

The Interface between the Nagoya Protocol on ABS and the ITPGRFA at the International Level

Potential Issues for Consideration in Supporting Mutually Supportive Implementation at the National Level

Jorge Cabrera Medaglia, Morten Walløe Tvedt, Frederic Perron-Welch, Ane Jørem and Freedom-Kai Phillips



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Access and
Benefit
Sharing

The ABS Capacity Development Initiative

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About the Fridtjof Nansen Institute (FNI)

The Fridtjof Nansen Institute (FNI) is an independent Norway-based foundation engaged in research on international environmental, energy and resource management cooperation. Within this framework the institute's research is mainly grouped around six focal points:

- Global governance and sustainable development
- Law of the Sea and marine affairs
- Biodiversity and biosafety
- Polar and Russian politics
- European energy and environmental politics
- Chinese energy and environmental politics

The main disciplines are political science and international law, but FNI researchers also hold degrees in economics, geography, history and social anthropology. The institute currently has a staff of about 35, including about 25 full-time researchers and 3-6 students.

FNI's activities include academic studies, contract research, investigations and evaluations. Annual turnover is around 30 million NOK.

FNI collaborates extensively with other research institutions and individual researchers, in Norway and abroad. It strives to make its expertise available and relevant to users as well as to the public at large. FNI research is published in international scholarly journals and books, as well as through the institute's own report series.

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Acronyms

ABS	Access and benefit-sharing
BL	Biodiversity Law
BS	Benefit sharing
CBD	Convention on Biological Diversity
CHM	Clearing-House Mechanism
CC	Certificate of Compliance
CGRFA	Commission on Genetic Resources for Food and Agriculture of the FAO
FR	Farmers' rights
GB	Governing Body of the ITPGRFA
GR	Genetic resources
ILC	Indigenous and local communities
IPR	Intellectual property rights
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
MAT	Mutually agreed terms
MTA	Material Transfer Agreement
NBSAP	National Biodiversity Strategy and Action Plan
NCA	National Competent Authority
PIC	Prior informed consent
PGRFA	Plant Genetic Resources for Food and Agriculture
SMTA	Standardized Material Transfer Agreement
TK	Traditional Knowledge
TT	Technology Transfer
UPOV	Union for the Protection of New Varieties of Plants

1 Introduction

After the adoption of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Utilization of Benefits Resulting from their Utilization (Nagoya Protocol, NP) in October 2010,¹ the development and implementation of ABS regulatory frameworks at national level will need to ensure that legislative, administrative or policy measures taken are consistent and mutually supportive with other existing ABS instruments. Such need is particularly prominent in relation to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), which establishes and implements a multilateral international ABS regime for plant genetic resources for food and agriculture (PGRFA). In response to this need the ABS Capacity Development Initiative commissioned CISDL and FNI to undertake a study to identify some of the main issues connecting the concept of ABS under the Nagoya Protocol and ITPGRFA. This paper describes the interface between the treaties in international law and implications that countries should take into account to implement the treaties in a synergistic way. The paper also highlights issues for consideration at the national level to implement these treaties in a mutually supportive manner through legal, administrative or policy measures.

It should be indicated that the main global tool for regulating rights and access to GR is the Convention on Biological Diversity (CBD). In addition to the CBD itself, the Nagoya Protocol will become a binding set of norms setting detailed rules on how ABS can be implemented in national legislation. Since the Nagoya Protocol is still not in force, and because many Parties to the CBD will not ratify for years to come, the CBD will continue to be the most widely applied rules for ABS. The fact that the CBD and the Nagoya Protocol are two different legal instruments and that the Protocol is a freestanding legal obligation is expressed in the EU draft regulation.² Article 4 of the Nagoya Protocol on the relationship between Nagoya Protocol and other instruments only applies in that context and not to the general rules provided by the CBD. Thus the relationship between the CBD and other instruments of international will not be solved directly by the new rules introduced in Article 4 of the Nagoya Protocol.

1.1 Structure and features of existing ABS measures and the treatment provided to PGRFA and the MLS under the ITPGRFA

Since 1993, many countries and several regions have established provisions on access and benefit-sharing (ABS) for biological and genetic resources through laws or administrative measures. A wide range of

¹ Convention on Biological Diversity, Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, 29 October 2010, Conference of the Parties to the Convention on Biological Diversity (2010: Nagoya, Japan) (CBD, Montreal QC, Canada, 2010), available at: www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf. [Nagoya Protocol]

² Draft EU ABS regulation, Preamble section (6) and (9).

mechanisms have been chosen to regulate access to biological and genetic resources and benefit sharing at the national level mainly in the provider countries. On the user country side there has been relatively little legislative, administrative and policy activity, leading to an imbalance between access and benefit-sharing rules.³ The Parties recognized the significance of experience with ABS systems in the terms of reference they set for the negotiation of the Nagoya Protocol, which drew on an analysis of existing legal and other instruments at national, regional and international levels relating to ABS, including access contracts, experiences with their implementation, and compliance and enforcement mechanisms.⁴

In light of the adoption of the Nagoya Protocol and the entry into force of the ITPGRFA in 2004, it is important to analyze how countries that have or are in the process of putting in place national ABS measures are implementing their ABS systems while taking into consideration both the provisions of the CBD (and now the Nagoya Protocol) and the ITPGRFA related provisions.

One feature of most of the current ABS regimes or measures is that they attempt to treat the different species, providers, users, uses and sectors by identical regulations. Some of the current national laws do not seem to recognize the particularities of genetic resources for food and agriculture. This is expected, given that the Convention on Biological Diversity does not distinguish among different categories of genetic resources whose conservation and sustainable utilization vary (according to whether they are wild, domesticated, microbial, etc.).⁵ The exchange and appropriation practices of genetic resources differ, however, in terms of their distribution and availability, the level of difficulty in reproducing them, and the existence or non-existence of market mechanisms for their exchange (among other factors).⁶

With few exceptions there has not been legislation which differentiates between the treatment of genetic resources for food and agriculture and those of other genetic resources. Differentiated treatment has been

³ Tvedt and Young. *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD*. Gland, IUCN, 2007. (IUCN Environmental Policy and Law Paper, No. 67/2)

⁴ CBD COP Decision VII/19 at Part D, Annex, para. (a)(i).

⁵ See Cabrera Medaglia, Jorge and López Silva, Christian, *Addressing the problems of Access: protecting sources while giving users certainty*; IUCN, Environmental Law and Policy Paper No. 67/1, Gland 2007.

⁶ *Ibid.* and Andersen, et al. *International Agreements and Processes Affecting an International Regime on Access and Benefit Sharing under the Convention on Biological Diversity – Implications for its Scope and Possibilities of a Sectoral Approach*. Lysaker, Fridtjof Nansens Institute, 2010. (FNI Report, No. 3/2010). For studies of particular sectors see Hiemstra, et al. *Exchange, Use and Conservation of Animal Genetic Resources*. Wageningen, Centre for Genetic Resources (Netherlands), 2006. (CGN Report, No. 2006/06); Rosendal, et al. 'Access to and Legal Protection of Aquaculture Genetic Resources: Norwegian Perspectives' in *Journal of World Intellectual Property* 9 (2006) 4; Olesen, et al. 'Access to and Protection of Aquaculture Genetic Resources: Structures and Strategies in Norwegian Aquaculture' in *Aquaculture* 272 (2007) 1 and Tvedt. *Seeking Appropriate Legislation Regulating Access and Exclusive Rights to Forest Genetic Resources in the Nordic Region*. Lysaker, Fridtjof Nansens Institute, 2011. (FNI Report, No. 9/2011).

developed (and is expected to be developed in the in future legislation), however, in connection with the implementation of the Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA) of FAO in each member country.

For instance some countries have already developed appropriate provisions on the ABS legislation enacted to comply with the CBD legally binding provisions and at the same time taken into account the ITPGRFA content and its approach to ABS to PGRFA covered by the MLS.⁷

The Norway Nature Diversity Act⁸ contains a number of provisions pertinent to ABS. Chapter II contains the general substantive provisions of the act, including sustainable use, management objectives for maintaining the diversity of habitat types and ecosystems,⁹ management objectives for species,¹⁰ general duty of care,¹¹ principles for official decision making,¹² the knowledge base for decision making,¹³ the precautionary principle,¹⁴ the ecosystem approach,¹⁵ the users pay principle,¹⁶ environmentally sound techniques and methods of operation,¹⁷ and other important public interests and Sami interest.¹⁸

Section 59 regulates genetic material in public collections, including the obligation of any person that receives genetic material derived from a public collection shall refrain, in Norway or abroad, from claiming intellectual property or other rights to the material that would limit use of the material such as use for food and agriculture, unless the material has been modified in a way that results in a substantial change. If IPR over genetic material are established contrary to the third paragraph, the competent authorities under the Act shall consider taking measures including bringing legal action, to ensure the promotion of the objective set out in section 57. Any person may invoke conditions under that paragraph against any person that, contrary to such conditions, seeks to enforce IPR. Regulations may be made regarding removals from collections, including setting such conditions as are mentioned in section 58. **Standard conditions laid down under the agreement apply to the removal of genetic material covered by the ITPGRFA.**

⁷ See on ABS legislation and Food Security the study prepared by Gurdial Singh et al *Framework Study on food security and access and benefit sharing for genetic resources for food and agriculture*, Background paper No. 42 of the CGRFA, FAO, Rome, 2009

⁸ Norway, Act relating to the management of biological, geological and landscape diversity, 2009 [Nature Diversity Act].

⁹ *Ibid.* at article 4

¹⁰ *Ibid.* at article 5

¹¹ *Ibid.* at article 6

¹² *Ibid.* at article 7

¹³ *Ibid.* at article 8

¹⁴ *Ibid.* at article 9

¹⁵ *Ibid.* at article 10

¹⁶ *Ibid.* at article 11

¹⁷ *Ibid.* at article 12

¹⁸ *Ibid.* at article 14

The Act contains and spells out a highly innovative approach to genetic materials from other countries, making Norway the first country, among developed and developing countries, to enact this kind of user measure. The import for utilization in Norway of genetic material from a state that requires consent for collection or export of such material may only take place in accordance with such consent. The person that has control of the material is bound by the conditions that have been set for consent. The state may enforce the conditions by bringing legal action on behalf of the person that set them.¹⁹

When genetic material from another country is utilized in Norway for research or commercial purposes, it shall be accompanied by information regarding the country from which the genetic material has been received (provider country). If national law in the provider country requires consent for the collection of biological material, it shall be accompanied by information to the effect that such consent has been obtained. If the provider country is a country other than the country of origin of the genetic material, the country of origin shall also be stated. The country of origin means the country in which the material was collected from in situ sources. If national law in the country of origin requires consent for the collection of genetic material, information as to whether such consent has been obtained shall be provided. Information under this paragraph is not known, this shall be stated. Regulations may also be issued prescribing that if utilization involves the use of TK of local communities or indigenous peoples, the genetic material shall be accompanied by information to that effect. Despite being a serious attempt to make user country legislation compatible with that of providing countries, there are still some weaknesses and challenges for enforcement of an ABS contract under the Norwegian Act.²⁰

When genetic material covered by the ITPGRFA is utilized in Norway for research or commercial purposes, it shall be accompanied by information to the effect that the material has been acquired in accordance with the Standard Material Transfer Agreement established under the Treaty.

The Norwegian Patents Act²¹ has since February 1st 2004 regulated a patent applicant's obligation both with regard to disclosure of origin of biological material and also prior consent if required in the country of origin. The disclosure obligation was expanded July 1st 2009 to also include traditional knowledge. **The Norwegian Plant Variety Act** has a similar provision.²² The Patents Act has a number of provisions relevant to ABS. If an invention concerns or uses biological material or traditional knowledge, the patent application must disclose the country from which

¹⁹ *Ibid.* at Article 60.

²⁰ Tvedt and Fauchald. 'Implementing the Nagoya Protocol on ABS: A Hypothetical Case Study on Enforcing Benefit Sharing in Norway' in *Journal of World Intellectual Property* 14 (2011) 5.

²¹ *The Norwegian Patents Act*, online: www.patentstyret.no/en/english/Legal_texts/The-Norwegian-Patents-Act/#chapter%203.

²² Section 4(3)

the material or knowledge was collected or received (the providing country).²³ It defines ‘biological material’ as material that contains genetic information, and can reproduce itself or be reproduced in a biological system.²⁴ However, the duty to disclose does not apply to biological material derived from the human body. The provisions on human genetic material do not apply to international applications.²⁵

If the providing country’s national law on access to biological material or use of traditional knowledge requires prior consent, the application shall state whether such consent has been obtained. If the providing country is not the same as the country of origin of the biological material or the traditional knowledge, the application shall also state the country of origin. For biological material, the country of origin is the country from which the material was collected from its natural environment and, for traditional knowledge, the country in which the knowledge was developed. If the information is not known, the applicant must state that. For biological material, the duty to disclose information applies even where the inventor has altered the structure of the received material. **If access to biological material has been provided in pursuance of Article 12.2 and Article 12.3 of the ITPGRFA, a copy of the standard material transfer agreement (SMTA) stipulated in Article 12.4 shall be enclosed with the patent application instead of the aforementioned information.** Breach of the duty to disclose is subject to penalty in accordance with s. 166 of the General Civil Penal Code. Yet, the duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.²⁶ Despite some of the clearest requirements for disclosure in patent act and in the plant variety protection act, it is far from certain that these requirements will lead to any effective benefit sharing.²⁷ The consequence in the penalty act is *finer* to the Norwegian government, and there is no explicit reference for the judge to rule that the one in breach of the disclosure requirement to share a certain amount of the earnings from the patent application without sufficiently disclosed information.

Norway provides a clear case of a country integrating into the ABS legislation (the Nature Diversity Act) relevant considerations arising out of the ITPGRFA not only at the moment of regulate access but also while developing ‘user measures’ to support the national legislation or requirements of other countries. Still profound analysis shows that these first generation user measures have potential to be improved as a more extensive body of practical experiences can be drawn.

²³ The Norwegian Patents Act at s. 8(b).

²⁴ The Norwegian Patents Act at Article 1(3).

²⁵ *Ibid.* at Article 33(2).

²⁶ Section 166 of the Civil Penal Code lays out fines or imprisonment for up to two years for providing false testimony in court, before a notary public, in any statement presented to a court as a party to or legal representative in a case, orally or in writing to any public authority as a witness in a case, or where the testimony is intended to serve as proof. The same penalty applies for any person who assists in or is accessory to false testimony.

²⁷ Tvedt. ‘Elements for Legislation in User Countries to Meet the Fair and Equitable Benefit-Sharing Commitment’ in *Journal of World Intellectual Property* 9 (2006) 2.

Bhutan is another example for a different region. The Biodiversity Act of Bhutan was enacted by the National Assembly the 4th of August 2003. The Biodiversity Act regulates three main issues: access to genetic resources and benefit sharing; the protection of TK and the plant breeders (and farmers) rights. The preamble recognizes, among others, the value of biological and genetic resources in the development of products, compounds and substances that have medicinal, industrial and agricultural and related applications and the need to protect and encourage cultural diversity by giving due value to the knowledge, innovations and practices of local communities in Bhutan, including the fundamental principles that prior informed consent (PIC) and mutually agreed terms (MAT) for benefit sharing must be secured before access can take place.

The scope of the Law is also very broad, covering all the genetic and biochemical resources including wild, domesticated and cultivated species of flora and fauna, both in-situ and ex-situ conditions found within the territory of Kingdom of Bhutan. Also the Act shall apply to the TK, innovation and practices associated with biodiversity.²⁸ **The Act shall not apply**, among others, where the biological material is used as a commodity for the purpose of direct use or consumption as determined by the Competent Authority (the Biodiversity Centre a body of the Ministry of Agriculture), based on the processes and end use of genetic resources, in accordance with the provisions of the Act; to the access, use and exchange of biological and genetic resources among local communities resulting from their traditional and customary practices; and **where the Competent Authority may determine plant and animal genetic resources access, which will be governed by Special Rules and Regulations or Conditions such as those established by multilateral systems for ABS, especially in the case of plant genetic resources for food and agriculture, in accordance with the international law .**

Bhutan is currently in the process of implementing a new Policy on Access and Benefit Sharing, which will imply a more detailed and legal certain system for access and benefit sharing. This Policy includes clear rules on access to PGRFA.

