intercropping practices.[929] To recap, although demographic data on small farmers in Malaysia is limited, there is a considerable scope for it to supplement subsistence agriculture.

In addition to the direct consumption of Bambara and its role in subsistence agriculture, it is also a potential replacement for wheat flour and other similar ingredients in commercial food production. This potential is particularly relevant to Bambara's role in addressing food security concerns in Malaysia: due to its high annual rainfall and low soil quality, the country's agricultural land is almost entirely unsuitable for wheat cultivation. Malaysia is therefore heavily reliant upon imports of wheat flour. However, the climate in Malaysia is largely amenable to Bambara cultivation. Bambara flour is also of a higher nutritional content than wheat based flour; therefore using Bambara as a substitute for wheat flour also has the benefit of improving nutritional security. It is possible to substitute up to 50% of the wheat flour in many baked goods with Bambara flour without adversely affecting food products. Thus, imported wheat flour could be significantly supplemented by locally sourced flour derived from Bambara groundnut. Such a substitution would be in line with the food and nutritional security goals set out in the National Food Policy, by improving the nutritional content of food and decreasing

[927] Alan Bryman, *Social Research Methods* (4th ed., Oxford University Press, 2012) at 432
[928] See, section 1.3 above
[929] The term 'intercropping' refers to planting and cultivating a two or more crops in close proximity. This is a technique that can be used to maximise the productivity of a given piece of land.

dependence upon imported food.[930] In order to make such a substitution possible, production farming of Bambara is required. This will require a stable, commercially viable variety of the Bambara groundnut to be available.

7.2.2 Developing Bambara in Malaysia

The first stage of developing new crop varieties is to acquire suitable germplasm. This can be achieved either through direct acquisition, through collaboration with other research projects or through gene banks. Each of these methods introduces a potential ABS related access concern.

The direct acquisition of genetic resources involves seeking out *in situ* samples of the crop varieties in question. It is undertaken directly by the farmers or researchers developing new varieties of Bambara in Malaysia. Direct acquisition by farmers is what would normally be conceived as traditional seed exchange practices. Direct acquisition by breeder or researchers involves obtaining samples from local farmers and other locations where the crop can be found, such as farms, self-seeded plantings or wild relatives of the cultivated crop. The information necessary to find samples is reliant upon word of mouth, i.e. through direct contact with farmers in a particular area, or through information provided by other researchers or previous encounters. It is preferable to obtain both wild relatives and samples of farmed varieties of underutilised species[931] for use in selective breeding programmes, as this will provide a larger pool of diverse genetic and physical traits. The process of obtaining sufficient genetic material through direct acquisition is inherently time consuming. Once germplasm has been acquired, it is necessary to cultivate and reproduce the material in order to ensure that its traits are stable, as these will be the basis for its selection in breeding and development activities. This process can take a number of years.

Germplasm is also acquired through collaboration with other linked research projects. In the case of Bambara, material is available through, local universities affiliated

[930] Ministry of Agriculture and Agro-based Industries Malaysia, *Dasar Agromakanan Negara 2011-2020* (National Food Policy) (Putrajaya, Malaysia, 15th December 2011)
[931] Which are not the subject of PVP

with the International Institute for Tropical Agriculture (IITA) involved in researching the crop in Nigeria, Ghana and Tanzania. This germplasm is acquired by the institutions as a result of their collaboration with local farmers. This exchange is mutually beneficial, as not only do local farmers provide researchers with germplasm, they also receive varieties through the collaboration.

Direct acquisition is advantageous during the early stages of research as it can circumvent the need to secure import and export permits for germplasm acquired from gene banks. This is not only a result of the bureaucratic weight of applying to the gene banks for access to the genetic material and for the relevant permits, it is also a result of extended time frame for acquiring germplasm suitable for development via this route. It can take between one to three years to access and acquire germplasm from a gene bank, quarantine and cultivate the material to the point where it is useful for further research activity.[932] However, acquiring material through gene banks is advantageous as it offers guaranteed diversity which is highly useful at a later stage in the research, when the value of undertaking the research and development activity has been established. This is relevant as it is necessary to establish the likely potential value of an underutilised crop species before investing time and resources into securing the necessary genetic diversity for productive breeding activities.

After the acquisition of genetic material, it is necessary to plant and cultivate the seeds in order to provide a workable volume of material for the purposes of further breeding and selection processes. It is also appropriate at this stage to evaluate the characteristics of the individual sample specimens. At this point, it is then possible to cross germinate samples with other varieties based upon the desired characteristics as a part of the selective breeding development process. This can take place either in a laboratory setting or through traditional field based selection.[933] Desirable traits include: yield, both in terms of number of nuts produced and weight of nuts produced; protein

[932] Germplasm acquired either through gene banks or from overseas needs to be grown and reproduced under controlled conditions in the local climate as it may not survive direct exposure to the local conditions

[933] Both processes take around the same amount of time, approximately 5 months. Lab based cross germination is a more costly process, however it has the advantage that it offers a greater degree of control over conditions than field-based selection.

content of nuts; the morphological traits of the plant, as this will impact upon whether a developed variety is suitable for a given growing environment;[934] date of maturity of the crop; response to drought. It is noteworthy that the desirable traits being assessed are those which are clearly linked to food and nutritional security concerns. It is probable that selected samples will be subjected to multiple measures of evaluation. Much of the on farm selection of Bambara is based around the colour of the seeds, although the link between the colour of the nuts and any nutritional or culinary advantage has not yet been established.

Sample varieties then need to be bred and cultivated over several growth cycles. They are then tested using bio molecular techniques in order to ascertain whether the samples acquired actually provide genetic variance required for breeding purposes. This is then scaled out into field trials, in order to assess the stability of a variety's characteristics over several breeding cycles and in varying environmental conditions. This process which may take a number of years and is essential to producing a variety that fits within the legal concept of a plant variety, as traditionally conceived. Once the field trials are complete, it is possible to disseminate the newly developed variety among farmers. If the variety is intended to be sold or grown commercially, it is at this stage that it would be appropriate to acquire plant variety protection for the newly developed variety.

As noted above in section 7.2.1, flour produced from the Bambara groundnut is a potential supplement for wheat flour in food production. Should Bambara flour or other Bambara based products prove successful, it will become necessary to upscale production. This would involve contracting commercial growers so that sufficient quantities can be cultivated for food production purposes. Therefore, it is advantageous for developers to acquire intellectual property protection, such as plant variety protection, over their new variety in order to protect their investment and research efforts.

The development of a new variety raises the issue as to how the benefits arising out of its development are distributed. In the case of a variety that has been

[934] For example, varieties of Bambara which spread as they grow are useful as a coverage crop; whereas more regular and 'bunched up' varieties offer easier management, particularly in terms of harvesting.

commercialised and maybe the subject of intellectual property protection, this will invoke direct benefit sharing obligations. The absence of a commercialised variety however, does not mean that there are not benefits linked to plant variety development activities. In fact, given the somewhat circular nature of plant breeding and development, those benefits may directly feed into the crop development process. This is the case for benefits which do not arise out of a specific ABS agreement, such as those available under the Multilateral System of the International Treaty for Plant Genetic Resources for Food and Agriculture, which are redirected on the basis of calls for funding. Thus far, two projects have been funded under the MLS in Malaysia. The first is focused on the development of Bambara. While the second is centred around a different underutilized crop species (taro), the rubric of the project is more specific to Malaysia and it highlights different aspects of the ABS dynamic. An outline of the projects follows.