Another example is the ABS regulations of Peru of 2008 issued through Ministerial Resolution 087-2008-MINAM (later on converted into National Decree No. 003-2009-MINAM). The regulations follow closely the main provisions of the Decision 391 (e.g. the definitions are the same contained in article 1 of the Decision). The scope covers all the genetic resources of which Peru is the country of origin, their derivative products, their intangible components and the migratory species found for natural reasons in the Peruvian territory²⁹

²⁸ Traditional Knowledge includes any knowledge that generally fulfills one or more of the following conditions: 1) Is or has been transmitted from generation to generation; 2) Is regarded as pertaining to a particular traditional group, clan and community of people in Bhutan; 3) Is collectively originated and held.

²⁹ Article 4.

Are **excluded** from the regulations among others the human genetic resources and its derivative products; the traditional and customary use of genetic resources for indigenous peoples and local communities; **the species included in Annex I of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA); the use of genetic resources for cultivation purposes within Peru;** and the activities which imply the economic use of non-timber natural resources to produce natural products (nutraceuticals and functional foods).³⁰

Some doubts also arose regarding the legal space provided by some ABS measures to implement the Multilateral System under the International Treaty. Peru, for instance, only excludes Annex I crops and forages from the scope of their domestic ABS measures, but not non-Annex I crops (native from Peru). Ecuador has similar provisions included in its ABS regulations.³¹

Finally some countries appear to implement the Treaty directly (under their international law systems) without the development of specific measures or requirements or the amendment of existent measures.³² However, this is not always clear when a country has ABS legislation (national or regional). One of the reasons mentioned for the lack of ratification of the ITPGRFA in Colombia has been the apparent contradiction between the ITPGRFA ABS provisions and another international obligation: the Decision 391 which is part of the communitarian law of the Andean Community. However, the authors were not able to identify any specific written legal opinion stating these concerns and providing some legal explanation for the interpretation of alleged legal conflict between the instruments. It however, illustrates the existence of opinions which consider that there is a potential contradiction between the regional ABS legislation and the ITPGRFA, thus requiring an amendment of the regional Decision in order to allow the ratification of the ITPGRFA.³³ For that reason, Colombia's draft

³⁰ Article 5.

³¹ See also the 'transitorio Quinto' of the Peruvian regulations; the provisions of the ABS regulations have created some uncertainty regarding the compatibility between the national legal framework and the IT and its related decisions; see Lapeña, Isabel et al, *Incentivos y desincentivos para la participación del Perú en el Sistema Multilateral del Tratado Internacional sobre Recursos Fitogenéticos para la Alimentación y la Agricultura*; (Bioversity, Rome, 2010). Ecuador, National Regulations for the implementation of CAN Decision 391 on ABS (2011), article 2.3.

³² According to the information available no country has developed specific regulations for the implementation of the IT. A draft measures is reported from Peru and few countries like Madagascar are seeking to create ABS measures which would implement both the IT and the CBD ABS provisions, see Halewood, Michael et al, *National level of implementation of the multilateral system of access and benefit sharing: notes on progress and points of intersection with the Convention on Biological Diversity*; discussion paper presented to the workshop on the Interface between the International Treaty and the Nagoya Protocol on ABS; GiZ Capacity Development Initiative, Rome, January, 2013. See also examples of national implementation of the IT SML in López Noriega, Isabel et al, *Assessment of progress to make the multilateral system functional: incentives and challenges at the country level*, in Crop Genetic Resources s Global Commons. Challenges in international law and governance, Halewood, Michael, et al (eds), Earthscan and Bioversity International, 2013.

³³ Nieto, Jimena, personal communication, 2012.

regulations on ABS³⁴ does not include – like Ecuador or Peru- any exception – or special treatment- from the scope of the ABS provisions to the PGRFA and of course not mention is made at all to the ITPGRFA and its SML.

Nonetheless, in some cases the synergistic implementation of CBD provisions on ABS and those of the International Treaty have presented some difficulties regarding the interpretation of the ITPGRFA versus the ABS legal framework. The case study of CATIE in Costa Rica is a good example of some of the difficulties and different understanding (or the lack of) regarding the implementation of the ITPGRFA in a country with ABS legislation and strong capacities to enforce it.

Table 1: The case of CATIE and ABS legislation in Costa Rica

The case of the potential agreement between National Competent Authorities (NCA) on ABS of Costa Rica and the Centro Agronómico Tropical de Investigación y Enseñanza (CATIE) a center with PGRFA included in the MLS under article 15. 5 of the ITPGRFA.

CATIE is an important research and educational institution in Costa Rica and the region. It holds some important collections and materials mostly in ex situ conditions. At the same time Costa Rica has extensive ABS legislation including the Biodiversity Law of 1998, the Decree No. 31514-2003 on access to in situ genetic and biochemical resources and decree No. 33697-2007 regulating access to ex situ genetic resources specifically.

Because CATIE makes regular transfers to PGRFA to different entities in and outside of Costa Rica and of the importance of its collections,³⁵ it decided to sign an agreement with the Governing Body of the ITPGRFA under article 15.5, therefore including materials into the MLS. CATIE also included materials not listed in Annex I of the ITPGRFA such as coffee and macadamia among others. In 2008-2009 CATIE and the NCA of Costa Rica (the Technical Office of the CONAGEBIO) began the process to sign a cooperation agreement (known in the ABS legislation of Costa Rica as a framework agreement and regulated now in the decree No. 33697-2007, Annex II).

The process raises some concerns and doubts from both parties related to the content and authority of the NCA. In the beginning the draft proposal coming from the NCA included a provision requiring that all the SMTA must be revised and further authorized in advance by the NCA in all the cases, in addition to the signature by the CATIE authorities. It also regulated only GR included in Annex I and not the Non Annex I PGRFA included by CATIE in the MLS (which transfer is made using the same SMTA following a resolution adopted at the Second Meeting of the GB)

³⁴

www.minambiente.gov.co/documentos/DocumentosBiodiversidad/proyectos_norma/proyectos/2012/250412_proy_dec_recursos_geneticos.pdf

³⁵ See on CATIE's collections Ebert, Andres, *Flujos de germoplasma facilitado por el Centro Agronómico Tropical de Investigación y Enseñanza dentro y fuera de Latinoamérica*, en Revista Ambiente y Recursos Naturales, No 53, CATIE y Bioersivity, Turrialba, abril del 2008.

and was silent regarding issues such as in situ conditions (in accordance to the provisions of article 12.3. H of the ITPGRFA)

After the initial opposition of the CATIE and several meetings and information exchange between the two parties, further drafts were circulated which deleted or modify some of the most controversial content (the obligation to present the SMTA to the Technical Office of the CONAGEBIO for approval, among others). The cooperation agreement has since been put on hold in order to clearly determine the existing legal framework in Costa Rica for the operation of the ITPGRFA and in particular the SML which is now subject to an independent legal analysis.

However, some of the main legal and policy concerns raised during the discussion and negotiation of the agreement illustrate the practical difficulties facing a country with ABS legislation and enough institutional experience while implementing the provisions of the ITPGRFA, such as:

- To what extent the implementation of the ITPGRFA requires a modification or amendment of the ABS legislation (biodiversity law and regulations) or the ITPGRFA provisions can be applied directly and automatically as international law in accordance to the provisions of the Constitution?
- The specific case of Non-Annex I crops included by CATIE in the agreement with the GB and its exclusion from the application of the Biodiversity Law and access regulations
- What role does the NCA play in the process of authorizing access under the ITPGRFA? Does the NCA has to approve in advance the SMTA before is signed or there is a posteriori intervention? Does the NCA have any legal powers in the process/what kind of intervention is envisaged from the NCA?
- How the NCA can monitor that the SMTA are in compliance with the ITPGRFA provisions (e.g. that the crops are going to be used only for food and agriculture; that crops not included in the MLS are not transferred, etc.); how and by which means and instruments the NCA can monitor the correct use of the SMTA considering that the GR in Costa Rica are all of them of public domain (they all are public property belonging to the State)?
- Finally, what are the implications of the ITPGRFA on the collection of in situ genetic resources (article 12.3.h) for the functioning of the ABS legal system? (the BL has no exception for the in situ collection of PGRFA covered by the ITPGRFA and there are no other norms which governs this particular situation or access to PRGFA included in the MLS but collected in situ. There are some regulations on the collection of biological materials but they expressly exclude from their scope the hypothesis when the intention of the user is to have access to genetic resources).

Source: Jorge Cabrera Medaglia's elaboration

Having looked on these national experiences of implementing ABS based on the CBD and the ITPGRFA, it is interesting to add the new ABS rules in the Nagoya Protocol to the analysis, to identify the relevant articles in the Protocol which touches the ITPGRFA.

2 The CBD and the Nagoya Protocol and the ITPGRFA: where the two International instruments meet: a legal perspective.

The following sections present the main provisions of relevance for a national implementation of both the Nagoya Protocol and the ITPGRFA. It attempts to identify the interface between both treaties and where their obligations meet with the purpose to promote a mutually supportive implementation at the national level. Then this paper does not pretend to analyze the implementation of the entire provisions of the instruments related to ABS just those that may require a mutual consideration in order to achieve a synergistic implementation at the national level of both treaties.

During the course of the negotiations of the Nagoya Protocol, the relationships between the Regimen and the ITPGRFA (as the only legally binding instrument on ABS besides the CBD) was subject to different analysis both at the academic level³⁶ and as part of the preparation for the negotiations.³⁷

In particular, the following issues contained in the Nagoya Protocol have been selected because they present a close relationship with the ITPGRFA provisions and are critical – from a legal point of view – for the national implementation of both instruments.³⁸

- Preamble
- Article 4 (relationship with other instruments and consequently the determination of the ‘scope’ of the Nagoya Protocol and to what extent its provisions are applicable or not to the PRGFA covered by the SML).
- Provisions on the protection of traditional knowledge or TK (and its relation to the concept and legal elements of FR under the ITPGRFA article 9).
- Special considerations of article 8 (c).
- Article 17 on monitoring utilization of GR and the internationally recognize certificate of compliance and the potential role of the SMTA under the ITPGRFA to prove the legality of access to PGRFA covered by the MLS at the appropriate check points designed (e.g. if a

³⁶ See Jane Bulmer, *Study on the relationship between an international regimen on ABS and other international instruments and for a which govern the use of genetic resources. The International Treaty on Plant Genetic Resources for Food and Agriculture and the Food and Agriculture Organization’s Commission on Genetic Resources for Food and Agriculture*; UNEP/CBD/WG-ABS/7/INF/3/Part 1, 2009

³⁷ Fridtjof Nansen Institute, *International Agreements and Processes affecting the International Regimen on ABS under the Convention on Biological Diversity. Implications for its scope and possibilities of a sectoral approach*, FNI Report 3/2010, 2010

³⁸ At the same time the IT may provide information and lessons useful for the potential implementation of other articles of the NP such as article 10 (Global Multilateral Benefit Sharing Mechanism), article 19 (Model Contractual Clauses) and 30 (procedures and mechanisms to promote compliance with the NP) among others.

plant variety protection office is designed as check point at the national level).³⁹

- Article 19 set a system for developing two types of ‘Model Contractual Clauses’: The first one is that Each Party shall encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms. This option is very relevant for the link to the regulation of GRFA in general. The second option is that the Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of sectoral and cross-sectoral model contractual clauses. Here also the COP is given a role in the development and overview over model clauses that might become a core of the relationship to the GRFA.

The clear understanding of these articles may clarify how to implement other provisions of the Nagoya Protocol in a proper manner while taking into consideration the ITPGRFA provisions: e.g. how to design legal measures or requirements for PIC and MAT (articles 5 and 6) and have also legal implications for the appropriate implementation of other provisions on the Nagoya Protocol (e.g. the precise content of the measures taken by Parties under arts. 15 and 16), among others.

In addition, at the national level there are other opportunities to promote a synergistic implementation of both treaties arising out of the Nagoya Protocol content and future activities, such as those related to capacity building and development (article 22) and awareness raising (article 23) among others. These are not explore here but can be part of a package of actions promoting synergies between the two treaties at the national level.

Finally, any analysis should take into account the objectives of both instruments, specially in the light of the content of article 4 of the NP.⁴⁰

2.1 Preamble

The Preamble of the Nagoya Protocol forms an integral part of the treaty because it has the same legal status as the remainder of the text in providing context for the interpretation of a treaty’s terms.⁴¹ The legal purpose is to provide assistance in interpreting terms and resolving conflicting interpretations of provisions or context for further negotiations. Giving due consideration to language in the Preamble can thus assist Parties in developing coherent and complementary legislation and

³⁹ As it is already required in some Plant Variety Protection Acts or regulations such as Ecuador and India.

⁴⁰ The objective of the Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological resources and the sustainable use of its components (article 1). The objective of the IT are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security (article 1).

⁴¹ Vienna Convention on the Law of Treaties, 1969, entry into force in 1980, Article 31(2).

policies implementing ABS on PGRFA and under the Nagoya Protocol.⁴² The text excerpts below provide Parties with part of the rationale behind a number of provisions in the Protocol, notably Articles 4 and 8.

Table 2: Relevant Statements from the Preamble to the Nagoya Protocol

<p><i>Recognizing</i> the importance of genetic resources to food security, public health, biodiversity conservation, and the mitigation of and adaption to climate change</p> <p><i>Recognizing</i> the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions</p> <p><i>Recognizing</i> the interdependence of all countries with regard to genetic resources for food and agriculture as well as their special nature and importance for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change and acknowledging the fundamental role of the International Treaty on Plant Genetic Resources for Food and Agriculture and the FAO Commission on Genetic Resources for Food and Agriculture in this regard,</p> <p><i>Acknowledging</i> ongoing work in other international forums relating to access and benefit-sharing,</p> <p><i>Recalling</i> the Multilateral System of Access and Benefit-sharing established under the International Treaty on Plant Genetic Resources for Food and Agriculture developed in harmony with the Convention,</p> <p><i>Recognizing</i> that international instruments related to access and benefit-sharing should be mutually supportive with a view to achieving the objectives of the Convention,</p>

2.2 The Legal Relationship between the Nagoya Protocol and other Treaties

Article 4 is central to understanding the relationship between the Nagoya Protocol and other treaties and instruments. It reads as follows:

Article 4. Relationship with International Agreements and Instruments

1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.
2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

⁴² Greiber et al *An Explanatory Guide to the Nagoya Protocol on Access to Genetic Resources and Traditional Knowledge*; IUCN, Environmental Law and Policy Paper No. 83, Bonn, 2012

3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

4. This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.

2.2.1 *Background*

Article 4 is the most relevant provision of the Nagoya Protocol to understand the relationships between the Nagoya Protocol and the ITPGRFA from the perspective of international law but with implications for the national implementation. The relationship between the Nagoya Protocol and the ITPGRFA were considered specifically during the negotiations, mostly under the discussion on scope⁴³ and finally in the negotiations on Article 4. The relationship between the international ABS regime and other specialised ABS systems like the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFAPGRFA) was first raised by Parties at ABS WG6 in Geneva under the main component of scope (which genetic resources are included/excluded from the Protocol). The need to discuss relationship issues under the rubric ‘scope’ continued until ABS WG9, when the ABS WG co-chairs tabled a non-paper on a legally binding ABS Protocol that was accepted by all Parties as basis for the final negotiation.⁴⁴

The notion that the ‘one size does not fit all’ was raised during the negotiations and was also considered by one Technical and Legal Expert Group. The possibility for the development and implementation of new specialized ABS agreements (sectoral approach) was supported by some countries. These countries suggested the option that the Nagoya Protocol could include a general provision recognizing existing or future specialized ABS sectoral approaches. These agreements would become *lex specialis* and therefore lift out certain groups of genetic resources from the Nagoya Protocol for the genetic resources or types of uses covered. The patent system recognises to a far more limited extent that ‘one size does not (necessarily) fit all’ and makes less specific rules regarding how that legal systems shall take sectorial differences into account. The TRIPS Article 27.3.b being the notable global example and the EU Patent

⁴³ See also for the history of the negotiations, Greiber, Thomas, et al; *An Explanatory Guide to the Nagoya Protocol on Access to Genetic Resources and Traditional Knowledge*; IUCN, Environmental Law and Policy Paper No. 83, Bonn, 2012

⁴⁴ See Morguera Elisa, et al, *Draft Commentary on the Nagoya Protocol*, version 2011 on file with the author

Directive a regional example of special treatment of an area of innovation.⁴⁵

The Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches⁴⁶ of the CBD established by COP IX reached some conclusions regarding the relevance of sectoral approaches to implement the Nagoya Protocol:

Table 3: Sectoral approaches and the IR: some conclusions of the Technical and Legal Expert Group

- The CBD does not differentiate between different categories of genetic resources or different sectors. However, in practice, several basic distinctions exist that could be used for the development of national or international regulations such as the nature of the application or the intended use (commercial versus non commercial, for food and agriculture, for pharmaceutical purposes, etc.); the physical nature of the resources or their location (marine, terrestrial, higher plants; microorganisms; found ex situ or in situ, etc.). At the international level the ITPGRFA provides an example of a specialized legal regime on ABS. These issues are related to the scope of the International Regimen as well as for the different components (especially ABS).
- The international regime could provide for minimal access and benefit-sharing requirements that apply across sectors if no specific system is in place. These default access and benefit-sharing provisions or minimum access and benefit-sharing requirements would cover all access and benefit-sharing activities in the absence of more specific systems for particular sectors.
- An enabling clause could allow for sectors to develop their own system with the agreement of contracting parties in order to respond to their particular needs.
- The international regime could be a framework agreement that sets a minimum international understanding and agreement of what is needed across the board that provides flexibility for sectors to develop their own access and benefit-sharing approaches, especially multilateral ones.