7.2.3 Benefit sharing projects funded in Malaysia

The first project to be funded through the benefit sharing mechanism in Malaysia concerned the Bambara groundnut and received funding in 2014.[935] The research undertaken as part of this project is linked with the discussion of the development of the Bambara groundnut that forms the wider theme of this research. The aim of the project is to, *inter alia,* conserve, develop and evaluate the crop's genetic diversity and are a step towards developing climate change tolerant varieties that will be capable of producing yields in agricultural land that is unsuitable for major crops. The research used material sourced from farmers' landraces, recently developed novel lines and crosses and varieties hosted by gene banks. The project is a multi-country co-development and transfer of technology project[936] which involves research institutions and personnel in Ghana,

[935] The title of the project is: 'Genetic trait characterisation of farmer and gene bank sources of Bambara groundnut for the development of drought tolerant lines in sub-Saharan Africa and South East Asia'. FAO, 'Full project proposal: Third call for proposals under the Benefit Sharing Fund' (2014) available at: http://www.fao.org/fileadmin/user_upload/faoweb/plant-treaty/Project-Proposals/W3B-PR-26-Malaysia_-_Technical_Proposal.pdf (accessed: 15th July 2020)

[936] Under the third call for applications to the Benefit Sharing Fund, applicants were invited to apply either as an 'Immediate Action Project'; these projects could receive up to 300,000 USD over three years for a single country application or up to 800,000 USD over three years as multi country application; or applications could be made as a 'Co-development and transfer of technology project' which were eligible to receive up to 150,000 USD over three years for a single country application and up to 500,000 USD over three years for a multi country application.

Indonesia, Malaysia and Nigeria, and on farm development in Ghana, Indonesia and Nigeria. It aims to increase overall food security in these regions, through developing and distributing improved lines of Bambara, which are drought resistant and possess other useful traits such as pest resistance and shorter cooking time.[937] The newly improved genetic material achieved through these research and development activities will be contributed to the gene banks of the International Institute of Tropical Agriculture (IITA) and all seed will be made publicly available with an emphasis on distributing the seed to resource poor farmers. The germplasm will be available for wider release upon the completion of the project. The information generated on the Bambara groundnut and its cultivation by the project will contribute to the information exchange aim of the ITPGRFA.

The genetic material used in this project is acquired from a mixture of sources, including directly from farmers involved in the project and accessions to the gene banks of the IITA. The material is refined through a breeding and growing process in which it is planted and grown both on farm and in controlled conditions. Varieties are selected for development on the basis of trait selection and their responses to cultivation conditions. The process of evaluating and developing the varieties necessarily incorporates both the traditional agricultural knowledge (TK) adjacent to the varieties involved in the project and the observations made by the farmers and growers during the project. This includes not only knowledge about the characteristics of the varieties, but also knowledge pertaining to optimal growth management, and the interaction between the crop genotype and various environments. The selection of valuable traits relies upon a cycle of feeding information back into the development process. This knowledge will be formalised over the course of the development process through conducting controlled field trials, which render the feedback and other agricultural knowledge into scientific data. Throughout this process, the transfer of material between crop scientists and farmers continues to take place. This particular project does not have a specific end goal; rather it is aimed towards the overall improvement of the quality and availability of Bambara germplasm, the only

[937] Shorter cooking time is identified as one of the key concerns affecting uptake of the crop. It will help food and financial security concerns by reducing associated food and labour costs. It also mitigates the environmental impact of using the crop as a food source.

restriction is that funding support from the benefit sharing mechanism is only available for a set period of time.

The second underutilised crop development project based in Malaysia was funded under the fourth call for proposals of the benefit sharing fund in 2018.[938] The project is centred on research and development of Taro (*colocasia esculenta*)[939] and is being undertaken by MARDI.[940] Malaysia is in the early stages of promoting the wider cultivation of taro as a staple crop. The purpose of the project is to strengthen and sustain on farm and community level conservation, utilisation and management of taro genetic resources. The project is multi-country in nature, and will take place across Fiji, Indonesia, Malaysia and the Philippines. It will use traditional taro varieties. These will be cultivated and screened for cultivars with promise for climate change mitigation and resilience to pests, diseases and drought and saline tolerance. Existing research on varieties sampled in Malaysia has predominantly taken place in Peninsular Malaysia. The project will involve on farm evaluation of local and farmers' varieties based upon a participatory approach; this will include surveying traditional knowledge concerning taro production and post-harvest management in order to establish best farming practices. The intended beneficiaries of the project are the small scale farmers who grow the crop for subsistence and potentially commercial purposes; the availability and redistribution of improved germplasm is intended to aid the development of domestic and export markets for the crop.

[938] Under the calls for proposals to the Benefit Sharing Fund, applicants were able to apply as either a single country or a multi country project. Single country projects can apply for up to 250,000 USD on the fourth cycle. Multi country projects can apply for up to 450,000 USD on the fourth cycle.
[939] Taro is a starchy root vegetable and one of the most ancient cultivated crops. It is included in Annex I to the ITPGRFA as one of the 64 most important crops; it continues to be a staple crop in the Asia Pacific region. High end estimates suggest that up to 500 million people are dependent upon the crop as a part of their dietary requirements. It can grow in marginal soils and can be cultivated under variable climatic conditions, and can be successfully cultivated on small farms of less than 0.25 ha (0.61 acres). This makes it particularly suitable for subsistence farming; it is popular in Indonesia, the Philippines and Fiji for this purpose.
[940] FAO, 'Conservation and sustainable utilization of Taro to increase food security and livelihood in marginalised communities faced with climate change: Fourth call for proposals of the Benefit Sharing Fund' (2018) available at: http://www.fao.org/3/ca5208en/ca5208en.pdf (accessed: 15th July 2020)

7.2.4 IP/ABS related issues arising out of the development of the Bambara ground nut in Malaysia

From sections 7.2.2. and 7.2.3 above, it is possible to identify a number of key areas to examine while considering the suitability the Malaysian ABS/IP framework for developments in underutilised crop varieties. The first set of concerns pertain to access to genetic resources and associated traditional knowledge. This can be divided into direct access, and indirect access through collaboration or partnership. Direct access to genetic material falls within the scope of the principles established by the Nagoya Protocol as embodied by the Access to Biological Resources and Benefit Sharing Act and the corresponding state ABS frameworks. It has to be noted that, it is not possible to entirely separate access and benefit sharing obligations from one another, and indeed, it is arguable that the existence of benefit sharing can be viewed as a measure of the success of access requirements. To that end, where benefit sharing is directly related to access to genetic resources, it will be considered alongside it.

The second concern is how suitable the intellectual property rights available in Malaysia are for developments in underutilised crop varieties. The two forms of plant variety protection available in Malaysia are considered in turn. Third, there are benefit sharing considerations which are not necessarily directly linked to access to genetic resources or associated TK. These benefit sharing activities, feedback directly back into the research and development of new plant varieties, or biological products. Thus, the sharing of benefits continues to support research and development. The analysis that follows will reflect this structure of concerns.