Since the Nagoya Protocol, in principle, applies to all types of genetic resources and all potential uses of genetic resources, and relevant ABS provisions of different types are addressed in a range of international instruments and processes outside the CBD,⁴⁷ it was considered

⁴⁵ *Agreement on Trade-Related Aspects of Intellectual Property (Annex 1C of the Agreement establishing the World Trade Organization)* [TRIPS Agreement], WTO, 15 April 1994 and *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions* [Directive 98/44/EC], 6 July 1998, [1998] OJ, L 213/13, entered into force 30 July 1998.

⁴⁶ UNEP/CBD/WG-ABS/7/2, 12 December 2008

⁴⁷ See Buck M and Hamilton, C., *The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising out of Their Utilization Under the Convention on Biological Diversity*, in *Review of European and International Environmental Law*, 20 (1), London, 2011.

necessary⁴⁸ to address the relationship of the Nagoya Protocol with other instruments related to its objective, content and mechanisms. This includes the International Treaty on Plant Genetic Resources for Food and Agriculture (the only existing ABS specialized instrument) and the processes under the FAO Commission on Genetic Resources for Food and Agriculture are also relevant for the Nagoya Protocol. During the negotiations it was suggested to exclude groups of GR from the scope of the Protocol. These ideas however did not reach it into the final text.

Furthermore, in the process of negotiation it was argued that an ‘international regimen’ on ABS already existed. This ‘**ABS Governance**’ is currently comprised of a variety of legal instruments, both binding and non-binding, of a national, regional, and multilateral nature. Given the complexity and wide range of aspects addressed by the IR (and now included in the Nagoya Protocol), it was considered unavoidable to establish appropriate synergies with some of them.⁴⁹

2.2.2 *Content of article 4. General implications of the first paragraph*

Article 4 was subject to lengthy negotiations reflecting fundamental differences in approach between those who considered that the Nagoya Protocol should be overarching instrument on ABS and those who considered that the Protocol is part of a broader international regimen on ABS, with it being the default instrument.⁵⁰ This article deals with the relationships with the Nagoya Protocol and other international instruments in general, including specialized instruments on ABS. It goes further and also includes work and practices of relevant international organizations. Some of the language of this article comes directly from CBD Article 22.⁵¹

Some recent multilateral environmental agreements contain a clause, sometimes referred to as a ‘saving clause’ in the preamble or in the operative text, stating the relationship between the instrument and other related instruments, in some cases specially those of commercial nature, such as the WTO. Article 4 is reflective of this approach of international

⁴⁸ The need to consider the provisions and development of this other instruments and processes in order to build a coherent instrument was a concern during the negotiations. For that reason COP 9 (Decision IX/12, paragraph 13 c) requested the Executive Secretary to commission a study on how an international regimen on access and benefit sharing could be in harmony and be mutually supportive of the mandates and coexist alongside other international instruments and for a which govern the use of genetic resources, such as the FAO International Treaty on Plant Genetic Resources for Food and Agriculture. In order to respond to this request, several instruments and for a were analyzed: the FAO IT and the Commission on Genetic Resources for Food and Agriculture; the World Trade Organization, The WIPO and UPOV, including their relevant agreements and treaties; the Antarctic System and the United Nations Convention on the Law of the Sea.

⁴⁹ Cabrera Medaglia, Jorge, *The International Regimen on ABS: elements; progress and perspectives*, IUCN Oficina Sur, Quito, 2006

⁵⁰ Buck and Hamilton, *op cit*

⁵¹ See also Decision X/1 which recognizes that the international regime is constituted of the CBD, the NP as well as complementary instruments such as the IT. It also recognizes that the objectives of the IT in harmony with the CBD, for sustainable agriculture and food security and noted with appreciation Resolution 18/2009 of the FAO Conference on policies and arrangements for ABS for food and agriculture.

environmental law. When such a clause appears in the operative text of a treaty it can indicate which treaty- the existing treaty or the new treaty, the Parties intended to prevail in the case of a conflict Vienna Convention article 30 (2) which provided that ‘when a treaty specifies that is subject to, or that it is not to be considered as incompatible with, an earlier or later treaty, the provisions of the other treaty prevail’ Under the Vienna Convention on the Law of the Treaties later treaties between the same parties dealing with the same subject matter supersede the provisions or earlier treaties, unless wording to the contrary in the later treaty.

The first part of this paragraph essentially repeats what is already included in Article 22 of the Convention. However, Article 22 also includes a second paragraph indicating the Contracting Parties shall implement the Convention with respect to the marine environment consistently with the rights and obligations of States under the law of the sea.

Nevertheless, second part of the paragraph address an aspect not covered in CBD Article 22, but found in other environmental multilateral agreements: the clarification that the paragraph is not intended to create a hierarchy between the Protocol and other instruments. Several aspects of this provision deserve specific comment: a) prior drafts of the Nagoya Protocol had taken a different approach: instead of stating that the intention of the paragraph was not to create a hierarchy (e.g. in favour of the Protocol or of the other agreement), it made clear the purpose was not to ‘subordinate’ the Protocol to other international instruments; b) despite the language used, it has been argued that in fact the Protocol created a hierarchy in favour of the biological diversity⁵²; c) this article addresses the relationship with **other existing international agreements**, the situation of the creation and implementation of new agreements is regulated in the following paragraph and the situation of specialized instruments on ABS is regulated in paragraph 4. 4.⁵³

2.2.3 *Second paragraph and the negotiation of future agreements (including ABS ones)*

The article in its second paragraph reaffirms the right of the Parties to develop and implement other relevant international agreements in general, and in particular, other specialized ABS agreements. The final outcome of some of them could be a new international instrument or in particular a new international ABS Agreement, for instance any potential new agreement on other types of Genetic Resources for Food and Agriculture under the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA). Already in July 2011 the CGRFA mandated the exploration of access and benefit sharing for sectors of genetic

⁵² Buck and Hamilton, *op cit*

⁵³ See also the Preamble of the IT which indicates that: Recognizing that this Treaty and other international agreements relevant to this Treaty should be mutually supportive with a view to sustainable agriculture and food security; Affirming that nothing in this Treaty shall be interpreted as implying in any way a change in the rights and obligations of the Contracting Parties under other international agreements; Understanding that the above recital is not intended to create a hierarchy between this Treaty and other international agreements.

resources for food and agriculture. The discussions in the CGRFA is divided in developing special regimes for farm animal genetic resources (AnGR), forest tree genetic resources (FGR), aquatic genetic resources (AqGR), microorganisms genetic resources (MicGR), invertebrates and ABS for plants outside the scope of the Multilateral System under the ITPGRFA. One option which is likely to be explored is to develop an umbrella for all these groups of GRFA in the Commission and develop model clause material transfer agreement (mc-MTA) for each area of genetic resources. This work also links to the possibilities to recognize MTAs under Nagoya Protocol Article 19 which opens for the COP also to work on specialized MTAs. Specialized ABS systems are candidates to be dealt with in the World Health Organization, for the Areas Beyond National Jurisdiction in the oceans and for Antarctica.

In the case of existing ABS specialized Systems (the ITPGRFA) this situation is regulated in paragraph 4. However, at the same time, there was a concern that new international agreements and their implementation, especially new ABS sectoral agreements, may run counter the objectives of the CBD and in particular of the Protocol (fair and equitable benefit sharing) creating a loophole in the Protocol and making difficult to satisfy the demand for fair and equitable benefit sharing. Thus the Protocol contains a safeguard; Parties may negotiate and implement any new international agreement to the extent these agreements are 'supportive and do not run counter the CBD and the Protocol objectives'. This qualification applies to both the general international instruments and the specialized ABS agreements.⁵⁴

2.2.4 *Mutual supportiveness*

Finally, any new international instrument developed or implemented shall respect and follow the following paragraph and shall be implemented in a mutually supportive manner as indicated in paragraph 3.

The term 'mutually supportive' has taken a particular meaning within the trade and environment context. The term is drawn from the work of the WTO Committee on Trade and Environment which has been reviewing the relationship between the WTO and Multilateral Environmental Agreements. It is also found in the most recent environmental multilateral agreements.

It has been argued that 'mutual supportiveness' has evolved into a principle of international law.⁵⁵ It requires, at the interpretative level, that States disqualify solutions to tensions between competing regimes involving the subordination of one regime to the other; and second, at the law-making level, that States exert good-faith efforts to negotiate and conclude instruments that clarify the relationship between competing regimes, particularly when interpretative reconciliation efforts have been exhausted.⁵⁶

⁵⁴ Greiber, Thomas et al *op cit*.

⁵⁵ Morguera Elsa et al *op cit*.

⁵⁶ Pavoni, quoted in Morguera Elsa, *op cit*.

Article 4(3) thus seems to relate to the first dimension of mutual supportiveness by requesting Protocol parties to disqualify interpretative solutions to tensions between the Protocol and other relevant international regimes involving the subordination of one regime to the other, when implementing the Protocol. This is further clarified by the Preamble, where parties recognize that international instruments related to ABS should be mutually supportive with a view to achieving the objectives of the Convention.⁵⁷

Finally, these three paragraphs should be read together. The first paragraph regulates the relationship between the former treaties and the Protocol and emphasizes that no hierarchy is created but any rights and obligations shall not damage or threaten biological diversity. Paragraph 2 makes clear the rights of Parties to develop and implement new instruments of different nature (commercial, environmental ones, specialized ABS agreements etc.) provided that they are supportive of the CBD and the Protocol. Paragraph 3 includes the obligation of the Parties to implement the relevant international instruments and the Protocol in a mutually supportive manner

Which are those relevant international instruments is not mentioned in the Protocol.

Paragraph 3 also addresses a very controversial and unusual relationship in international law: the reference to **relevant and useful ‘work’ and ‘practices’ under such agreements or relevant international organizations**. Several aspects can be commented. First, the wording just requires parties to pay ‘due regard’ (see also article 8 on special considerations. In international law ‘ongoing work or practices’ has no status. For instance the Statute of the International Court of Justice (art. 38) does not consider these as a source of international law. To link the implementation of the Nagoya Protocol to such non-binding unwritten, unrecognised and sometimes even unpublished elements would ultimately increase the legal uncertainty of the ABS system.⁵⁸ Such a provision would essentially link implementation of the Protocol to one or more moving targets, in the form of the ever evolving ‘ongoing work and practices’ of various international bodies and instruments. The reference to ‘practices’ has no corresponding equivalent in general public international law. ‘General practice recognised as law’ is one of the sources of international law according to Article 38 of the Statute of the ICJ, thereby recognising customary international law as a general source of law. Customary international law develops through the cumulative and accepted practices of states in accordance with what is deemed or perceived to be a legal obligation (*opinio juris*). This is more specific and much narrower than the broad and unspecified term ‘practices’. The unqualified, non-specific reference to practices would mean subordinating the Protocol to an undefined body of practice. It would also introduce a considerable degree of legal uncertainty and unpredictability into the Protocol.

⁵⁷ See Morguera, Elsa, et al *op cit*.

⁵⁸ Tvedt and Rukundo. *Functionality of an ABS Protocol*. Lysaker, Fridtjof Nansens Institute, 2010. (FNI Report, No. 9/2010).

Not all kinds of work or practices deserve to receive due regard, only those that are ‘useful’ and ‘relevant’. Work may include negotiations, discussions, resolutions, etc. and practices any type of concrete measures taken to implement an instrument. In any case, the practical distinction between both seems less relevant. It has been suggested that the Work of the FAO Commission on Genetic Resources for Food and Agriculture could be considered under this paragraph.⁵⁹

In any case the ongoing work and practices shall be supportive and not run counter the CBD and the Protocol objectives.

2.3 Paragraph 4 and the ITPGRFA

Paragraph 4 clarifies that the Protocol is the instrument for implementing the CBD provisions on ABS. Whether it was recognized that other relevant instruments coexist along with the Protocol, the Protocol is considered the implementation mechanism of the CBD ABS provisions. During the negotiations it was suggested that the Protocol (or the IR) was just one more of the instruments dealing with ABS, including, for instance, the International Treaty. The paragraph makes clear the central position of the Protocol in the context of the ABS Governance.

The paragraph deals with a specific situation: the relationship with specialized ABS instruments. So far the only specialized instrument is the ITPGRFA, a closer look at the relevant rules on ABS in the ITPGRFA is subject for section B. There is not, however, any mention of the ITPGRFA (except in the preamble). Prior texts had included a specific reference to the ITPGRFA, specially seeking to exclude the instrument to the Protocol Scope. Finally, any express reference disappeared from the text.

There are however, several clarifications and conditions which will govern the relationship between both instruments.⁶⁰ First, the specialized instrument shall be ‘consistent’ with and do not run counter the objectives of the CBD and the Protocol. However, the language used in this provision is weaker than the other paragraphs (which use the word supportive). Thus it is required that the specialized instrument be just consistent not supportive of. This is potential recognition of the fact that a specialized instrument on ABS may include different approaches and implementing mechanisms, which can depart from the CBD and Nagoya Protocol bilateral approach.

Second, the other qualification relates to the membership: if a Party is not a Party of the specialized instrument, then the Nagoya Protocol provisions will apply to all the genetic resources transactions. This is also relevant because, so far ITPGRFA has 128 Parties and the CBD 194. Therefore a number of CBD parties are not members or Parties of the ITPGRFA.

⁵⁹ See also Hamilton and Buck indicating that the work of Decision of the GB of the IT to use the SMTA for Non- Annex I crops under article 15 is an example of such work or practices.

⁶⁰ See in general Greiber, Thomas et al, *op cit*.

The priority given to the specialized instrument over the Nagoya Protocol is limited and qualified: just to the genetic resources covered and for the purpose of the specialized instrument. However, the first part of the sentence is not complete clear about its implications. The Scope of the ITPGRFA is all the genetic resources for food and agriculture, but the scope of the Multilateral ABS System is much narrower: the genetic resources included in Annex I (under the management and control and in the public domain of contracting parties and those included voluntarily by legal and juridical persons) and – in practice- the non Annex I genetic resources included for CGIAR and other centres in accordance to article 15 are transferred under the same SMTA.

Regarding for the purpose, the paragraph makes clear, in this case, that the use of GR covered is only exclude from the Nagoya Protocol for the purposes of the instrument, for instance in the case of the ITPGRFA just for food and agriculture, not for pharmaceutical or other uses (such as industrial ones).

Therefore is critical to understand which resources are covered (which is dealt with below).

In summary 4.4 is not a blanket exclusion for the specialized instrument such as the ITPGRFA, but rather that the exclusion applies only where and to the extent that the genetic resources in question are used for the purpose of that specialized instrument (food and agriculture).⁶¹

It is clear that, in the context of the ITPGRFA, the exception applies only:

- a) for the resources covered by the specialized instrument;
- b) for the parties of both instruments (not for non parties of the ITPGRFA but parties of the Nagoya Protocol);
- c) for the purpose set in the instrument (food and agriculture).

Therefore if a country is not a party of the IT access to PGRFA will be governed by the CBD/NP bilateral approach (requiring essentially PIC and MAT) unless a country- based on its own national priorities and decision- provides an special treatment for PGRFA. The same applies for access to plant genetic resources for other uses such as industrial or pharmaceutical ones.

Therefore critical issues for the interface are:

- a) Determining the precise scope of the ABS component of the ITPGRFA (which resources are covered).
- b) Understanding the of ‘food and agriculture’ as well as of utilization, and conservation for research, breeding and training for food and agriculture.
- c) Determining the national authorities/entities responsible for granting access (under the CBD/Nagoya Protocol and for signing the SMTA

⁶¹ See Hamilton and Buck, *op cit.*

(under the IT) and improve cooperation and information exchange amount them to clarify and respect their respective legal competences; built trust and minimize any sense of competition between both types of entities.

- d) Developing appropriate provisions on the ABS measures developed under Nagoya to create legal space for the implementation of the ITPGRFA special approach to ABS to PGRFA. This may include not only appropriate provisions providing room of space for the MLS in the ABS measures (such a ‘carve out’ clause or a anticipate the enactment of specialized legislation to implement the multilateral system) but also options for monitoring from both authorities of the compliance with the terms of access: e.g. a future changes in use can be seen as a breach on the contract but also as a violation of the ABS measures of a country to the extent that the country provides a limited and qualified exception to the applicability of the ABS measure.
- e) Contracting parties of the NP may consider to ‘paid due regard’ to some of the practices of the countries in implementing the SML.⁶² However, the drafting of the article does not imply an automatic recognition in the national legal framework of such practices, unless the States wishes to do so.
- f) Finally, any interpretation of the IT an NP provisions should be done with the purpose of creating mutual supportiveness between the instruments.

2.4 Article 8 c) – Genetic resources for food and agriculture and food security⁶³

Paragraph 8 c refers to the importance of genetic resources for food and agriculture and their special role for food security. However, this provision does not constitute a strong obligation as it only requires parties to ‘consider the importance’ of those resources and does not demand any specific action.⁶⁴ Article 8 c) reflects the fact that most domestic ABS frameworks that currently exist do not sufficiently address the special characteristics of genetic resources for food and agriculture. While recognizing the special nature of PGRFA several countries and regions do not agree with a broad exclusion of the Protocol of this type of GR. They were concerned that explicit recognition of genetic resources for food and agriculture would not result in an exclusion of GRFA from the scope of the ABS Protocol (this was linked to discussions on the ITPGRFA in Article 4).⁶⁵

⁶² See Hallewood et al *op cit*, indicating that for instance countries may consider- in the light of article 4.3- the situation of recipients of PGRFA under the SMTA in sates that are not parties of the IT but are parties of the NP and the passing on of that materials as anticipated by the SMTA without obtaining additional authorization from a competent authority.

⁶³ See Decision II/15 and Decision V/ 5 on the special features and characteristics of PGRFA

⁶⁴ See Greiber et al, *op cit*.

⁶⁵ See Morguera, Elisa, et al, *op cit*.

Reading this article jointly with article 4, gives a party the option to insert a clause in its ABS legislation or regulatory requirements waiving Annex I PGRFA used for the purpose stated in the ITPGRFA. Parties may also consider other genetic resources for food and agriculture that are important for food security while developing and implementing their ABS legislation in accordance to the Nagoya Protocol. The provision must be read and applied in the context of other related references in Article 4, in the Preamble and in the CBD COP 10 decision adopting the Nagoya Protocol.⁶⁶

2.5 Traditional knowledge and farmer's rights

The establishment of farmers' rights, as recognized in Article 9 of the ITPGRFA,⁶⁷ is an acknowledgment of the immense contributions made by local and indigenous communities to the conservation and development of plant genetic resources globally.⁶⁸ While Farmers' Rights to the protection of traditional knowledge and equitable participation in benefit-sharing and decision-making frameworks are established in the ITPGRFA, the treaty is neutral on 'farmers' privilege', or the right of farmers to save, use, exchange and/or sell farm-harvested seeds.⁶⁹ Notwithstanding, the ITPGRFA does not limit domestic rights of farmers, rather, responsibility for protecting both explicit and implicit rights is vested with national governments.⁷⁰

The protection of Traditional Knowledge (TK) stems primarily from Article 8(j) of the CBD, which obliges the Parties to the treaty, subject to the development of national legislation, to:

respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.⁷¹

Linkages between biodiversity and human livelihoods have existed for millennia, providing the basis of human development far before the rise of modern society.⁷² Throughout the ages, as the sophistication and

⁶⁶ Morguera, Elisa et al, *op cit*.

⁶⁷ Food and Agriculture Organization, International Treaty on Plant Genetic Resources for Food and Agriculture, 3 November 2001 (FAO: Rome, Italy 2009) available at: <ftp://ftp.fao.org/docrep/fao/011/i0510e/i0510e.pdf>. [ITPGRFA]

⁶⁸ *Ibid*, Art. 9.1; Gerald Moore and Witold Tymowski, *Explanatory Guide to the International Treaty on Plant Genetic Resources for Food and Agriculture* (International Union for the Conservation of Nature and Natural Resources (IUCN): Glad, Switzerland, 2005) at 14-15. [Moore & Tymowski]

⁶⁹ *Ibid*, Art. 9.2.

⁷⁰ *Ibid*, Moore & Tymowski at 15.

⁷¹ Convention on Biological Diversity, 5 June 1992, 31 I.L.M. 818 (entered into force 29 December 1993), at Art.8(j). [CBD].

⁷² Lyle Glowka, Françoise Burhenne-Guilmin, Hugh Synge, et al, *A Guide to the Convention on Biological Diversity* (IUCN: Gland, Switzerland and Cambridge, UK, 1994) at 48, available at: <http://data.iucn.org/dbtw-wpd/edocs/EPLP-no.030.pdf>. [CBD Explanatory Guide].

frequency of human engagement with biodiversity grew, a broad body of knowledge and practices in relation to the use of biological resources expanded simultaneously. While the CBD makes various references to interlinkages between indigenous communities and biodiversity, including preambular language noting the dependence of indigenous groups on traditional use of biodiversity,⁷³ the role of women in biodiversity conservation,⁷⁴ and in Article 10(c) on encouraging protection for customary use of biological resources,⁷⁵ it is Article 8(j) that provides the legal basis for the expanding protection of TK.⁷⁶

During COP-4, set in Bratislava, Slovakia, May of 1998, the Parties set in place an Ad Hoc Open-Ended Inter-sessional Working Group on Article 8(j) and Related Provisions.⁷⁷ The Article 8(j) Working Group has implemented *customary* rules of procedure which afford indigenous peoples equal status to Parties, established a Voluntary Trust Fund to Facilitate the Participation of Indigenous and Local Communities in the Work of the CBD,⁷⁸ and developed a multi-year programme of work on the implementation of Article 8(j).⁷⁹ While the protection of TK was enshrined in the CBD via Article 8(j), the CBD itself lacked a formal definition of TK, differing clarification of terminology to the World Intellectual Property Organization (WIPO) in conjunction with the Ad Hoc Working Group on Article 8(j).⁸⁰ Accordingly, following years of consultation with various partners through the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, WIPO has developed a comprehensive position on TK, defining it as:

‘(...) know-how, skills, innovations, practices, teachings and learning, resulting from intellectual activity and developed within a traditional context. [Further] Traditional knowledge is knowledge that is dynamic and evolving, resulting from intellectual activities which is passed on from generation to generation and includes but is not limited to know-how, skills, innovations, practices, processes and learning and teaching, that subsist in codified, oral or other forms of knowledge systems. Traditional knowledge also includes knowledge that is associated with biodiversity, traditional lifestyles and natural resources.’⁸¹

⁷³ *Ibid*, CBD preamble paragraph 12.

⁷⁴ *Ibid*, CBD preamble paragraph 13.

⁷⁵ *Ibid*, CBD Art. 10(c).

⁷⁶ Kathryn Garforth and Christine Frison, Key Issues for the relationship between the Convention on Biological Diversity & the International Treaty on Plant Genetic Resources for Food and Agriculture, (Quaker International Affairs Programme: Ottawa Canada, 2007) at 11 [Garforth and Frison]; *Ibid*, CBD Explanatory Guide at 48.

⁷⁷ *Ibid*, Garforth and Frison.

⁷⁸ COP 8 Decision VIII/5, available at: www.cbd.int/decision/cop/?id=11017.

⁷⁹ COP 10 Decision X/43, available at: www.cbd.int/decision/cop/?id=12309.

⁸⁰ COP 6 Decision VI/10, paragraphs 31-34, available at:

www.cbd.int/decision/cop/?id=7184; WIPO, Traditional Knowledge – Operational terms and Definitions, WIPO/GRTKF/IC/3/12.

⁸¹ WIPO, The Protection of Traditional Knowledge: Draft Articles,

WIPO/GRTKF/IC/21/4 (2012), at 6, available at:

www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_21/wipo_grtkf_ic_21_4.pdf

Farmers Rights (FR) finds specific protection in Article 9 of the International Treaty on Plant Genetic Resources for Food and Agriculture.⁸² Focused on establishing a bundle of rights directly relating to farmers, the approach taken in the ITPGRFA harmonizes Farmers Rights with Article 8(j).⁸³ The rationale for the preservation of FR comes from recognition by the Parties of the substantial contribution made by local and indigenous communities to the conservation and development of plant genetic resources, the efforts of which have a significant impact on food and agriculture production and security globally.⁸⁴ While Article 9.1 creates no formal legal obligation, it is an acknowledgement of the mounting respect for the role played by indigenous communities in the development and preservation of socially valuable farming knowledge and practices.⁸⁵

Formal articulation of FR comes via Article 9.2 of ITPGRFA, which states:

(...) the responsibility for realizing Farmers' Rights, as they relate to plant genetic resources for food and agriculture, rests with national governments. In accordance with their needs and priorities, each Contracting Party **should**, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including:

- (a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
- (b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and
- (c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture. (...)

Irrespective of the fact that FR will differ greatly from nation to nation by virtue of the nature and scope of their domestic legislation, the rights enshrined in the ITPGRFA provide the core of FR and are by no means intended to be exhaustive.⁸⁶ The protection of TK provided in Article 9.2(a), given the scope of IT focusing on plant genetic resources for food and agricultural production, has a much more narrow scope juxtaposed to Article 8(j) of the CBD which is aimed to address a broader range of biological resources. However, the ITPGRFA protection of TK is not limited to TK as embodied in traditional lifestyles as outlined in Article 8(j) of the CBD, allowing for a broader safeguarding of TK as it relates to agriculture and food production.⁸⁷

⁸² Food and Agriculture Organization, International Treaty on Plant Genetic Resources for Food and Agriculture, 3 November 2001 (FAO: Rome, Italy 2009) available at: <ftp://ftp.fao.org/docrep/fao/011/i0510e/i0510e.pdf>. [ITPGRFA]

⁸³ Gerald Moore and Witold Tymowski, *Explanatory Guide to the International Treaty on Plant Genetic Resources for Food and Agriculture* (IUCN: Gland, Switzerland and Cambridge, UK, 2005) at 68, available at: <http://data.iucn.org/dbtw-wpd/edocs/EPLP-057.pdf>. [ITPGRFA Explanatory Guide]

⁸⁴ *Ibid.*, ITPGRFA Art. 9.1.

⁸⁵ *Ibid.*, ITPGRFA Explanatory Guide, at 68.

⁸⁶ *Ibid.*, ITPGRFA Explanatory Guide, at 72.

⁸⁷ *Ibid.*

In developing domestic legislation to protect FR, States have acknowledged a broad definition, suggesting that these rights are encompassed in Article 8(j) of the CBD. Portugal, in Decree-Law No.118 of April 20, 2002, established a legal regime for the protection of local varieties and associated traditional knowledge.⁸⁸ TK is provided a broad definition by the Portuguese Decree, encompassing both tangible and intangible elements associated with the commercial application of local varieties, including knowledge, methods, processes, products and designations as they relate to agriculture, food and industrial applications.⁸⁹ Similarly, the Andean Community of Nations in Decision 391 has developed a Common Regime on Access to Genetic Resources, which provides protection to traditional practices, know-how and innovations in concert with the protection of biological diversity.⁹⁰

In contrast to both the CBD and ITPGRFA, the NP provides an increased level of protection for Farmers' Rights and associated TK through Article 5 on Fair and Equitable Benefit Sharing, Article 7 on Access to TK associated with GR, and Article 12 on TK associated with GR specifically. Cumulatively, the NP establishes a basic framework to protect TK in a manner that supports certain farmers' rights.

Fair and equitable sharing of benefits arising from the utilization of TK is derived from Article 5(5) of the Nagoya Protocol. Implementing Article 8(j) of the CBD, Article 5(5) covers the utilization of TK associated with GR and recognizes that the use of such knowledge should lead to the equitable sharing of benefits based on MAT. By recognizing TK associated with GR as warranting MAT for access and use, indigenous farmers who have specialized functional expertise relating to PGRFA are afforded a unique position where the right to access is vested with the indigenous community alone.

The protection afforded to TK in Article 5(5), read together with Article 7, make up the bedrock provisions of the Nagoya Protocol in relation to GR.⁹¹ Pursuant to Article 7, Parties are obliged to establish measures to ensure TK associated with GR held by ILC are only accessed with PIC or the approval and involvement of the community, and with MAT.⁹² By making PIC or approval and involvement the key requirement, aside from acknowledging that the TK in question is vested with the indigenous community, the NP brings to light the need for access to GR related TK to provided based on a genuine understanding on the part of the providing

⁸⁸ Portugal, Decree-Law No.118/2002 of 20 April 2002, available at: www.cbd.int/doc/measures/abs/msr-abs-pt-en.pdf. [Decree-Law 118/2002]; World Intellectual Property Organization, Composite Study on the Protection of Traditional Knowledge WIPO/GRTKF/IC/5/8 (2003) available at: www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_5/wipo_grtkf_ic_5_8.pdf. [WIPO – Composite Study]

⁸⁹ *Ibid*, Decree-Law 118/2002 at Art.3.

⁹⁰ Andean Community of Nations, Decision 391 – Common Regime on Access to Genetic Resources, at Art.7, available at: www.comunidadandina.org/ingles/normativa/d391e.htm.

⁹¹ *Nagoya Explanatory Guide*, *supra* at 88.

⁹² Nagoya Protocol, *supra* at Art.7.

community of the rational and goals underlying access.⁹³ While the NP obliges Parties to take measures in relation to the protection of TK, it does provide for flexibility in domestic implementation in terms of if the indigenous community must have either PIC or approval and involvement. This distinction allows Parties to determine if they will design a mechanism based on PIC as a term of art, requiring a particular standard, or via simply approval and involvement in the process. Notwithstanding the distinction between PIC and approval and involvement, indigenous farmers as holders of TK relevant to the discovery, extraction, use, or application of GR are granted the right to engage in the process under MAT ensuring that their TK is preserved and only accessed based on their approval.

In contrast to the general requirements of Article 5 and Art 7, Art 12 of the NP holds a uniquely procedural role.⁹⁴ First, the customary norms, and community protocols and procedures of indigenous communities are to be taken into consideration by Parties in the execution of their obligations under the protocol, pursuant to Art.12(1). Parties are to consult both non-codified and codified indigenous practices, when creating their domestic measures to protect TK giving indigenous communities exceptional influence over the method and design of the mechanism of choice. Second, pursuant to Art.12(2), consultation and participation of indigenous communities is explicitly required in designing mechanisms to inform potential users of TK about their obligations under the protocol. Again, this places increased influence in the hands of indigenous communities, as the impacted or concerned party, in determining the measures which are to be taken. Third, Parties are to support indigenous communities in developing community protocols relating to TK and fair and equitable benefit sharing, establishing minimum requirements for MAT, and forging model contractual clauses for benefit sharing agreements relating to the use of TK associated with GR.⁹⁵ Lastly, and arguably most important, the customary use and exchange of genetic resources and associated TK amongst indigenous communities is to be minimally impacted by the NP, via Art.12(4). This requirement protects the traditional use and exchanges leveraged by indigenous communities for generations to preserve inter-community transfer of genetic material for preservation and food security.

Taken in concert, Art.5, Art.7 and Art.12 clearly take into account FR as envisioned by the ITPGRFA. Indigenous communities are granted: (i) fair and equitable benefits arising from the use of GR or associated TK, (ii) the right of PIC, or approval and involvement, under MAT in the usage of GR or TK, (iii) are afforded participatory rights in the creation of the mechanisms applied domestically and, (iv) the customary guidelines, use, and exchange of GR and TK developed over the generations by indigenous farmers are preserved and not restricted. On the whole, the NP provides clear, cogent and comprehensive protection for Farmers' rights.

⁹³ *Nagoya Explanatory Guide, supra* at 110.

⁹⁴ *Ibid, Nagoya Explanatory Guide*, at 138.