7.3.1 Issues arising out of access to genetic resources

Direct access falls within the scope of the ABRBS Act, and depending upon location, the Sabah Biodiversity Enactment and the Sarawak Biodiversity Regulations. As is noted in section 7.2.2, direct access is a preferred method of acquisition during the early stages of research and development, as it allows the collection potentially wide variety of samples, and is theoretically quicker and less bureaucratic than accessing material through gene banks. Direct access falls clearly within the scope of the definition in s. 5.1 ABRBS, of

taking a biological resource from where it is kept, grown or found for the purposes of research and development.[941] This concept is fairly straightforward. However, the next stage becomes more complex, as the ABRBS Act distinguishes between research and development for commercial (including potentially commercial) and non-commercial purposes and imposes different obligations upon the party accessing the biological resources accordingly. Anyone engaging in commercial or potentially commercial research is required to have entered into a benefit sharing agreement with the relevant competent authority before a permit to access the resources is granted.[942] The Act does not define commercial or potentially commercial purposes, however it does define 'non-commercial' as academic or non-profit oriented.[943]

Although this distinction looks relatively clear-cut on paper, in the context of the development activities described above, it can be seen that it is not so straightforward. The argument can be made that users of biological resources should err on the side of caution, and assuming that any research and development activity that has any possibility of resulting in a commercial development should be treated as such. However, we can see in section 7.2.2 above, that in the initial stages of the research, which includes the stage in which the material is being collected, the value of the exercise may well be unknown. Collected samples of plant genetic material have the potential to prove useless for the breeding activities for which they were intended. Thus, the suggestion that anyone undertaking research and development involving biological resources that may have remote potential commercial value, could create a significant burden for researchers at the risk of no reward. It also means that there may be no advantage for researchers to undertake the direct collection of germplasm. If the administrative efforts required to access local germplasm are too great, then it simply will not provide any advantage for developers over using material accessed through indirect means, such as through seed banks, as material acquired through seed banks has the advantage of guaranteeing a certain quality of samples.

[941] SBE, art 15; SBR, art. 4
[942] ABRBS, s. 12.2(a), S. 22(1)
[943] ABRBS, s.4

This is not intended to criticise this framing too harshly, as it is clearly intended to serve the interests of Malaysian owners of biological resources. However, if there is a presumption that the use of genetic resources will be commercial, then this needs to be supported by a simple ABS framework that makes clear the obligations of users and is widely accessible. Progress towards this can be seen in the ABS frameworks in Sabah and Sarawak; however, this is not matched in peninsular Malaysia. The need for an accessible ABS framework is central to supporting research and development utilizing genetic resources, including developments in underutilised crop species. Difficulties in understanding the obligations linked to accessing genetic resources were repeatedly cited by research scientists as an obstacle to research and development, especially in the early stages.[944] This included both the clarity of the pertinent legal framework and the relevant administrative arrangements. The discrepancies in the federal arrangement were also cited as a factor; as crop development activity taking place in one part of Malaysia will frequently rely upon resources gathered in another state or federal territory.

The effect of this is that it curbs the material gathering activities that researchers are willing to undertake; as they did not wish to fall afoul of their ABS obligations.[945] Participants also commented that they did not understand how their obligations had changed specifically as a result of the introduction of the ABRBS Act. This was especially true in the case of associated traditional knowledge, as the ABS provisions pertaining to accessing TK were considered to be more nebulous, both in terms of what constituted TK and in terms of what might constitute a use of that TK.[946] Indeed, some participants suggested that in situations where they were certain that they were able to take and use physical samples of genetic resources, they would still actively avoid discussing farming and breeding practices with its owners in order to ensure compliance. This was the case even where farmers or owners were willing to share their insights. It is particularly interesting to note researchers concerns about mishandling TK, as in Malaysia traditional knowledge is defined as knowledge originating in a specific group. This indicates quite

[944] Participant comments; Interview January 2019
[945] Participant comment; Interview January 2019
[946] Participant comment; Interview January 2019

clearly that there is a need for wider understanding as to what is classified as traditional knowledge.

This is unfortunate for research and development involving underutilised crops, as this lack of understanding of ABS obligations appears to be serving to limit access not only to necessary biological resources, but also to agricultural knowledge that may prove useful whilst being confident that they are not infringing their ABS obligations. As a consequence, this has the effect of limiting or reducing their potential to help address food security concerns. It also prevents benefits from feeding back into the development cycle. It is important to note that this does not necessarily mean that the ABS framework is failing here. It seems more likely that this indicates a lack of outreach or education by the relevant authorities to ensure that the potential users of biological resources are aware of their ABS obligations. Without effective awareness of these, it is difficult to further gauge whether the access requirements under the ABRBS Act serve to support of limit research and development.

There are two branches to indirect access to biological resources. The first is access to material from an institution, and the second is access to material through a facilitating institution. Accessing material for development through gene banks or associated institutions requires little comment as it is based upon an established process - material transfer agreements, in particular, the standard material transfer agreement established under the multilateral system to the ITPGFRA. The main barrier to accessing this material is appropriate expertise to navigate the application and potentially the bureaucracy associated with importing or exporting the material, or moving it between states. However, despite this, participants with the relevant expertise commented that generally, this process was straightforward, if time consuming. It was noted that this method was essential to the continuation of established Bambara research programmes.[947] It is therefore fairly obvious to state that the greater availability of germplasm facilitated through the MLS serves to support developments in underutilised crop species and in turn,

[947] Participant comment; Interview January 2019

helps to address food security concerns, even if the mechanism is only useful to a restricted group of applicants.

The alternative means of indirect access to biological resources through an intermediary institution, such as through the Sabah or the Sarawak biodiversity centre.[948] This overlaps somewhat with direct access to biological resources. To a large extent, this is the type of access that appears to be envisioned by the ABS framework. Both of these institutions appear to have clear and accessible systems for applying for access permits either for the collection of material found in the state or in their collections.[949] It was noted earlier that participants, in this case researchers, had difficulty understanding their obligations when it came to their treatment of genetic material and associated traditional knowledge, and therefore adjusted their behaviour accordingly. However, the same participants remarked that they had no issues either with understanding the need for, or the means of obtaining an access permit. These points appear to be somewhat at odds with one another. This juxtaposition is interesting, as it serve to pin point where the ABS framework is troublesome for the users of biological resources. If users understand the necessity of permission for access, but have difficulty navigating their behaviour towards biological resources and its holders while conducting research, then it seems that the critical area in which improvements could be made that would facilitate access to and use of biological resources is the clarification of the obligations and restrictions placed upon users. The ABRBS Act does not govern users' behaviour towards biological material that they have accessed, beyond the general principles of ABS. Similarly, the Sarawak Biodiversity Regulations does not establish any specific behavioural obligations for researchers beyond the general principles of access and benefit sharing and the normally applicable restrictions, such as permit requirements, regulation of exports or rights over discoveries.[950] Nor does the Sabah Biodiversity Enactment. Rather, what seems to be

[948] Also relevant is the genetic material stored by MARDI. However, the genetic material held by MARDI is primarily contains industrial crops.
[949] Sabah Biodiversity Centre, 'Access License Application' available at: https://sabc.sabah.gov.my/content/access-licence-application (accessed 15th July 2020); Sarawak Online Research Application System; available at https://www.sbc.org.my/research-regulations-permit/research-permit-application (15th July 2020)
[950] SBR, ss. 6-12, 17

missing is a broader, general understanding of users' obligations towards biological resources.