⁹⁵ *Ibid, Nagoya Protocol*, Art.12(3)(a-c)

2.6 Article 17 on Monitoring and Utilization of GR

Another relevant article of the Nagoya Protocol for the implementation of the ITPGRFA at the national level relates to the provisions of the Nagoya Protocol on monitoring and utilization of GR (the establishment or designation of check points and the internationally recognized certificate of compliance).

The Protocol regulates in article 17 a highly contentious and relevant issue for the negotiations of the Nagoya Protocol: the monitoring of the utilization of GR through designated check points and the role of the CC.

CBD COP Decision VIII/4C established an Expert Group (EG) on an internationally recognized certificate of origin/source/legal provenance. The EG identified a number of points common for all proposals of a certificate, including that it could be required for presentation at specific checkpoints in the user countries, inter alia patent and in general IP applications. Most certificate proposals envisage a system of checkpoints at which disclosure of the certificate of origin would be required for the purposes of processing IP applications, among other things. Compliance with disclosure requirements would be facilitated where an internationally recognized certificate could act as evidence of conformity with national and international law.

The certificate can contribute to the monitoring and traceability of genetic resources. It could be required in patent and plant variety rights applications to provide evidence of compliance with national legislation on ABS, including prior informed consent and mutually agreed terms, thus fulfilling a role in supporting the disclosure of origin requirement. However, learning from observations at the 23th meeting in the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC-23) in Geneva February 2013, the progress is slow in the negotiations of a system for requiring disclosure of country of origin of GR and TK.

Both the designation of check points and the issuance of a certificate raise some questions regarding the role of the SMTA as a proof of the legality of access to specific genetic resources in a country member of the ITPGRFA. The certificate and in general the monitoring of GR raise the issue of the role of the SMTA in the cases of access to PGRFA under the ITPGRFA/SML. In this cases instead of a formal permit and the correspondent certificate once is notify to the CHM, it has been suggested that the SMTA may be considered as proof of the legality of access by the designed check points.

According to Chiarolla – quoting the CGIAR centres – the SMTA can function as a certificate of source (now known as certificate of compliance, with the source of origin of the PRGFA being the MLS itself).⁹⁶

⁹⁶ Chiarolla, Claudio, The question of minimum standards of access and benefit sharing under the CBD International Regime: lessons from the International Treaty on Plant Genetic Resources from Food and Agriculture, in *Asian Biotechnology and Development Review*, Vol 10, No. 3 July 2008, India and CGIAR Submission by the International Agriculture Research Centres of the CGIAR to the Group on Technical Experts on an internationally recognized certificate of origin/source/legal provenance. *Compilation of submis-*

Garforth and Frison also suggested that any design of the certificates (when it was under discussion as a possibility at the negotiations of the Nagoya Protocol) should consider the special treatment of PGRFA under the ITPGRFA.⁹⁷

This connection becomes clearer from the reading of the Norway Nature Diversity Act (provided before in this paper) and also from the Norway proposal on disclosure provisions made WTO. The proposal of Norway of June 14 2006 indicates that the disclosure of origin under the WTO must be consistent with the ITPGRFA SML.⁹⁸

In conclusion, another linkage between the Nagoya Protocol and the ITPGRFA could be the establishment of check points and the role of the SMTA in providing legal evidence of the compliance with the ABS legislation. In this latter situation, there are however to significant difficulties for national implementation. First, the ABS permit issued at the point of access (article 6) will become the internationally recognized certificate once is notified to the CHM. Nevertheless, the SMTA does not require in accordance to the current practice any formal permit for an NCA. Secondly, the SMTA content does not necessarily reflects the minimum requirements of the certificates as established in article 17.4.

sions provided by the parties, governments, indigenous and local communities, international organizations and relevant stakeholders, UNEP/CBD/GTE-ABS/1/3/add2.

⁹⁷ Garforth and Frison *supra*

⁹⁸ Communication from Norway, *The Relationship Between the TRIPS Agreement, the Convention on Biological Diversity and the Protection of Traditional Knowledge*, IP/C/W/473 (June 14, 2006).

3 Identifying legal issues in the ITPGRFA of relevance for ABS in CBD/NP and core questions in IPRs law

3.1 Introduction to the ITPGRFA in the light of the CBD

ABS discussions are often confined to consideration of two alternative approaches: the CBD or the ITPGRFA. This section looks at elements of the ITPGRFA where there are regulatory grey zones and partial overlap with the CBD/NP. The objective is to contribute in identifying issues that need to be solved in national implementation of these two legal systems in domestic legislation and policies. Yet the two instruments have partly overlapping overall objectives and are set to serve different purposes however regulating the same objects. Therefore, despite any legal frictions between them, discussions concerning how to make ABS work would benefit from a clearer conception of the connections between the two ABS systems and the link to the IPRs – patents and plant breeders' rights. Links between ABS and IPRs are often explored at the level of international law, whereas the interesting conflicts and convergences first become evident at the implementation stage and in domestic legislation. Approaching the ITPGRFA and ABS from a purely legal perspective can easily become something of a hollow exercise unless IPR perspectives are taken into account.

The plant sector is currently the only one where access is granted under two ABS schemes in combination with two other systems for securing IPRs (patents and plant breeders' rights). In this legal landscape, it is of particular interest to examine the legal points at the intersection of the ABS regimes, on the one hand, and the systems for IPRs, on the other. In this perspective it is interesting to note that the two latest edited books on the ITPGRFA and how to make the system function (*Plant Genetic Resources and Food Security*, and *Crop Genetic Resources as a Global Commons*), have not a single section dedicated to the relationship with the patent system or plant breeders' rights system. That IPR is not made a topic of a single chapter, not even in the part called 'Critical Reflections', is an especially glaring oversight since the topic is to explore the 'Global Commons', as one the titles says.

The methodology adopted for the analysis is that of public international law. It involves a text-based reading of treaties, interpreting them in conjunction with and in light of less binding sources of law such as minutes from meetings, other documents and legal theory. This section has no opinion on policy or related political questions. It performs a technical legal analysis and seeks to contribute to a better understanding of the interaction of these systems.

The ITPGRFA differs substantially from the CBD, as the treaty as a whole applies to one specific group of organisms, i.e. plant genetic resources for food and agriculture (PGRFA). While negotiations on the NP have slowed implementation of CBD somewhat, the system for ABS regarding some PGRFA under the Treaty has entered into the implementation phase. The Multilateral System for ABS has become the legal

instrument for the already ongoing exchange of accession of PGR in the international collections, while adding a number of national collections to the MLS.⁹⁹ One empirical question is of core interest, but will not be explored here, is whether the MLS has led to more exchange of, and better access to, PGRFA.

The Multilateral System for ABS under the treaty applies only to PGRFA under specific circumstances, i.e. when certain accessions of PGRFA are in the public domain, are accessed for specific uses, and under the condition that no IPRs hinder the further exchange and access of the material received from the MLS. These limitations in the scope of the MLS need to be better understood if we are to clarify the legal relationship between the two instruments. There is an increasing focus on the so-called ‘moving’¹⁰⁰ or ‘dynamic’¹⁰¹ scope of ITPGRFA, which underscores the importance of a clear picture of the scope of the special ABS system under the MLS to better understand implementation issues for the CBD and NP.

3.2 An interpretative look at ABS in the ITPGRFA – what is covered by ABS in the MLS?

The Multilateral System of Access and Benefit Sharing (MLS) under the Treaty was set up to address certain specific needs regarding the international collections of plant accessions for breeding, taking into account the ‘special features of plant genetic resources’.¹⁰² When the CBD was finalized, negotiating parties recognized that some important issues were left without satisfactory solutions in international law. In section 4 of Resolution 3 from the Nairobi conference, where the text of the CBD was agreed, reads:

4. Further recognizes the need to seek solutions to outstanding matters concerning plant genetic resources within the Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Sustainable Agriculture, in particular: (a) Access to ex-situ collections not acquired in accordance with this Convention; and (b) The question of farmers’ rights.

The quoted section 4 is the only place in Resolution 3 where the term ‘access’ is used; ‘benefit sharing’ does not appear in the resolution. The wording indicates that the particular access issue in need of resolution was access to ex-situ collections not acquired according to the rules of the

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www.planttreaty.org/inclusions?field_mls_noti_inclu_type_owner_value_many_to_one=Contracting+Party [accessed 18th January 2013].

¹⁰⁰ Visser. ‘The Moving Scope of Annex I: The List of Crops Covered under the Multilateral System’ in *Crop Genetic Resources as a Global Commons – Challenges in International Law and Governance*. Edited by Halewood, et al. New York, Routledge, 2013.

¹⁰¹ Louafi and Bhatti. ‘Efforts to Get the Multilateral System Up and Running’ in *Crop Genetic Resources as a Global Commons – Challenges in International Law and Governance*. Edited by Halewood, et al. New York, Routledge, 2013, p.187.

¹⁰² For more information of the negotiations that led to the Plant Treaty and the difficult political challenges encountered along the way, see Andersen. *Governing Agrobiodiversity: Plant Genetics and Developing Countries*. Aldershot, Ashgate, 2008, pp. 87–115.

CBD. This sets the background for the interpretation of the rules in the ITPGRFA concerning the MLS, as the scope of the Treaty is much broader than these collections.

The ‘international collections’ (i.e. the Consultative Group on International Agricultural Research and other relevant organizations) were recognized as having a particular role in strengthening conservation and sustainable use of PGRFA. Visser also refers to the ‘status of the IARC collections formed a major element of the discussions’.¹⁰³

There is no language in the Resolution which indicates that PGRFA were as such excluded from the scope of Article 15 of the CBD, only that accessions in ‘ex-situ collections’ needed a special solution compared to a strict application of the sovereign rights recognized in the CBD. As the preamble to the Standard Material Transfer Agreement (SMTA) confirms, the MLS provides a way in which countries can ‘exercise their sovereign rights over their Plant Genetic Resources for Food and Agriculture’.

The ITPGRFA, adopted in 2001 and in force since 2004, is generally aimed at promoting the conservation and sustainable use of plant genetic resources for food and agriculture (PGRFA)¹⁰⁴ and the fair and equitable *sharing* of the benefits arising from the utilization of these resources.¹⁰⁵ One main difference between the ideas informing the CBD and the MLS is that benefit sharing under the ITPGRFA is linked to a specifically defined trigger point for when benefit sharing shall take place. Consequently, benefit sharing is detached from the individual access situation and individual provider. Moreover, the most types of PGR utilization do not trigger the benefit sharing obligation, also unlike the CBD (more on the benefit sharing trigger later).

The MLS is highly relevant for ABS because it is the first sectorial approach to ABS, and could provide useful lessons for the implementation of ABS, including whether and if so, how, sectoral ABS can be dealt with to meet the objectives of the CBD (under NP Art. 4 and Art. 19). It has been characterized as a ‘dynamic ... global and innovative framework’ by the Secretary of the ITPGRFA.¹⁰⁶ This might indicate that one can expect dynamic arguments in the interpretation of relevant provisions in the Treaty, which can be expected to impact the relationship with the CBD and the NP.

¹⁰³ Visser, ‘The Moving Scope of Annex I: The List of Crops Covered under the Multilateral System’, 2013, p. 274-276.

¹⁰⁴ PGRFA are defined as ‘any genetic material of plant origin of actual or potential value for food and agriculture (Art. 2).

¹⁰⁵ ITPGRFA Art. 1.1

¹⁰⁶ Bhatti, et al. *Contracting for ABS: The Legal and Scientific Implications of Bioprospecting Contracts*. Gland, IUCN, 2009. (IUCN Environmental Policy and Law Paper, No. 67/4), p. 187.

3.2.1 *Certain crops – species and genera*

The MLS is a core component of the ITPGRFA as it is further set out in Articles 10 to 13.¹⁰⁷ Whereas the ITPGRFA as such covers all PGRFA, its ABS system in the MLS covers only certain crops. ITPGRFA Article 11.1 defines the scope of the MLS as ‘the plant genetic resources for food and agriculture listed in Annex I’, i.e. 35 food crops and 29 forage plants. Annex I crops include major staples crops, as well as a range of other plants widely used for food and agriculture. Annex I is a negotiated list of species that are pooled for particular purposes. At the level of politics, opinion is sharply divided on whether to expand this list or not.¹⁰⁸ The political differences on the coverage are annotated by Visser who notes that African countries at one point suggested nine food crops for inclusion, whereas European countries at the same time proposed as many as 287.¹⁰⁹ Disagreements over the list ‘revealed deep political divides’, writes Visser, on how to manage PGRFA.¹¹⁰ These are rather empirical observations, but they become relevant as an auxiliary argument in legal argumentation in indicating that countries are bound only to the Annex and the treaty wording to which they have formally agreed. Seen in the light of the general principle that countries have sovereign rights over their genetic resources, including plant genetic resources, this perhaps calls for a closer reading of the wording so as to establish the coverage they have left in the global common of the MLS. Clearly, crops which are not on the Annex list fall under the general scope of the CBD and NP when it comes to ABS.¹¹¹ A series of issues other than ABS are regulated in the other parts of the ITPGRFA which do not establish the MLS. E.g. farmers’ rights and conservation topics apply to all PGRFA, whereas the CBD and NP regulate ABS outside the MLS.

From a legal perspective, Article 11.1, in combination with the Annex, sets a limit on the mandatory material to be included under the MLS. This does not prevent collections applying the SMTA and the same terms and conditions to a wider number of species and subspecies to the extent that there is no ABS legislation impeding this action.¹¹² Countries and collections are free (have jurisdiction) to include more species under the same regulatory regime as those PGRs being mandatory under the MLS.

¹⁰⁷ Louafi and Bhatti, ‘Efforts to Get the Multilateral System Up and Running’, 2013, p. 194.

¹⁰⁸ Fraleigh and Harvey. ‘The North American Group: Globalization That Works’ in *Plant Genetic Resources and Food Security: Stakeholder Perspectives on the International Treaty on Plant Genetic Resources for Food and Agriculture*. Edited by Frison, et al. London, Earthscan, 2011, p. 116 refers to the opinion of the U.S.: the list is ‘far too short and should be expanded’. It is an interesting position for a country which is not even party to the Treaty. Europe has expressed a similar view, according to Visser and Borring. ‘The European Regional Group: Europe’s Role and Positions during the Negotiations and Early Implementation of the International Treaty’ in *Plant Genetic Resources and Food Security: Stakeholder Perspectives on the International Treaty on Plant Genetic Resources for Food and Agriculture*. Edited by Frison, et al. London, Earthscan, 2011, pp. 72–73. See also Visser, ‘The Moving Scope of Annex I: The List of Crops Covered under the Multilateral System’, 2013, p. 265-266.

¹⁰⁹ Visser, ‘The Moving Scope of Annex I: The List of Crops Covered under the Multilateral System’, 2013, p. 266.

¹¹⁰ *Ibid.*, p. 272.

¹¹¹ See also Visser, *ibid.*, pp. 268-269.

¹¹² Such wider application has been a topic for e.g. the Nordic Gene Bank.

Again Visser observes the absence of provisions or system to review and amend the Annex in the ITPGRFA.¹¹³ This, combined with the political differences, such as those between Africa and Europe, indicate that the scope of Annex I is not easily moved and would require consensus among Contracting Parties.¹¹⁴ Legally speaking, one can ask whether amendments to the Annex require a separate ratification process by the Contracting Parties to the ITPGRFA. The sharp political divisions among countries, combined with the principle of countries having the sovereign rights over PGRFA not included in the Annex, are strong arguments in favor of a separate ratification process if the Annex shall be amplified and thus increasing the scope of the MLS.

The list in the Annex refers to different taxonomic levels and biology is not a static science, this creates some uncertainty in determining the exact scope of coverage of the Annex. Whereas the list in the Annex gives some legal certainty for which crops are covered, the extent to which wild relatives of cultivated crops are covered introduces a certain level of uncertainty.

3.2.2 *In the Public Domain*

The next specification of the scope of the coverage of the MLS is that it covers ‘all plant genetic resources for food and agriculture listed in Annex I that are under the management and control of the Contracting Parties and in the public domain.’¹¹⁵ A purely literal interpretation of the wording, with its double use of the conjunction ‘and’, suggests these criteria must be present for PGR to be mandatorily included in the MLS. Thus, linguistically, the paragraph imposes three *cumulative* criteria: PGR being under the *control* of the state; *managed* by the state; and recognized as being considered *public domain*. Thus, only accessions which fall under all these three criteria are mandatorily included in the MLS by the Contracting Parties.

For Annex I crops accessions which do not meet these criteria, countries retain their sovereign rights and discretion to decide whether a certain PGR shall be included in the MLS. Thus, PGRFA not qualifying accordingly, are not mandatorily governed by the MLS.

The first criterion is that plant genetic resources ‘in the public domain’ are mandatorily included in the MLS for the Contracting Parties to the ITPGRFA. The term ‘public domain’ has not been defined in the wording of the ITPGRFA, which leaves it to an interpretation of the wording to determine whether a certain resource is mandatorily included in the MLS or not.¹¹⁶ The *Oxford English Dictionary* (online) defines ‘public domain’ as ‘the state of belonging or being available to the public as a whole, especially through not being subject to copyright or other legal restric-

¹¹³ Visser, ‘The Moving Scope of Annex I: The List of Crops Covered under the Multi-lateral System’, 2013, p. 279.

¹¹⁴ This view is shared by Visser, in *ibid.*, p. 279.

¹¹⁵ ITPGRFA Art. 11.2.

¹¹⁶ *Vienna Convention on the Law of Treaties* [VCLT], United Nations, 23 May 1969, 1155 UNTS 331, entered into force 27 January 1980 Art. 31.

tions.¹¹⁷ The first part of this definition is broad and not linked to IPRs. This is confirmed by the reference to *especially*, which indicates a broader concept than only IPR to be relevant for the understanding of *public domain*. Secondary sources of international law become relevant for its interpretation.¹¹⁸

Correa is one of the very few to have explored what is meant by ‘public domain’. However, he limits the scope of possible interpretations by stating that ‘there are two possible meanings for the concept of ‘public domain’.¹¹⁹ He identifies ‘public property’ first by lending from **administrative law**, then by what is **not covered by any Intellectual Property Rights**.¹²⁰ These are the only possible alternatives for interpreting ‘public domain’. ‘The concept of ‘public domain’ that is used in the ITPGRFA’, he concludes, ‘should be understood in the context of intellectual property rights.’¹²¹

These two ways of understanding ‘public domain’ cannot, Tvedt as the author of this section shall argue, be the only ones based on the relevant legal sources. First the two options set out by Correa are explored, before searching for other interpretative approaches.

‘Public domain,’ in the context of the ITPGRFA, *should*, according to Correa, be understood in the context of IPRs.¹²² Let us explore the legal argument behind this assertion. He takes as his point of departure that the sovereign rights of countries under the CBD include the competence to regulate public or private property rights to genetic resources.¹²³ This is a well-established principle, and applies equally to plant genetic resources. Government can thereby assign a variety of public, semi-public, private, or semi-private rights.

One such approach to regulating property rights to genetic resources, which Correa takes as another point of departure, is to use administrative law and declare that genetic resources belong to the public. This is the case in Norway, where, under the Nature Diversity Act, ‘Genetic material obtained from the natural environment is a common resource belonging to Norwegian society as a whole and managed by the state.’¹²⁴

Marienhoff, an Argentinean public law professor, explains the legal concept of ‘*Dominio Público*’ in Argentinean law as a legal regime entailing

¹¹⁷ <http://oxforddictionaries.com/definition/english/public%2Bdomain?q=public+domain> [accessed 18. February 2013].

¹¹⁸ *Statute of the International Court of Justice* [ICJ Statute], United Nations, 26 June 1945, Article 38.

¹¹⁹ Correa. ‘Plant Genetic Resources under the Management and Control of the Contracting Parties and in the Public Domain: How Rich Is the ITPGRFA’s Multilateral System?’ in *Crop Genetic Resources as a Global Commons – Challenges in International Law and Governance*. Edited by Halewood, et al. New York, Routledge, 2013, p. 182.

¹²⁰ *Ibid.*, p. 182-183.

¹²¹ *Ibid.*, p. 184.

¹²² *Ibid.*, p. 184.

¹²³ *Ibid.*, p. 182.

¹²⁴ *Naturmangfoldloven / Nature Diversity Act*, Norway, LOV-2009-06-19-100, Section 57, first para.

that certain goods are '*inalienable e imprescriptible*'.¹²⁵ This concept of public property rights implies that the public's right to access and use these goods is inalienable and cannot be delimited by or expropriated into a private exclusive right. *Dominio Público*, as a concept of administrative law, entail one manner in which the country can declare resources to be held commonly. This indicates that the concept is linked to the regulation by the state.

The Norwegian act illustrates that declaring resources to be either in the public domain or under other types of rights is a manner to exercise the sovereign rights over the resources. These are examples indicating that the '*public domain*' concept entails a degree of freedom for governments for regulating the status of a certain material.

When interpreting 'public domain' in the context of the other rules of the MLS, the prohibition on taking out IPRs on the material 'in the form received' resembles an idea of establishing a positive public domain or common pool by the MLS. This prohibition becomes in that sense an argument in favor of interpreting 'public domain' as referring to the PGR declared by the state to be a common resource, under any kind of administrative law regulation, as indeed is the case in Norway.

The sovereign rights of countries can be used to establish other kinds of property right-statute to genetic resources. Countries have the jurisdiction to regulate property in a number of ways. One of them is to assign a common property right to genetic resources to indigenous or local peoples. Another is to assign private property rights as a successive right to the sole holder of biological material. In both situations, interpreting 'public domain' as referring to the administrative law system of a common right would establish a distinction and leave PGR under other kinds of government-declared property schemes outside the scope of the MLS. Interpreting 'public domain' in light of the sovereign rights to genetic resources in general provides a strong argument for linking 'public domain' to the resources declared by the government to be owned or held by the public.

The second way of understanding 'public domain', according to Correa, is to take it as meaning all resources not subject to intellectual property right protection, either because the right has expired; the knowledge has been known and IPR protection cannot be obtained; or, in the case of objects outside IPR, because they are not eligible for protection.¹²⁶ The consequence of this reading is that the common pool becomes defined as those resources that are not being privatized under another legal system of law (IPRs). Its scope becomes, moreover, dependent on another legal system than that set out in the MLS. Understanding 'public domain' as being the outside the IPR systems does not harmonize very well with the prohibition in the MLS to apply for IPRs to material in the form received.

¹²⁵ Marienhoff, Miguel S.: *Tratado de Derecho Administrativo Tomo V: Dominio Público*, Buenos Aires: Abeledo-Perrot, p. 24.

¹²⁶ Correa, 'Plant Genetic Resources under the Management and Control of the Contracting Parties and in the Public Domain: How Rich Is the ITPGRFA's Multilateral System?', 2013, pp. 182-183.

If ‘public domain’ was understood in this manner, the MLS would appear as a negatively defined common whose borders were set by another property rights system.

Correa refers to Kaul et al. 2003 who maintain that ‘public domain’ can be understood as ‘a collection of things available for all people to access and consume freely’.¹²⁷ If ‘public domain’ is linked to what is outside IPR, Kaul et al. must be wrong insofar as a patent would reduce availability to all. In many countries the situation is such that genetic resources cannot be accessed and consumed for free, even if they fall outside IPR protection. So a reading of ‘public domain’ in this light would fail to recognize other private rights to genetic resources (apart from IPRs) and common rights to genetic resources, such as, for example, ILCs rights based on statutory or customary legal grounds, according to the country. The argument derived from Kaul et al. is therefore, in my view, rather an argument for the first rather than the latter alternative discussed by Correa.

The ‘administrative decision’ interpretation of ‘public domain’ will give governments discretion to define the scope of what is in the public domain of the country. ‘It is unlikely’, Correa adds, ‘that the negotiating parties would have left the determination of which material are, or are not, in the multilateral system basket to the total discretion of the parties.’¹²⁸ Again there are legal sources which can challenge the view expressed by Correa: From looking at the legal background to the pre-CBD negotiations of the ITPGRFA to resolve the outstanding issue of international collections, the factual situation indicates that countries originally intended to maintain their regulatory freedom to include more or less PGRs in the MLS. This is further supported by the principle of sovereign rights in international law; due to the politically tense negotiations leading to the Treaty, it seems unlikely that governments would have linked the scope of the MLS to the patent system and other IPR systems. This is further attested by the Treaty’s recognition of the MLS as a means of exercising the sovereign rights of a country over PGR.

Correa also points to the ambiguity in the concept ‘public domain’ as an argument in favor of the ‘outside IPR’ option.¹²⁹ But the argument that negotiating parties could have chosen a clearer term is not a decisive argument of law, as it could also be said that negotiating parties taking ‘public domain’ to mean ‘outside IPRs’ could easily have expressed more clearly in the wording. However, in general, unclear wording seldom indicates that states wish to diminish their discretion or sovereignty for the future. The ambiguity therefore is rather an argument for the administrative law approach than the IPR-reading of the term. Thus, this argument cannot ‘tip the balance’ as Correa suggests.¹³⁰

¹²⁷ *Ibid.*, p. 183.

¹²⁸ *Ibid.*, p. 184.

¹²⁹ *Ibid.*, p. 184.

¹³⁰ *Ibid.*, p. 184.

The main differences between linking ‘public domain’ to the outside of IPRs and leaving governments with the discretion under their sovereign rights to genetic resources, is that the power to decide the scope of the ‘public domain’ rests with the patent system under the first option, and with governments under the second. The consequence of choosing one of these two options will be further identified below where we seek to clarify practical implementation questions and grey zones between the CBD/NP and the ITPGRFA.

‘In the public domain’ could be understood in both a practical and a concrete manner, and be interpreted in the light of the ‘outstanding matters’ the negotiations in the FAO were going to resolve. The outstanding matter awaiting resolution was, as stated in Nairobi Resolution no. 3, paragraph 4, ‘Access to *ex-situ* collections not acquired in accordance with this Convention.’ These *ex-situ* collections could be understood as publicly available and thus in the *public domain* in a more practical and less legally specific manner. Thus, there is a third way of understanding ‘public domain’ as simply ‘made available through the system of *ex-situ* collections.’ This third possibility finds support in the objectives driving the negotiations for a MLS system to care for the needs of the existing *ex-situ* collections.

When Correa and Manzella¹³¹ would have it that ‘public domain’ *should* be understood as linked to what is not covered by IPRs at a specific point of time, it is more of a policy recommendation than the legally binding conclusion from normative sources. In fact, using the argumentative term *should* indicates that there is a lot of policy freedom in the choice of how to apply the term. As seen in this section, the normative sources give stronger support to the *administrative law* approach, than to the *outside IPR* approach. In section d) below we are going to test these two options for interpretation on a selection of practical and difficult cases or situations.

3.2.3 *Management and control of the Contracting Parties*

After the challenging question of the legal status of the material being in the ‘public domain,’ the next two criteria for mandatorily including plant genetic resources in the MLS is that they are under the ‘management and control of the Contracting Parties.’ As mentioned above, the use of ‘and’ as the conjunction indicates that these two criteria are cumulative (as is the case with ‘public domain’), have independent meanings, and call for two individual assessments of the factual situation.

‘Contracting Parties’ refers to the countries that are members of the ITPGRFA. In other words, no other entities than countries are obliged to make PGR available under the MLS because of the ITPGRFA. Private

¹³¹ Manzella. ‘The Design and Mechanisms of the Multilateral System of Access and Benefit Sharing’ in *Crop Genetic Resources as a Global Commons – Challenges in International Law and Governance*. Edited by Halewood, et al. New York, Routledge, 2013, p. 153.

collections are therefore not mandatorily included in the MLS, and very few such non-governmental collections are included.¹³²

The next criterion is that the PGR must be under the *control* of the Contracting Party. Thus PGR controlled by the government are mandatorily included in the MLS (provided that the two other criteria are met). The interpretative question is what is meant by ‘control.’ Practical control of the Contracting Parties could be understood as the possession or holding of the accessions where the plant genetic resources are found. Here, the distinction between the property right or legal statutes of the material is set in the ‘public domain’ criterion, and the ‘under control’ can be understood as actually and legally held as accession over which each Contracting Party has both legal and factual control. Control does not necessarily mean *having a property right* to a certain material. It is easy to agree with Correa when he writes that a ‘distinction must be established between rights over a physical entity as such (physical property) and over the genetic information contained in these resources (intangible property).’¹³³

This is reflected in the Norwegian Nature Diversity Act. Even though the public has the right to Norway’s genetic material, the competence of the government to grant access ‘does not limit the right of any owner or other entitled person to deny access on other grounds a) to the biological material, or b) to the land from which the genetic material is obtained.’¹³⁴ Thus, either the landowner or the holder of a certain genetic material now enjoys the competence to *control* physical access to the accession.

The linkage to the interpretation of ‘control of the Contracting Party’ is that this criterion implies that merely the accessions actually and legally controlled by the government are mandatorily included in the MLS.

Control, Correa suggests, ‘call[s] for the capacity to exercise physical acts over the resources.’¹³⁵ This would lead the ‘control’ criterion in the direction of meaning that holding the accession by the government is sufficient and required to meet this criterion. Indeed, for Correa, ‘holding the resources is sufficient.’¹³⁶ If, however, the holding of the physical material accrues to a government by means of an illegitimate act of collection, where the rights of the farmers have been violated or other holders have not consented to having their physical samples or accessions ‘controlled’ by a government, one could perhaps argue that the term ‘control’ has both a factual and legal side: the material must be factually

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www.planttreaty.org/inclusions?field_mls_noti_inclu_type_owner_value_many_to_one=Natural+or+legal+person [accessed 18th January 2013].

¹³³ Correa, ‘Plant Genetic Resources under the Management and Control of the Contracting Parties and in the Public Domain: How Rich Is the ITPGRFA’s Multilateral System?’, 2013, p. 181.

¹³⁴ *Naturmangfoldloven / Nature Diversity Act*, Norway, LOV-2009-06-19-100, Section 58, second para.

¹³⁵ Correa, ‘Plant Genetic Resources under the Management and Control of the Contracting Parties and in the Public Domain: How Rich Is the ITPGRFA’s Multilateral System?’, 2013, p. 182.

¹³⁶ *Ibid.*, p. 182.

be held and this holding must not be the result of an illegitimate or illegal act.

This leads us to the third (linguistically first) criterion, that the PGR must be ‘under the management’ of the Contracting Party to be mandatorily included in the MLS. A purely linguistic understanding of ‘management’ of a genetic resource indicates that some steps of handling, taking care of, conserving, or storing the resources must take place. If this wording is interpreted in light of the outstanding matters referred to in Nairobi Resolution no. 3, ‘management’ could be understood as being an accession in an ex-situ collection.¹³⁷ ‘Those resources’, Correa suggests, ‘that the contracting parties do not handle physically (or ‘manage’), directly or by a third party under their instruction, do not form part of the multi-lateral system.’¹³⁸

The next step is to look at some difficult cases and discuss them in light of these criteria with a view to gaining a clearer idea of where the implementation challenges lie.

3.2.4 *Practical examples and grey zones*

It is important, Selim and Bhatti suggest, that ‘countries – particularly developing countries – take the legal and administrative steps to identify the materials in their countries that are part of the multilateral system.’¹³⁹ This indicates the importance attached to testing and clarifying these general legal considerations and to clarifying any grey zones by the Secretary of the ITPGRFA. From the perspective of implementing the CBD/NP and the ITPGRFA, clarifying these limitations is of crucial interest because PGR outside the MLS are covered in principle by sovereign rights (if there are no other reasons to explain why the resource is outside the scope of the CBD).

One practical example is PGR held by farmers. Accessions of plant genetic material held by farmers could be in the public domain, if the ‘outside IPR’ interpretation is applied. If that interpretation becomes the standard one, farmers’ PGR will meet *this* criterion mandatory inclusion in the MLS. If the ‘administrative law’ approach is chosen, it would depend on the legal regime of the particular country whether they would be in the public domain or not. If they are kept on farm, neither the ‘managed’ criterion nor the ‘under control’ criterion would be met, meaning that farmers’ accessions would fall outside the scope of the MLS.

The situation becomes less clear when the government takes a role in the conservation or preservation of farmers’ PGR. Regardless of which of the

¹³⁷ VCLT, Article 31.1 which refers to the interpretation to happen ‘in the light of its object and purpose’ of the treaty.

¹³⁸ Correa, ‘Plant Genetic Resources under the Management and Control of the Contracting Parties and in the Public Domain: How Rich Is the ITPGRFA’s Multilateral System?’, 2013, p. 181.

¹³⁹ Louafi and Bhatti, ‘Efforts to Get the Multilateral System Up and Running’, 2013, p.188.

two interpretations of ‘public domain’ is applied by the Contracting Party, if the government takes a role in the conservation of a back-up collection of the farmers’ seeds, then the management and control criteria become closer to being fulfilled. A core question is whether an understanding between the farmer and the collection that the latter holds the PGR on behalf of the farmer or keeps it ‘in trust’ is enough for the material to be outside the farmers’ ‘management and control’? Such accessions would be managed by the government as the collection would be taking different steps with regard to the material. It could also easily be considered as being under the control of the government.