What appears to be the most explicit direction as to users' obligations is the requirement in Sarawak to notify the Biodiversity Council in the case that a discovery is made based upon biological resources accessed in the state.[951] The phrasing of the provision is such that:

> 'where research and development leads to the discovery of any compound, chemical or curative agent, molecule or product which has pharmaceutical, medicinal, therapeutic, nutritional, industrial or agricultural value, properties or potential, the person or body undertaking the research shall notify the Chief Executive Officer and an application for intellectual property rights in regard to the discovery shall be made in accordance with the benefit sharing agreement'.

This provision is interesting because it does describe a specific obligation of users towards biological resources they have accessed; a duty to notify once a discovery is made. However, the formulation of this provision is fairly vague. Presumably, the development of a crop variety is considered to be a 'product' as none of the other descriptors fits well. At least on paper, the triggering requirement does not fit well with the agricultural research and development paradigm that is being explored here. As is explored in section 7.2.3 above, the process of developing viable crop varieties takes place over several breeding cycles and it is not always possible to determine the impact or influence of specific genetic material on the resultant variety. Similarly, the use of agricultural knowledge in the development of crop varieties is a process of feeding information into the breeding and development process. It is not necessarily possible to weigh the value of individual contributions. There is the possibility that the original use of the material and the commercially viable variety may be separated by years of development. In the same vein, it is unlikely that there is a triggering moment in which

[951] SBR, s. 17(1)

the value of any particular biological or knowledge based contribution to the breeding process becomes apparent.

The complexity of these issues, combined with the fact that they are likely to change on a case by case basis, is presumably the very reason why they are not more comprehensively addressed in the legislative and regulatory framework. It can also be argued that these details are absent from the legislative and regulatory provisions because it is intended to be determined on an individual contractual basis, as an access agreement is effectively a contractual mechanism. However, the two ideas are not mutually exclusive. It is possible to develop general principles or guidelines governing the behaviour of users towards biological resources and to impose specific obligations through individual ABS agreements. More importantly, this would need to be supported by some form of outreach or educational programme, to make sure that this information is communicated. This aspect is critical, as it is a lack of understanding that needs to be addressed. Greater certainty in this regard would surely serve to help address food security concerns, as addressing researchers concerns and encouraging their use of Malaysia's biological diversity will provide a wider resource base for the development of new crop varieties and increase the likelihood of the development of new and useful crop varieties. It would further serve to safeguard the interests of the holders of biological resources. Furthermore, based upon the comments made that researchers would actively avoid engaging in discussion with the holders of biological resources, it might serve to facilitate the incorporation of agricultural traditional knowledge in to the research and development process.

A linked but separate issue is the requirement under the ABRBS Act, to distinguish between commercial and non-commercial use. It has already been noted that based upon the definitions of commercial and non-commercial use in the ABRBS Act, it seems to be necessary to assume that a use of biological resources is commercial unless undertaken by certain applicants and that such applications require a benefit sharing arrangement to be in place as a condition of access. This strict construction has the potential to be problematic for research and development that is reliant upon genetic resources,

particularly crop variety development, as we have already explored, the viable commercial product may be considerably distant in time from the accessed biological resources. At the point of access, the utility of any given biological resources for variety development remains unknown.

There is limited evidence as to how this challenge might be navigated. It is useful to consider how this has been addressed by existing benefit sharing arrangements; however, there are few examples to draw upon. Indeed, the only benefit sharing agreement that has been concluded in Malaysia since its implementation of the Nagoya Protocol concerns access to *Litsea Cubeba* or LitSara, as it has since been trademarked.[952] The agreement is between the Sarawak Biodiversity Centre and five indigenous communities.[953] Although the exact terms of the benefit sharing agreement are confidential, it is publicly known that it pertains to the use of *litsea* in product development and the sustainable harvesting of *litsea*. It is unfortunate that the confidential nature of the benefit sharing arrangement limits the extent to which it is possible to extrapolate, more generally, how benefit sharing arrangements might work out. Although the intellectual property right associated with LitSara, the trademark of the name, is registered to the Sarawak government,[954] in line with the Sarawak Biodiversity Regulations, the Sarawak Biodiversity Centre has declined to comment on the how the benefits arising out of the sales of trademarked goods might be distributed. This prevents us from engaging in a detailed analysis of how the agreement reflects the six elements IP aspects of successful and effective benefit sharing identified by WIPO.[955] It is however, interesting to note that the approach taken by this benefit sharing agreement, i.e. that the trademarks

[952] *Litsea Cubeba* is a member of the laurel family which thrives in the wild in Sarawak. Locally known as pahkak or tenem, different parts of the plant are traditionally used by the indigenous people of Sarawak for a number different of purposes, including as a flavouring for food or as a natural medicinal remedy for stomachache or back ache. The essential oil derived from the plant is trademarked as LitSara for Sarawak. It has a range of uses, including personal care products which are free from additives, such as antibacterial wet wipes, natural insect repellent, body wash, cleansing oils and soap.
[953] the Bidayuhs of Kpg Kiding, Padawan; the Lun Bawangs of Long Telingan and Long Kerebangan, Lawas; and the Kelabits of Pa'Ukat and Pa'Lungan.
[954] LitSara has been trademarked in a number of categories for various products. See, 'Intellectual property rights: LitSara trademark' available at: https://www.litsara.com/index.php/r-d/intellectual-properties (accessed: 15th July 2020)
[955] See section 5.3.3.1 above

are held by the Sarawak government, is in line with WIPO's suggestion that it may not be appropriate for government agencies to apply for IPRs jointly with resource holders.

What we do know about the LitSara benefit sharing agreement is that it did not emerge overnight. In fact, the benefit sharing agreement was the product of a relationship established and developed between the Biodiversity Centre and the resource holders over a period of several years, and which involved multiple periods of consultation and feedback from the resource holders, including on how the benefits are distributed.[956]

The LitSara case is not wholly applicable to the crop development paradigm being considered here, as it pertains to the development of biological resources and traditional knowledge at least partially undertaken by the Sarawak Biodiversity Centre itself. It is also different from the crop development paradigm in the sense that some of the applications of LitSara are established in the traditional knowledge of the resource holders. Nonetheless, it brings into focus a significant distinction between ABS on paper and in practice: that access to biological resources is not necessarily a one-off event, and that the successful negotiation of a benefit sharing agreement may take a considerable period of time. Thus, while a benefit sharing agreement may come first on the literal meaning of the legislative provisions, the reality of investigating the potential of biological resources is a process and it is possible that the benefit sharing arrangement may come about after the potential of the biological resources has been established.

Prior to its adoption of its ABS framework, the Sarawak government was also party to a series benefit sharing agreement concerning calanolides.[957] Calanolides are naturally occurring compounds that can be isolated from trees indigenous to Sarawak, and have anti-HIV properties. They were discovered as the result of a bioprospecting expedition.[958] Although there was no ABS framework in place in 1986, a Memorandum of Understanding (MOU) was reached between the NCI and the Department of Forestry of Sarawak, allowing

[956] Personal communication, Sarawak Biodiversity Centre (February 2019)
[957] Calanolide A is derived from *Calophyllum lanigerum var austrocoriaceum*, a rare member of the Guttiferae or mangosteen family. The samples were obtained from the forests near Lundu, in the south of Sarawak. Forest Department of Sarawak, 'The *Calophyllum* Story' available at: https://forestry.sarawak.gov.my/page-0-170-603-The-Calophyllum-story.html (accessed: 15th July 2020)
[958] The bioprospecting expedition was undertaken by the National Cancer Institute, a branch of the National Institute for Health of the USA.

the study and supply of the material. However, the Sarawak State government was unhappy with the distribution of benefits arising from the MOU.[959] The agreement was renegotiated by a legal team led by the State Attorney General and the assistant director of research of the Forestry department. The new MOU set out detailed terms for the contentious aspects of the agreement, including capacity building future financial benefits and intellectual property rights.[960] Subsequently, a synthetic route to producing calanolides was developed. Per the terms of the MOU, this triggered the negotiation of a benefit sharing agreement between the company developing potential pharmaceutical products from the synthetic calanolides and the Sarawak Government. The *ad hoc* benefit sharing agreement took over a year to be negotiated and included provisions which distributed future intellectual property rights and resulting royalties allowed for continued local involvement though capacity building.[961]

Although the calanolide example does not exactly parallel the agricultural research and development paradigm, it perhaps resembles it more closely than the LitSara benefit sharing agreement, as it is an outside party seeking to access biological resources through the local institutions. It highlights two relevant points. First, that the commercial viability of a development changes over time and with research. Second, it reiterates the significance of a continued relationship between the institutional and the developers in negotiating a successful benefit sharing agreement.

It is arguable that two examples are insufficient to draw truly meaningful conclusions. However, what can be taken away from these examples is the importance of the dialogue between the holders of the biological resources at issue and the potential

[959] In particular, the distribution of the future potential benefits of the research and development activities. At issue were intellectual property concerns, including patents and right to issue licenses for subsequent drug developments, as well as other financial benefits from the use of the biological resources, including royalty payments. See, n957 above, confirmed in communication with Sarawak Biodiversity Centre, February 2019.
[960] The agreement included, *inter alia,* co-inventorship and the distribution of the financial benefits arising out of the use of the compounds for research and provided for the future payment of royalties should a drug be synthesized from the compound. It also included capacity building provisions, including creating the obligation for the NCI to assist the state in the development of local capability to undertake isolation, screening, fractionation and structural elucidation of naturally occurring compounds - capability with the potential to support further local investigation and development of the state's biodiversity.
[961] Mohamad Osman, 'Malaysia: Recent Initiatives to Develop Access and Benefit-Sharing Regulations' in Santiago Carrizosa, Stephen B. Brush, Brian D. Wright & Patrick E. McGuire (eds.) *Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity* (IUCN, Gland, 2004), at 245-246

user. Nonetheless, it is important that we note that they are relaying the same message about the process of access. Namely, that the situation is not as black and white as it appears in the legislation. Rather than being a onetime transaction, it might be more appropriately viewed as a dialogue. This is particularly true in cases where an actual product does come to fruition.

7.3.2 Issues pertaining to intellectual property protection

7.3.2.1 - The suitability of plant variety protection under s. 14(1) for innovations in underutilised crops

As discussed in chapter 6, s. 14(1) of the PNVP Act contains the Malaysian formulation of traditional plant variety protection and conforms closely to the international standard. There is nothing about this *per se* which prevents it from being useful in supporting the development of underutilised crop varieties. The availability of PVP can provide an incentive for the development of crop varieties, and the acquisition of a plant breeders' right over a variety is arguably a necessary measure if the developer of a crop variety wishes to use their variety for any kind of food production. This is relevant to Bambara's potential to be used in commercial food production or as a supplement for imported food supplies such as wheat flour. This is reflective of the traditional justification for the existence of intellectual property protection: the availability of PVP serves to assure developers that their efforts and investment are protected. Along these lines, the availability of IP protection for underutilised crop varieties can help address food and nutritional security concerns by protecting breeders' rights while facilitating the commercialisation of underutilised varieties.

The difficulty with applying conventional plant variety protection to underutilised crop varieties is that the availability of PVP is dependent upon the availability of DUS Test Guidelines for the variety in question. Due to the fact of being underutilised, it is unlikely that DUS Test Guidelines are available for any given underutilised species. Test guidelines are not available for the Bambara groundnut in Malaysia. This effectively renders conventional PVP unavailable for Bambara varieties. Thus, the lack of relevant Test

Guidelines severely limits the utility of conventional plant variety protection for supporting the development of underutilised crop species.

The development and implementation of test guidelines by the PVP Office generally follows greatest perceived need: i.e. where there is greatest commercial need. This is reflected by the species for which guidelines are already available. For example, test guidelines exist for a number of ornamental species which have considerable export value.[962] Thus, the onus falls upon developers to work with the PVP office in order to establish the need for guidelines for a particular species.

It is important to note here that DUS test guidelines are not normally developed in isolation. In Malaysia, they are usually developed with reference to existing UPOV test guidelines, or alongside other states' PVP bodies, in particular, members of the EAPVP.[963] This means that one option is to look for guidelines elsewhere; if these are available then this will considerably streamline the process of developing and implementing Test Guidelines in Malaysia. A systematic search has failed to turn up test guidelines for the Bambara.[964] This is not particularly surprising given its status as a niche crop. Thus, any hope for PVP under s. 14(1) supporting innovations in underutilised crop species would be dependent upon the development of new, suitable guidelines. Given the fact that the Malaysian PVP system is still in the process of getting on its feet, especially where the development of test guidelines is concerned, it is unlikely that the development of test guidelines for niche crop species will become a priority for the Plant Variety Protection Office in the near future. If we recall that in terms of underutilised crop species, Bambara is in fact widely cultivated, this does not leave much scope for traditional plant variety protection to support innovations in lesser cultivated underutilised and niche crop species. This assertion can be extended to apply beyond Malaysia. Whilst it is difficult to generalise given the unique situations of individual states and their PVP systems, traditional UPOV style plant variety protection is relatively homogenous. Therefore, it can be stated with a considerable degree of certainty that the absence of appropriate test guidelines precludes

[962] These are: Dendrobium, Chrysanthemum, Lily, Mokara and Vanda
[963] Personal communication, Department of Agriculture (February 2019)
[964] Date of last search: May 2020

traditional PVP from supporting developments in underutilised crops or being a useful tool for addressing food security concerns.

7.3.2.2 The suitability of plant variety protection under s. 14(2) for innovations in underutilised crops

On paper, the possibility of PVP for traditional and farmers' varieties provides a useful opportunity for developments in underutilised crops, as it offers the potential for farmers, local communities and indigenous people to protect and exploit varieties that they have bred or discovered and developed. Thus, by virtue of the comprehensive nature of the protection afforded traditional and farmers' varieties under the PNVP Act, it has the potential to encourage developments in subsistence agriculture and support local food security by offering the breeders of these varieties the same IPR as commercial breeders.