Collecting farmers’ PGR creates other legal grey zones of practical significance. Let us take the example of a case in which the collector is not a governmental representative, but a representative of a global ex-situ collection. Let us say the material is in Annex I, or is related to Annex I species, and it is collected and put into any of the collections already defined as covered by the MLS. The collector can target resources in the wild, on farmers’ land or, for example, different types of community-based collections among farmers. In all these three examples, the material is not *managed* by the state, nor *controlled* by a state, and it is not necessarily declared by the country as being in the *public domain*. Thus, the material will be outside the mandatory MLS in the country. If such material is collected, the act of collecting will technically legally fall outside the MLS, as the criteria for mandatory inclusion in the MLS are not met. In all likelihood, then, access to these PGR will be governed by the CBD, national ABS laws, and any customary or other legal norms inside a country. If the country in which the collecting has taken place does not regulate access, it will be harder for parties to claim that the collection is in conflict with domestic norms in the provider country.¹⁴⁰ Such ongoing collecting happens in a legal grey zone between the CBD, NP, and ITPGRFA. Providing countries, where the activities take place, need therefore to consider whether they should exercise their sovereign rights or direction and put PGRs into the global common pool of the MLS. Here, the common interest in documenting and conserving the PGR can stand against the interest of exercising the sovereign rights of the country where the seeds are collected.

Another example which deserves attention is when a country holds a particular collection of an Annex I crop with particularly unusual features. If it is included in a governmental collection and kept there in ex-situ conditions, the accession will easily meet the management and control criteria. If ‘public domain’ is understood as ‘outside IPR,’ that criterion will be met (as this special PGR is not under any IPR) and the very distinctive material will be *mandatorily* included in the MLS. Here, how ‘public domain’ is understood becomes crucial. Let us add that the material has been bred for decades by certain identifiable groups of ILCs.

¹⁴⁰ *En passant*, it is interesting to draw a connection to the scope of the draft EU proposal for the NP implementing act as proposed by the Commission. Here, the temporal scope leaves collections of any GR before NP enters into force outside the scope of ABS. Thus, material collected in the past, present and future – until the NP comes into force – in the EU and the providing country would fall outside the scope of the due diligence requirement for collections.

If the ‘public domain’ definition is legally linked to the IPR systems, these resources will not be protected by any IPR, and thus mandatorily included in the MLS system, regardless of the distinctiveness of the accessions. If ‘public domain’ is understood as an opening for the countries to define what is recognized as being in the public domain or not, a distinctive legal status can be attached to the material. Here, the ITPGRFA idea of universal access, in the absence of an agreement on the sharing the benefits with the communities that have developed and preserved these particular PGRs, will trump the benefit-sharing clauses of the CBD in general. Ironically, it could create a disincentive for the country to preserve these resources in a national collection. If left on the farm without any governmental management or control, these resources will be outside the scope of the Contracting Parties.

Yet another group of collections, also providing useful examples, is collections held internationally. They are typically recognized as being in the public domain, and, indeed, this is one of the *raison d’être*s of the MLS. According to the ITPGRFA Internet page, the number of accessions held in these centers is high.¹⁴¹

3.2.5 *Concluding on the criteria for inclusion in the MLS*

Legally speaking, a large number of other examples in the grey area between mandatory inclusion in the MLS and where ABS is being governed by CBD/NP, could be constructed. These technically more complex cases require further thought when countries are to implement the ITPGRFA and CBD/ NP.

One possibility of resolving the relationship between the MLS and the CBD/NP is for a country to declare that all PGR are outside the scope of ABS as governed by national laws implementing CBD/NP. We have seen that the MLS only targets a set of crops and under certain conditions; if a general exception is made for all PGR, non-MLS accessions will end up not being governed by any ABS rules.

3.2.6 *Potential grey zones of free riding*

Regarding inclusion in the MLS, there is a large geographical grey zone which is in need of attention. It arises because not all countries in the world with users of PGRs are members of the ITPGRFA. This raises the question of whether ‘free riders’ should have the same access to the MLS as entities from countries having contributed to the establishment of the common pool by becoming members of the Treaty. Many important countries like the U.S., China, Russia, Argentina, Chile, South Africa, Mexico, Bolivia, and New Zealand are not full members of the Treaty. How, then, should access to the MLS collections for entities from these countries be dealt with? Legally, there are no provisions in the Treaty regulating access to MLS PGR for entities from all countries. Non-

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www.planttreaty.org/inclusions?field_mls_noti_inclu_type_owner_value_many_to_one=International+Center [Accessed on 18th January 2013]

members can be said to be free riders in this common pool system as they do not necessarily follow the same terms on access to their PGR listed in Annex I. Granting their companies access on the same terms could be held as creating a misbalance in the system as these countries do not share their PGR with the global community. This is not necessarily a legal problem, just an observation to better understand the role of the common pool. Under legal principles, non-member countries holding genetic resources still have discretion to exercise their sovereign rights over them, including PGRFA. But at the same time, users of PGR in those countries enjoy the same common pool liberties as other citizens. A private user of the MLS will be bound by the MSTA as this is a standard agreement parties enter into when receiving the material. This creates a factual grey zone, which governments might have in mind when implementing the ITPGRFA along with CBD/NP in national legislation.

3.3 Legal questions arising for PGR on the way out of the MLS

The previous sections explored the coverage of the MLS with a special view to the legal grey zones and the questions which need to be clarified to make the relationship between the MLS and ABS under CBD/NP clear. The next section explores issues that arise when material is taken out of the MLS for further use. There is a body of organs set up to take policy decision and take care of the function of the MLS;¹⁴² the institutional structure will not be explored further here.

3.3.1 *Types of legal uses of PGR from the MLS*

There is an essential condition targeting the user of the facilitated access to PGR under the MLS which the parties to the Treaty agree to award to other parties: Such access, according to the wording of the ITPGRFA Art. 12.3 (a),

... shall be provided in accordance with the conditions below: (a) Access shall be provided solely for the purpose of utilization and conservation for research, breeding and training for food and agriculture, provided that such purpose does not include chemical, pharmaceutical and/or other non-food/feed industrial uses.

The wording sets out certain specific objectives or reasons for seeking access and define them as the only legitimate ones under the MLS. The MLS is established for specific uses, the main criteria being the use of the material for 'food and agriculture' as the accepted purpose of access. This means that non-food and non-agricultural uses are outside the scope of the MLS.

¹⁴²Manzella, 'The Design and Mechanisms of the Multilateral System of Access and Benefit Sharing', 2013, pp. 157-158; Moore. 'Protecting the Interests of the Multilateral System under the Standard Material Transfer Agreement' in *Crop Genetic Resources as a Global Commons – Challenges in International Law and Governance*. Edited by Halewood, et al. New York, Routledge, 2013 on the Third Part Beneficiary and Louafi and Bhatti, 'Efforts to Get the Multilateral System Up and Running', 2013, pp. 190-191.

The purpose of *food* production could possibly be interpreted, delimited, and determined by externally verifiable facts. The term ‘agriculture’ is wider and less easily interpreted, determined and applied. Here biofuel, carbon capture, and cash crops appear as types of use which are connected to the use of land, and thus probably agriculture in a wider sense.

One relevant question is whether the ‘and’ between food and agriculture here makes the two elements cumulative in the sense that agriculture must be interpreted narrowly and confined to where it contributes to food production. Here, the objective of the ITPGRFA being food security, becomes a normative argument. One could say that since food security is one of the core objectives of the Treaty, agriculture beyond securing food production falls outside the scope of the legal intentions for access through the system. No detailed interpretation has been accepted as yet. For the sake of clarity between the CBD/NP and ITPGRFA, it is important to clear this issue up because access for non-food and non-agricultural intentions falls outside the scope of the MLS and is by principle governed by the general ABS rules.

There is also a legal grey area between using accessions of PGR for ‘research, breeding and training’ in the field of technical biotechnology and gene technology. If a single gene is identified in material received from the MLS, the question is whether this use is legal under the MLS. It can hardly fall under ‘breeding’ or ‘training,’ so the alternative must be ‘research.’ It would probably be covered by ‘research’ since the wording does not use any qualifying word describing the type of research intended.

A pragmatic implementation of the MLS might be an argument for not paying too much attention to these legal intricacies. If member states to the ITPGRFA accept that accessions are used for a broader purpose than what follows from the wording of the Treaty, it would be a political decision that should be informed and taken in an open manner. However, since the SMTA mainly regulates benefit sharing when utilisation results in a plant variety as the product, it could be that access through the MLS for subsequent non-authorized uses falls into a blind spot in the system, and might proceed without benefit sharing. For these reasons, these legal questions concerning the limitations of the MLS deserve more attention than is currently the case. Contracting Parties to the IPGRFA would probably prefer to take an informed decision on whether they accept such a blind spot in the open access system of the IPGRFA.

3.3.2 *The Standard Material Transfer Agreement (SMTA)*

The **Standard Material Transfer Agreement (SMTA)** is the practical legal tool for all transfers of genetic material under the MLS. It enables rapid access as no negotiations are needed. It was adopted by the parties in 2006, and provides a standardised means by which countries can exercise their sovereign rights to a specific and limited selection of plant genetic resources for specific uses. It also implies a standardised approach to gaining prior informed consent and mutually agreed terms. The Secretariat ‘believes that the SMTA is a cornerstone of’ the

ITPGRFA.¹⁴³ Access is provided free of charge, and if a fee is charged, it shall not exceed the minimum cost involved (Art. 12.3.b). All available passport data and related information are to be provided together with the material (Art. 12.3.c).

Technically and legally speaking, there are two sets of norms in the SMTA that are closely interlinked and of crucial significance for the maintenance of the common pool of PGR: the *link to IPRs*; and *benefit sharing* under the MLS. Manzella, who takes it upon himself to explain the ‘nuts and bolts’ of the MLS,¹⁴⁴ mentions neither benefit sharing nor the relationship to patent law among the four objectives of the SMTA.¹⁴⁵

3.3.3 *The legal links to the patent system and the plant breeders’ rights*

The core provision that contributes to determining the relationship between the MLS and IPRs, is Art. 12.3.d:

Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System.

This is further specified in SMTA Art 6.2:

The Recipient shall not claim any intellectual property or other rights that limit the facilitated access to the Material provided under this Agreement, or its genetic parts or components, in the form received from the Multilateral System.

At first glance, this seems like a ban of the use of IPRs, but the wording implies a more lenient limitation on the right of the recipient of material to take out IPRs. The wording refers to three ‘objects’ that cannot be the object of IPRs: ‘plant genetic resources’; ‘their genetic parts’; and ‘components’. Before commenting and interpreting each of these items, the qualifying wording referring to any three of these objects requires some comments. It is only these three items ‘in the form received’ that cannot be the object of an IPR. Patent law and plant breeders’ rights must be explained if we are to understand what is meant by this apparent limitation. In patent law, any object qualifying as an invention, being novel, and including an inventive step and has industrial application shall be awarded a patent. The concept ‘invention’ does not correspond to any of the three objects described in the Plant Treaty. Patent law does not use any of the three terms: ‘plant genetic resources’, ‘their genetic parts’, or ‘components’. Nor does the ITPGRFA use patent-law terminology. There is therefore no correspondence between the terms of patent law to which ITPGRFA Art. 12.3.d adheres. Nor is there an identical term in patent law to ‘in the form received’. On this point, too, the linguistic

¹⁴³ Louafi and Bhatti, ‘Efforts to Get the Multilateral System Up and Running’, 2013, p. 194.

¹⁴⁴ Manzella, ‘The Design and Mechanisms of the Multilateral System of Access and Benefit Sharing’, 2013, p. 150.

¹⁴⁵ *Ibid.*, p. 154.

discrepancies between the Treaty and patent law terminology present a challenge to the use of patent law to secure the rules under the Treaty. These linguistic challenges will probably stand in the way of making the limitations in the legal use of the patent system functional. The ITPGRFA and the SMTA may need to adhere more closely to the terminology of the patent system to avoid unlawful patenting.

In patent law, the novelty and inventiveness criteria are both assessed from a common baseline, the *prior art*. In this perspective, it is interesting to assess whether the inclusion of a certain accession of plant genetic resource in a collection managed under the MLS means it is included in the *prior art*. *Prior art* is a technical patent term which defines what the patent system recognizes as already existing and thus not patentable. The inclusion of a sample in a collection is necessarily not sufficient for it to qualify automatically as *prior art* in patent law. This can be illustrated by the *Biogen* case, where the question at stake was whether the deposit of the gene in a gene bank could sufficiently be considered as *prior art* and thus not meet the condition of *novelty*.¹⁴⁶ The Enlarged Board of Appeal argued that the gene ‘had not been made available to the public by this publication itself or through this publication from the gene bank.’¹⁴⁷ If there is a need for screening a gene bank, the Board held, then the deposit in the gene bank does not constitute a part of the *prior art*.¹⁴⁸ In that case, the DNA would be ‘hidden in the multitude of clones of’ the gene bank, and could not, therefore, be part of the *prior art*. The Board also required a more comprehensive publication of the resources in a gene bank to be part of the *prior art*. The consequence of this is that a patent can be granted and establish one exclusive right to an object which the wording of the SMAT would not allow. There are incentives and work is going on to improve the access of patent examiners to the information in databases of gene banks. Negotiations have been going on for a long time in the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore under the WIPO on whether the patent system could include a requirement of disclosing the origin of the material used in the invention.

The main observation here, however, is that there is a lack of attention to the mechanisms both in patent law and in the MLS to ensure that accessions governed by the MLS are excluded from being patented in a form received.

Further, ‘genetic parts’ and ‘components’ have no corresponding terminology in the patent system. One connection between these concepts and the patent system could have been in the definition of *prior art*. It is, however, only the genetic parts or components described in a manner which will be disclosed in a textual *prior-art* search that will be recognized as *prior art* as the baseline for assessing novelty and inventiveness. These technical legal discrepancies illustrate the current inability of the

¹⁴⁶ *Biogen v. Boehringer Ingelheim Pharma AG*, [1989] T 0301/87, Board of Appeal, EPO, 16 February 1989, , paragraph 3.3.2.

¹⁴⁷ *Ibid.*, paragraph 5.2.

¹⁴⁸ *Ibid.*, paragraph 5.4.

patent system to ensure in all cases that material from the MLS is not patented.

When a certain PGR, genetic part, or component is described or published in a manner that is recognized as *prior art*, the next question is whether the novelty or inventiveness criteria are met. The novelty criterion involves a simple comparison between each item recognized as *prior art* and the description in the patent claims. This assessment entails a linguistic comparison in which the threshold for not meeting the novelty criterion in some patent systems is that the item of *prior art* is found to be non-identical with the described invention. The assessment is not congruent with an assessment of whether the material is described as identical to the criterion of 'in the form received'. This means that a slight difference between the two written sources can be sufficient to merit a patent – regardless of whether the object is close to the *form* in which it was *received*, only in a slightly different description. When knowing that patents, according to many patent offices, can be granted to naturally occurring genes, viruses, and other micro-organisms, the mere pre-existence of the material in a collection governed by the MLS is not sufficient to fail the novelty criterion.

The inventiveness assessment takes another approach by assessing whether the invention as a whole differs from the total body of *prior art* before the patent application. The content of this assessment is whether the new invention is non-obvious when assessed in light of the body of existing literature. This assessment is qualitatively different from that embedded in the 'in the form received' assessment. Here, the patent office examines the body of *prior art* with the object for the patent application.

This has been a brief look at patent law in the context of the attempt in the SMAT and MLS to prevent the privatization of material obtained from the collections from having a deleterious effect on the common pool. The above discussions revealed fundamental challenges in the relationship between the patent law assessments and the criteria chosen to safeguard the MLS as a common pool of PGR.