The criterion of 'identifiable' has the potential to be particularly useful as it allows traditional and farmers' varieties to be assessed without reference to DUS test guidelines; it may also allow local environmental factors to be accommodated in assessing an applicant variety. In the case of the Bambara groundnut, it would be possible for applicants to register their variety on the basis of identifiable traits, such as colour, seed size or plant morphology. The registration of the variety is then able to serve as an assurance of seed quality, in addition to protecting the breeder's interests.

It is unfortunate that any opportunity offered by s. 14(2) is strictly hypothetical. To date, no farmers, local communities or indigenous peoples have applied to protect their plant varieties under s. 14(2).[965] Because of this, it is not possible to truly scrutinise the utility of the alternative criteria of new, distinct and identifiable for developments in underutilised crops. The fact that no applications have been received also means that it is not possible to assess whether there are practical or technical barriers to registering a traditional or farmers' variety.

However, the lack of uptake does not necessarily mean that the form of the alternative PVP as expressed in the PNVP Act is in itself inappropriate. It is useful to consider the possible reasons for the lack of uptake of PVP under s. 14(2). The Plant

[965] Personal communication, Department of Agriculture (January 2019)

Variety Protection Office (PVPO) has suggested that where farmers are interested in registering a variety for the purposes of commercialisation, then they have applied for conventional PVP under s. 14(1).[966] This suggests that where farmers are aware of the benefits of registering a variety, they are also sufficiently knowledgeable about the technical requirements of conventional plant variety protection. The lack of applications from local communities and indigenous peoples may be the result of practical difficulties experience in making those groups aware of the availability of plant variety protection for their varieties; it also may be a consequence that potential applicants have not yet been convinced of the benefits of registering their varieties. Participants have indicated that both are relevant factors, with emphasis on the latter. If this is the case, then we can conclude that it is the implementation and operation of the PNVP Act that is the issue, rather than its content. Indeed, conducting effective outreach programmes has been cited as a significant challenge to the implementation of the PNVP Act.[967]

Participants have also observed that farmers, including small farmers and farmers situated in rural communities, are generally creative and will vary their uptake of crop species to meet their own needs or what they consider to be market niches, and often engage in selective breeding and development practices to emphasise the traits which they consider desirable.[968] It is clear that variety development practices are a regular feature of small scale farming in Malaysia. It is also apparent that there is a gap between the availability of the IPR and its uptake. The DOA is aware of this issue.[969] This then raises the question as to what are the barriers to uptake of PVP for traditional and farmers varieties? It is not possible to speculate on the answers to those questions without further information from the relevant stakeholders. This presents a substantial challenge due to the lack of demographic data on farmers and farming practices in Malaysia.

[966] Personal communication, Plant Variety Protection Office (January 2019). View also expressed by in a comment by a participant not directly associated with the PVPO, in an interview in January 2019.
[967] Personal communication, Department of Agriculture (February 2019)
[968] Observations of farmer creativity in breeding and farming practices include: observing market place trends in both available crops and their characteristics
[969] Personal communication, Department of Agriculture (February 2019)

Another likely contributing factor is that ten years is not a particularly large amount of time for a system of plant variety protection to have been in place. The PVP regimes of many European states predate UPOV.[970] Similarly, patent protection has been available in its modern form in Malaysia since 1983,[971] although various notions of patent protection have been available in select parts of Malaysia since 1871.[972] Thus, the system is juvenile in nature and likely requires further time to allow it to properly serve all of the relevant stakeholders. As discussed above, the PVPO's efforts during this time have been focused upon developing adequate DUS Testing Guidelines for priority crops. It has also been noted that there is limited demographic data available on farmers in Malaysia, including the extent to which farmers cultivate their own or local crop varieties. Given this, the amount of effort required on the part of the PVPO to ensure that the local communities and indigenous people are aware of the availability of protection for traditional and farmers' varieties is considerable. In the light of the lack of uptake of PVP under s. 14(2) and the other competing priorities in establishing the Malaysian system of plant variety protection (such as establishing DUS test guidelines) it is perhaps not surprising that protection for traditional and farmers' varieties has failed to successfully launch.

7.3.2.3 Plant variety protection in Malaysia so far

The uptake of PVP in Malaysia has been gradual since its introduction. To date, there have been 111 grants of plant variety protection. It is important to note that this figure is likely to be inaccurate, as the current information published by the PVP Office is out of date. Updated information has been requested and promised by the PVP Office several of times, however it has not materialised. For this reason, this section is limited to making general remarks on the trends on the uptake of plant variety protection.[973] The applicants have primarily been a mixture of public research institutions and commercial

[970] Sean C. Butler, *A guide to UK and EU plant variety rights* (Cambridge, Cambridge University Press, 2005) at 3-9
[971] Patents Act 1983 (Act 291)
[972] Ida Madieha bt. Abdul Ghani Azmi & Jeong Chun Phuoc, *Patent Law in Malaysia: Cases & Commentary* (2nd Ed., Sweet & Maxwell Asia, Subang Jaya, 2015) at 1-3
[973] According to the PVP Office, the reason for the information being out of date is personnel and institutional changes taking place at the PVP Office (Personal Communications; PVP Office, January 2019-February 2020)

breeders.[974] The main type of plant variety for which PVP has been granted is ornamentals with 61 protected varieties, followed by forest plants (19) and cereals (14). The remaining registered varieties are a mixture of fruits, vegetables and industrial crops (such as cocoa). Thus, based upon this information, plant variety protection does not yet play a substantial role in supporting developments in food crop varieties in Malaysia. This is true for both commercial crop species, such as rice and underutilised species. However, it does not disprove the link between the availability of PVP and plant-based innovation, as the clear uptake in PVP for ornamental demonstrates that developers seek IP protection where there is a commercial market for the resulting plant. It is also likely that commercial agricultural staple crops, such as rice, are protected as registered as protected varieties elsewhere, especially given that Malaysia is reliant upon the import of seed for food supply.

The other important take away is that there are, based upon the available information, only five varieties registered to individuals. This raises questions as to PVP is accessible to farmers who develop varieties; whether they are aware of the option to apply for PVP or whether they simply do not believe it to be of value. When reconciling this data with the assertion by the PVP Office that where farmers are interested in registering a variety for the purposes of commercialisation, then they have applied for conventional PVP under s. 14(1)[975] there are two possible explanations: either there is little interest in farmers or other agricultural developers registering their varieties for commercialisation, or the information does not convey the complete picture of farmers' understanding of PVP. Unfortunately, deducing an answer to this query would require input from farmers, which due to the lack of demographic data has not been possible to procure.

7.3.4 The role of Benefit sharing in supporting developments in underutilised crops in Malaysia

It is difficult to comment on whether benefits arising directly out of ABS agreements in Malaysia serve to support agricultural innovation, including innovations in underutilised

[974] Including: MARDI, Sabah Forestry Development Authority, and the National University of Malaysia.
[975] Personal communication, Plant Variety Protection Office (March 2019)

crop species, due to both the country's limited experience with ABS agreements and the limited information available. At present, there are only two concrete examples to draw from, the historic Calanolide agreement and the Litsara agreement (considered in section 7.3.1 above), the only ABS agreement to be concluded in Malaysia since the entry into force of the Nagoya Protocol, under the amended Sarawak Biodiversity Regulations. Neither of these examples pertains to agricultural development specifically. However, it is possible to make some general observations.

It can be observed from the historic Calanolide agreement that the appropriate transfer of technology and capacity building facilitates research and development involving biological resources. It might also be inferred that the presence of a clear agreement on future royalties derived from intellectual property rights and royalties serves to encourage the continued research and development of the biological resources in question; however, this is a speculative suggestion. The relevance of any observations drawn from the Calanoloide case is limited by the *ad hoc* nature of that agreement.

In the Litsara case, the exact terms of the benefit sharing arrangement are confidential. Thus, while the Sarawak Biodiversity Centre is willing to disclose some details of the functioning of that arrangement, it is not possible to comment upon how and whether any financial, rights or royalties based benefits serve to support research and development involving *litsea cubeba.* The superficial evidence would suggest that the existence of the benefit sharing arrangement does support research and development, based upon the availability of various LitSara products.[976] However it is difficult based upon this limited information, to make any kind of assertion that the benefits arising directly from a similar arrangement might support agricultural innovations, including those involving underutilised crop species, or support improvements in food security.

From these two cases, we can deduce that the existence of these benefit sharing arrangements supports research and development using biological resources generally, and that they appear to support that research and development taking place in the

[976] See, https://www.litsara.com/index.php/products (accessed: 15th July 2020)

communities in which the resources are located. *Prima facie*, both agreements adhere to the benefit sharing principles set out in the CBD and the Nagoya Protocol; thus, if the principles of access and benefit sharing are sound, then it is reasonable to assert that the availability of benefits will serve to support research and development involving biological resources, including underutilised crop species. However, based on these two cases alone, there is insufficient evidence to make such a concrete assertion, beyond the fact that the availability of benefits may facilitate access to genetic resources and therefore support research and development in that manner.

It is more straightforward to analyse the relationship between indirect benefits, such as those arising out of the MLS to the ITPGRFA and to assess their utility in supporting agricultural developments, including developments in underutilised crops in Malaysia. As outlined in section 7.2.2 above, there is a clear link between the benefits distributed through the multilateral system and the facilitation of the exchange of germplasm and financing of breeding activities. This is true for both at the subsistence level and potentially commercial varieties, even if the registration and commercialisation of the varieties is on the distant horizon. Clearly, this mechanism supports the addressing of food security concerns, as intended, by facilitating access to germplasm and improved varieties. Indeed, the availability of funding from the multilateral system has been cited as necessary to stimulate research into producing improved varieties of underutilised crop species.[977]

It is possible to hypothesise as to the impact for those directly involved in the funded projects: access to improved varieties will improve crop quality and yield for the farmers that grow these varieties and contribute to both their own food and nutritional security and more widely in their communities. Equally, improved access to germplasm and funding of research and development activities for researchers should continue to make further improved varieties available and support food and nutritional security more widely. This is true for both the Bambara and Taro projects.

[977] Participant comment; Interview January 2019

It would be very difficult to measure the scale of this in any definitive way; however, it seems reasonable to surmise that there is an overall net positive impact. The main criticism that can be levelled at indirect benefit sharing as a means of encouraging innovation in underutilised crops is the fact the impact of these benefits is limited, as only certain projects are selectively funded under the multilateral system.

7.4 Summary

From the exploration of the process of developing underutilised crop varieties, we have learnt that the development of a stable and useable variety is an extended process, taking place over numerous growth cycles that relies upon both the exchange of germplasm and information. Additionally, we have discovered that it is difficult to establish the value of the genetic material when it is added into the breeding process; therefore, it may be difficult to pinpoint the value of a given contribution with absolute certainty.

Concerning access, it is clear that direct access to genetic resources is problematic in the context of the ABRBS Act. Greater awareness of users' responsibility towards biological resources and a greater understanding as to what constitutes traditional knowledge would serve to encourage and reassure researchers when collecting crop samples. Such improvements do not necessarily need to be incorporated into the legislative regime; however, they do need to be adequately communicated to the users of biological resources. It is probable that this would lead to greater uptake of germplasm in to the crop variety development process and produce an overall positive contribution to addressing national food security concerns. Additionally, indirect access to material through institutional links is essential to the continuation of formal breeding programmes for underutilised crop species. This appears to be the most important mechanism for promoting developments in underutilised crops.

Furthermore, it has become apparent that the distinction between commercial, potentially commercial and non-commercial research is not as clear cut as it appears on the statute; and that access to biological resources is not a onetime event. In order for ABS mechanisms to function adequately, it is necessary to establish and maintain a

relationship between the providers and the users of biological resources. Thus, in all probability the success of access and benefits sharing depends upon extra-legal factors.

With respect to intellectual property protection for innovations in underutilised crops in Malaysia, while traditional plant variety protection under s. 14(1) is a potentially viable option for developed varieties, it lacks the necessary technical support, including DUS test guidelines. What is more, it does not seem likely that these will become available in the near future. The alternative plant variety protection under s. 14(2) appears to be almost perfect for underutilised crop varieties developed by indigenous or local people. However, given the total lack of uptake and its uncertain future, it does not seem to be of any real use. Therefore, for the time being, the intellectual property rights available in Malaysia do not support innovations in underutilised crop species and cannot be said to incentivise their development. Accordingly, it is not possible to state that IP protection, as constructed in Malaysia, is a useful tool for addressing food security concerns. Yet it is not possible to disprove the potential link between IP protection for underutilised crop species and improvements in food security concerns, as the available IPRs are insufficiently realised to discredit them entirely.

Finally, it has been noted that it is difficult to assess the contribution of individual benefit sharing agreements generally. Perhaps the most that can be said is that based upon the existing cases in Malaysia, successful benefit sharing arrangements have the potential to be useful in supporting developments in underutilised crop species and in turn helping to address food security concerns. However, it is possible to state with confidence that the benefits arising out of the multilateral system to the ITPGRFA are essential to the continued research and development of useful varieties of underutilised crop species in Malaysia.

Chapter 8: Conclusion

8.1 Introduction

This chapter will bring together the findings and conclusions of the previous chapters. It will recap the process of the work thus far. It will discuss the strengths and weaknesses of the research and make recommendations for future study.

8.2 Thus far

It has been the purpose of this study to investigate the position that intellectual property protection should be a useful tool in addressing food security concerns. This has been analysed through the lens of supporting developments in underutilised crop species. Exploratory in nature, it has set out to understand how the relevant legal framework serves stakeholders in underutilised crops, on the basis that this should be able to encourage innovation and in turn lead to improved food security.