The other type of IPR is plant breeders' rights (PBR). These rights are also granted according to national procedures whereby the merits of a claimed plant variety are assessed. The criteria differ from those of the patent system, and PBR are only applicable for one particular type of object: a plant variety as defined in the International Convention for the Protection of New Varieties of Plants 1991 (UPOV 91) as a 'plant grouping within a single botanical taxon of the lowest known rank' regardless of whether a certain variety meets the criteria for being protected or not. Here *one* core issue is whether the claimed plant variety has been marked or commercialized as a plant variety before. Genetic parts or components are not as such protectable under the PBR system. A breeder is defined in UPOV-91 either as one who has bred, or discovered and developed, a plant variety (UPOV 91 Art. 1). For the first activity, the result of a breeding process is something else than PGR in the form received. The second grouping, however, implies a lower threshold of activity on the received material. Here, an accession *in the form received* can be

considered as discovered; this is a question which is parallel to the one raised with regard to patent law. There will be an assessment of how ‘developed’ an accession received from the MLS must be, in order to not disqualify it under the ‘in the form received’ criterion. Also here there is no necessary connection between the interpretation of the wording of the ITPGRFA and the criterion in UPOV 91. The extent to which plant material must be modified before it is no longer regarded as being ‘in the form received’ under this Article is uncertain.

Whether a patent or a plant breeders’ right will be granted depends on practice in the patent system. How these rules will interplay with those of CBD, ITPGRFA, and NP is still to play out in detail in practice. It is likely that concrete legal disputes will arise, but to our knowledge there has not been any court case in the world where the issue has been a patent versus a right based on ABS. Whether these questions will be resolved by a national court under patent law or by the dispute settlement mechanism in the ITPGRFA is also still to be seen.

3.3.4 *Legally binding benefit sharing*

The other main legal topic in the SMTA concerns the benefit-sharing mechanisms. According to the CBD system there are two contractual mechanisms for deciding benefit sharing: future benefits can be specified at the point of time of access (CBD Art 15. 4 and 5) or at the point of time of utilisation, when the success of the use is better known (CBD Art. 15.7 second para.). Thus, the general rule in ABS is that a contract between provider and user sets the conditions for benefit sharing. This approach is also followed in the NP.

For MLS in the ITPGRFA there is no corresponding system for agreeing an individual level of benefit sharing. In the discourse regarding the ITPGRFA, it is often said that ‘facilitated access to PGRFA is in itself a major benefit.’¹⁴⁹

Furthermore, *monetary benefit sharing is fixed* in terms of shares from the sale of products developed by use of material from the Multilateral System, as set out in the SMTA. Instead of leaving the parties to the private law contract to determine the trigger point and level of benefit sharing (as in ABS as we know it from CBD), the Treaty itself sets the trigger point. Art. 13.2.d.ii states:

- (ii) The Contracting Parties agree that the standard Material Transfer Agreement referred to in Article 12.4 shall include a requirement that a recipient who commercializes a product that is a plant genetic resource for food and agriculture and that incorporates material accessed from the Multilateral System, shall pay to the mechanism referred to in Article 19.3f, an equitable share of the benefits arising from the commercialization of that product, except whenever such a product is *available without restriction* to others for further research and breeding, in which case the recipient who commercializes shall be encouraged to make such payment. (Emphasis added)

¹⁴⁹ Manzella, ‘The Design and Mechanisms of the Multilateral System of Access and Benefit Sharing’, 2013, p. 155.

And further in the SMTA Art. 6.7:

In the case that the Recipient commercializes a Product that is a Plant Genetic Resource for Food and Agriculture and that *incorporates Material* as referred to in Article 3 of this Agreement, and where such Product is not available without restriction to others for further research and breeding, the Recipient shall pay a fixed percentage of the Sales of the commercialized Product into the mechanism established by the Governing Body for this purpose, in accordance with Annex 2 to this Agreement. (Emphasis added)

The benefit obligation is set here as a fixed percentage of 1.1 percent of the net sales of the protected product through the time of protection.¹⁵⁰ This benefit-sharing obligation is eased if the product is available for further research and breeding. This prompts one to ask what is meant by ‘available without restrictions’.

Alternatively, the user can opt for paying according to Article 6.11c of the SMAT:

The payments shall be based on the Sales of any Products and of the sales of any other products that are Plant Genetic Resources for Food and Agriculture belonging to the same crop, as set out in Annex 1 to the Treaty, to which the Material referred to in Annex 1 to this Agreement belongs.

Annex 3 sets the level of payment here to 0.5 per cent¹⁵¹ of the all the sales of the products based on the same crop.¹⁵²

Under the CBD, the obligation to conduct benefit sharing is linked to the ‘utilization’ of genetic resources. Under the ITPGRFA, utilization is not set as a trigger point. The trigger point is far more narrowly defined in the Treaty and the SMTA.

The wording here leaves unanswered two particular questions of legal interpretation: what is meant by the phrases ‘that incorporates Material’ and (the most discussed wording) ‘such Product is not available without restriction to others for further research and breeding.’

The second question tends to be interpreted as follows: If a product resulting from the use of material from the MLS is protected by patents,¹⁵³ then the fixed share (0.5 percent) of the sales must be paid into the benefit-sharing mechanism. If the result of the use of the material is protected by a plant breeders’ right, then, according to convention, it is assumed to be outside the benefit-sharing obligation. The wording, however, rather than linking the benefit-sharing obligation to a specific type of property rights, relies on a particular circumstance (available without restrictions). This circumstance is *in casu* whether the product is

¹⁵⁰ *Standard Material Transfer Agreement [SMTA]*, ITPGRFA Governing Body, 16 June 2006, Resolution 1/2006 Annex 2.

¹⁵¹ *Ibid.* Annex 3.

¹⁵² See also Manzella, ‘The Design and Mechanisms of the Multilateral System of Access and Benefit Sharing’, 2013, p. 156.

¹⁵³ Andersen, et al., *International Agreements and ABS*, 2010.

not available without restrictions. One manner in which a product can be available under certain restrictions is through IPRs, but there are other ways than the patent system that can establish restrictions in this sense. For example, a registered plant variety is, according to *seed legislation*, not available without (technically and legally speaking) restriction. In these cases, there are indeed restrictions, but they are not IPR-based restrictions. Also the manner in which the experimental use under patent law is practiced and the manner in which breeders' exemptions are practiced can make the product *more or less* restricted. A certain degree of legal uncertainty is therefore attached to this criterion. It reduces predictability for the users of genetic material from the system, since the trigger point of the benefit-sharing obligation requires interpretation and can vary among countries depending on the level of restrictions.

It is the *product* that triggers benefit sharing. From a purely linguistic interpretation of the wording, it means that a *patented process* resulting from material obtained from the MLS does not trigger benefit sharing. Linking the trigger point to the restriction on the product and not on the material in the common pool might coincide with other changes in patent law which contributes to the trend of applying for process patents (and thereby also gain indirect product protection). The situation in these cases is arguably that since the wording uses the term 'product', then the decisive argument also in these cases is that the product is inaccessible, and thus covered by the benefit-sharing obligation.

If the product is not protected or protected and still available for use, research, and development, then benefit sharing is optional. The idea behind these rules is to maintain the common pool as it was originally.

The first criterion to trigger the benefit-sharing obligation concerns the link between the material received from the MLS and the *incorporated Material* in the final product. For determining whether a user has triggered a benefit-sharing obligation, the link between the product mentioned above and the wording 'that incorporates Material' from the MLS is assessed. Here, a concrete assessment of whether any material from the MLS has been 'incorporated' in the product for which breeding or research has been restricted. This is a very difficult assessment both in law and in fact. It is difficult in law because one needs to determine at which point a certain material was incorporated. The wording 'incorporated' suggests the putting of something into a larger whole in a manner that consumes the element. Linguistically, it could be understood as a reference to genetic technology (or recombinant techniques), as in a situation where a gene is modified and transferred to another plant into which it will be 'incorporated'. If only used in traditional breeding, saying that a number of accessions are 'incorporated' into the new product is less obvious given a strictly linguistic interpretation. And even if the interpretation of 'incorporated' can be understood in a fairly broad manner, there remains the difficult question of assessing the relationship between the accessions obtained from the MLS and the final product for which the benefit-sharing mechanism is being assessed. This issue has been discussed in the bodies of the ITPGRFA but without reaching a definitive, legally binding conclusion.

‘The plant breeding sector’, according to Van den Hurk, ‘was of the opinion that benefit sharing should only take place when a great part of the genetic resources could be found back in the final product; a minimum of 25 percent should be incorporated.’¹⁵⁴ In addition, she holds that an ‘identifiable trait of value or essential characteristic’ should be proved to be present.¹⁵⁵ These proposed links between the material received from the MLS and the final product require a high degree of identity. The closer the link between any material received from the system and the product required, the less the new products will be mandatorily covered by the benefit-sharing obligation.

This assessment also prompts questions concerning difficult evidence and information in addition to the purely legal questions. The questions and challenges are, however, not peculiar to MLS situations. They are very difficult questions indeed, and have yet to be resolved by the CBD or NP, or in any consistent contractual practice. A parallel question is whether a patent applicant shall be obliged to disclose the origin of material used in the innovative process.

This identification issue and incorporated question also arise in a different situation. Typically, a product will be developed (at least in traditional plant breeding) based on a several materials. These materials will typically come from a number of collections. The MLS contributes to resolving this challenge for PLGRFA. Moreover this is a similarly difficult and unresolved question for material governed by the CBD and/or NP. Whether the material comes from sources outside the MLS, within the MLS, from domestic sources or from a number of different countries – the problem will be to assess whether any incorporation, even insignificant, should not count as triggering the benefit-sharing mechanism in the SMTA.

‘Financial contributions from various entities have been made into the Benefit-Sharing Fund’ according to Manzella.¹⁵⁶ What he forgets to say is that almost none of these funds have been shared benefits as the SMTA or the rules of the MLS require, but rather voluntary country contributions. As Visser states, ‘[o]nly if the ... benefit-sharing arrangements and the funding strategy in particular, appear to be successful and not negative effects resulting from the execution of the intellectual property rights, might the occasion arise for an expansion of the list of crops.’¹⁵⁷ This he states in the context of discussing the list of crops in the Annex; but it has wider implications in terms of the success of the benefit-sharing mechanism to receive economic benefits from the users and receivers of the large number of accessions being transferred under the MLS.

¹⁵⁴ van den Hurk. ‘The Seed Industry: Plant Breeding and the International Treaty on Plant Genetic Resources for Food and Agriculture’ in *Plant Genetic Resources and Food Security: Stakeholder Perspectives on the International Treaty on Plant Genetic Resources for Food and Agriculture*. Edited by Frison, et al. London, Earthscan, 2011, p. 168.

¹⁵⁵ *Ibid.*, p. 168.

¹⁵⁶ Manzella, ‘The Design and Mechanisms of the Multilateral System of Access and Benefit Sharing’, 2013, p. 159

¹⁵⁷ Visser, ‘The Moving Scope of Annex I: The List of Crops Covered under the Multilateral System’, 2013, p. 279.

Non-monetary benefit sharing is to be facilitated between the contracting parties independently of the transfer of material. This includes making available information on PGRFA; transfer of technology for the conservation and sustainable use of PGRFA; and capacity building in terms of education and training, improvement of facilities, and research cooperation for the conservation and sustainable use of PGRFA (Art. 13.2). The resemblance to the options found under the CBD and NP is more marked for non-monetary benefit sharing than it is for the monetary benefit sharing discussed above.

3.4 Overall discussions and finding for the ITPGRFA

3.4.1 *Assessing the SMTA of the MLS as a common pool drawing on open source*

Against this backdrop, the MLS was developed with features of a *common pool of genetic resources* into which all contracting parties (countries) place a selection of plant genetic resources of Annex I crops that are in their public domain and under their control. In addition, the contracting parties invite all their holders of such material to include it in the MLS (Art. 11.2). Accessions of plant genetic resources which are outside the *public domain*, such as the resources held in private collections, are not included in the MLS. Countries are to take appropriate measures to encourage their inclusion, but this remains a factor limiting the success of the MLS.

The MLS has thus been characterised as a common pool.¹⁵⁸ Common pool thinking is based on a balance struck between participants' willingness to put material into the pool and their interest to take something out of it. The principle of Open Source software makes the source code freely available to the public for use and modification, but such modifications and innovations must remain in or be shared with the common pool under the same conditions as the modifier obtained the material in the first place. Under this principle in the MLS, countries have a sovereign right to their genetic resources, i.e. to include in a common pool a limited and well-defined list of PGRFA. The users and primary beneficiaries, however, are not obliged to share their inventions with the MLS. There is no mechanism for requiring the one developing a product from material found in the common pool to share his inventions or products with the pool. In this context, the primary beneficiaries do not contribute to the growth of the common pool. Theoretically, a plant breeder in the food or agriculture sector could have been asked to allow access to the research results on the same terms as he obtained the material in the first place. The SMAT does not impose such a requirement. And in any case, it would introduce a negative incentive for using material from the MLS as a common pool. Openness is merely a recipient-side issue, and does not impinge on the results of the research.

¹⁵⁸ Halewood, et al. 'The Global Crop Commons and Access and Benefit-sharing Laws – Examining the Limits of International Policy Support for the Collective Pooling and Management of Plant Genetic Resources' in *Crop Genetic Resources as a Global Commons – Challenges in International Law and Governance*. Edited by Halewood, et al. New York, Routledge, 2013, pp. 1-36.

The MLS differs from the ABS system as practiced under the CBD thus far. It involves a common pool of genetic resources with standardized access standards and a detached system for benefit sharing with a set trigger point. The detaching of benefit sharing implies that benefits are not shared with the providers but with a limited number of internationally selected projects. According to the benefit-sharing figures so far, the money that has been shared has mainly come from donor countries. The original idea and rationale was to let the users share a fair and equitable part with the providers, but this has still be realized.

4 Conclusions and recommendations for promoting a synergistic implementation at the national level of the CBD/NP and the IT

The following key issues need to be taken into consideration for a mutually supportive implementation of the NP/CBD ABS and the IT relevant provisions. There is a need to

- Identify and create legal space for the implementation of the MLS in the national legal framework, including ABS laws (providing appropriate exceptions to the national ABS legislation; assessment of the direct implementation of the IT as international law in national law; anticipating the passage of specialized legislation in the current legal framework, etc.). When creating such legal space it is crucial to clarify the grey zones and close the blind spots.
- Determine the national authorities responsible for the signature of SMTA in the country (this includes a clear determination of the national resources included in the SML in accordance to the IT provisions) and strengthen cooperation and exchange of information between them and the ABS/ NCA in order to build trust and reduce the potential competition between both. Provide clarity about the legal powers of each entity in the process of handling the ABS request.
- Promote national processes for the protection of TK in a way which includes the issue of farmers' rights as appropriate (traditional knowledge associated with plant varieties/agriculture practices; farmers groups as beneficiaries of the TK regimens, including the PIC/MAT requirements envisaged in the NP, etc).
- Explore further the development of the concept of utilization – as found in the NP – to better determine the scope of ABS laws and the implications for plant breeding within the country.
- Regulate in-situ access to genetic resources covered by the MLS (on state-owned lands such as protected areas) in a synergistic way in order to achieve mutual supportiveness between the CBD/NP and the IT in the light of the objectives of both instruments. It is critical for the appropriate implementation of both the NP and the IT (to avoid lack of certainty regarding the competence and treatment of the request from the environmental authorities) to ensure coordination and clarification of the legal procedures (collection rules) and roles, for instance, of the environmental authorities in charge of the management of protected areas (national parks) when wild relatives of Annex I crops are found.
- Clarify in the ABS legislation the legal space/rights for the inclusion of PGRFA in the MLS (Annex I) by physical and juridical persons (the Parties of the IT are supposed to provide incentives for this inclusion), considering the legal regimen governing property rights on genetic resources in each country and the reference found in the IT to the concept of 'holders' of genetic resources (Article 11.2 and 3).

- Draft and apply the trigger points in the benefit-sharing mechanism in a manner that facilitates the flow of also monetary benefits from the main user of the system to the Benefit-Sharing Fund.
- Determine at the national level the potential role of the SMTA as proof of compliance with ABS legislation in the designated check points under the NP. Once the NP entry into force a COP/MOP decision on this matter could be useful.
- Improve cooperation and information exchange in cases of non-compliance with the SMTA (between entities responsible for the signature and ABS NCA) to the extent that non-compliance under the terms of the SMTA can be understood as non-compliance with the ABS laws of the country, e.g. an illegal use of an ABS exception, etc.
- Clarify the relationship between ABS in CBD, NP, and IT and their respective relationship to the IPRs systems, the patent system and national systems for plant breeders' rights when each of these systems is implemented into domestic law and domestic practice.
- Develop joint-capacity building/development and awareness-raising activities by the NP and IT focal points/NCA (taking into consideration the content and objectives of each instrument in capacity-building and other related actions promoted by the CBD, the IT, and capacity development projects and initiatives). National committees including members from the environmental, scientific and agricultural sector may be established in order to promote a better understanding of fundamental issues and to improve trust and coordination among institutions/agencies.

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