The study has sought to define the true scope of the obligation under article 27.3(b) of the Agreement on Trade Related aspects of Intellectual Property (TRIPS); it has scrutinised the utility of protection for plant varieties as provided for by the International Union for the Protection of New Varieties of Plants (UPOV); it has considered how biodiversity regulation has developed the concepts of access and benefit sharing as a counterbalance to biopiracy and the appropriation of genetic resources and traditional knowledge. A key theme has been the interaction between the required standards of intellectual property protection and the mechanisms governing access to genetic resources and the benefits arising from their use. Additionally, it has examined the interaction between the two major access and benefit sharing regimes, namely those of the Nagoya Protocol and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). Finally, it has examined the national framework for both IP protection for plant varieties and access and benefit sharing in Malaysia, before turning its attention to how that applies to the actual processes involved in researching and developing underutilised crop species.

This thesis has produced an answer to the question: Can intellectual property protection support developments in underutilised crops? And the answer is yes, provided that the system of IP protection is constructed in such a manner as to accommodate underutilised crop species. The second question whether intellectual property protection is a useful tool for addressing food security concerns is less straightforward to answer. As indicated in chapter one, definitively proving the utility of intellectual property rights for any given purpose requires arguing against a set of counterfactual scenarios.[978] Therefore, we must return to the original premise: that the availability of appropriate, useful and accessible intellectual property protection will help address food security concerns. On that basis, and given the current state of the Malaysian PVP legislation, the answer must be no, at present. However, that answer is of course, limited to Malaysia. The answer is likely to be yes elsewhere: either in states where UPOV plant variety protection is suitable for the crop species used to meet its food security needs, or in states where the IP framework that accommodates its diverse farming practices.

8.3 Strengths and limitations of research

The fundamental strength of this research is that it is unique in the intersectional nature of the inquiry. There is an existing body of research which considers the utility of underutilised crop species as a tool for addressing food security concerns, both on a small and large scale. There is a very limited amount of research that considers the issue of underutilised or niche crop species and intellectual property protection. There is also a considerable material on the relationship between intellectual property and food security. However, this work is novel in addressing these issues in a linked manner. It has cut across the issues from a new vantage point, and sought to analyse them in a balanced and comprehensive manner.

A further strength of the research is the mixed-methods approach used in the investigation. It has combined doctrinal and qualitative approaches to critically examine not only the relevant legislative framework from the standpoint of an academic lawyer,

[978] See section 1.2 above

but more importantly the standpoints of key actors. The qualitative aspect, achieved through semi-structured interviews and observation, is vital to the success of the work. It serves to introduce the first hand evidence of stakeholders selected on the basis of vested interests in either the success of IP protection for plant-based innovations or access and benefit sharing in Malaysia. Their contribution has provided reliable input on the challenges faced in the development of underutilised crop species that would have not otherwise been available.

The extent of the success of the qualitative aspect is limited by participants that were available and willing to take part in the study. It would have been beneficial to incorporate the views of other stakeholders, such as small farmers who farm underutilised varieties directly into the analysis. Unfortunately, the researcher did not have the opportunity to organise field-based research to gather qualitative data from these stakeholders, despite considerable and consistent efforts. To a certain extent, the analysis has also been limited by the disruption caused by the changes in personnel at the Malaysian governmental bodies surveyed. Nonetheless, the author believes that that the contributions of the participants were essential to the outcome of the research.

The study is also limited in that it is restricted to plant variety protection and alternative plant variety protection. Considering the role of other IPRs, such as patent protection or geographical indicators as tools for supporting either developments in underutilised crops or addressing food security concerns has been beyond the scope of the present research.

8.4 Research findings

Having examined the pertinent legal framework in the previous chapters, we have seen that they bear potential to be useful for supporting developments in underutilised crop species. On paper, the concepts of access to genetic resources, the sharing of the benefits arising from their use, and intellectual property protection for plant-based innovations appear to be distinct from one another. Yet, the investigation of the crop development processes has demonstrated that the reality is more complex and that the concepts are often interconnected.

To recap: while it is possible to construct article 27.3(b) TRIPS as being linked with interrelated ABS concerns, the Agreement provides for the minimum standard of an enforceable intellectual property right. This can be achieved either through patent or *sui generis* IP protection. However, the increasing use of so called 'TRIPS plus' bi- and multilateral trade agreement is effectively reducing member states options to implement their own *sui generis* IP solution, by requiring member states to accede to the UPOV system of plant variety protection.

UPOV provides the *de facto* standard for plant variety protection. This is potentially compatible with underutilised plant varieties that have been sufficiently developed to be useful as a commercial variety, provided that appropriate technical support is available. It is likely not suitable for smaller scale developers of underutilised or niche crop species; however there is insufficient information to state this definitively. The fundamental concern with UPOV is the resistance of its governing bodies to allow states parties to implement other plant variety protection solutions alongside UPOV PVP.

Concerning access and benefit sharing, the Convention on Biological Diversity offers guiding principles, rather than a firm ABS regime. It is clear that the availability of plant genetic material through the multilateral system of the ITPGRFA serves to stimulate and encourage developments in underutilised crop species listed in Annex I. It is less clear at this stage to establish a link between the access principles set out in the Nagoya Protocol and facilitating the development of underutilised crop species. However, it is certain that the two regimes should serve a complementary role, in order to ensure that access to both publicly and privately held germplasm are adequately governed and regulated. This will benefit both providers and users of genetic material.

Regarding intellectual property rights, it is clear that there is potential for plant variety protection, as it is constructed under the PNVP Act, to support developments in underutilised crop varieties. However, this potential has not been matched by the implementation of the act, both institutionally and in the development of appropriate test guidelines. It is disappointing that there is no evidence to support the utility of the alternative form of plant variety protection that appears on paper to be well suited to

supporting developments in underutilised crop species. As we have in chapter six, alternative plant variety protection has an uncertain future in Malaysia. Thus, the ability of either type of plant variety protection as envisaged under the Protection of New Varieties of Plants Act to support innovations in underutilised crop species remains speculative for now.

In terms of access to biological resources, we have seen that while the principles governing access are sound, greater clarity and awareness of access obligations are obstacles to research and development involving underutilised crop species in Malaysia. Resolving this is essential to both supporting further development activities, and respecting the rights of resource holders.

With respect to benefit sharing mechanisms, it is difficult to comment upon the utility of individual benefit sharing agreements as a means of supporting research and development activities in Malaysia, due to the novelty of the ABS regime and the confidential nature of the benefit sharing agreement that has been concluded under it. Nonetheless, there is a clear link between the benefits funded under the multilateral system to the ITPGRFA and both the formal development of underutilised crop species and the increased availability of germplasm and improved varieties to farmers. Given this, it is clear that the multilateral system is a useful tool for addressing food security concerns, in line with its aims.

8.5 Opportunities for further research

It is noted that this research has been undertaken when the both the plant variety protection system in Malaysia is in a state of suspended animation and the access and benefit sharing framework is in the early stages of its life. Thus, it would be worth revisiting the questions addressed here once the ambiguity surrounding the PVP system has been resolved and there has been greater development and use of the ABS framework, as the same question may well produce a different outcome. It would also be able to provide greater certainty for stakeholders.

It would also be worthwhile to transplant this investigation elsewhere. While this research has analysed the issues from the vantage point of the Bambara ground nut in Malaysia, it would be useful to build upon the foundations of the research considering the international regimes in chapters two to five, as a basis for an analysis either of the IP/ABS framework of another state where underutilised crop species are a potential food security solution; or the lens could be used to assess the viability of IP protection for a different underutilised or niche crop species.

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