



# Bridging the Gap on Intellectual Property and Genetic Resources in WIPO's Intergovernmental Committee (IGC)



By David Vivas-Eugui  
Anamika, Innovation Policy Advisors



International Centre for Trade  
and Sustainable Development

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ICTSD welcomes feedback and comments to this document. These can be sent to Ahmed Abdel Latif ([aabdellatif@ictsd.ch](mailto:aabdellatif@ictsd.ch)).

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## LIST OF ABBREVIATIONS AND ACRONYMS

ABS	Access and Benefit-sharing
ATK	Associated Traditional Knowledge
BIO	Biotechnology Industry Organization
BRDRs	Biodiversity-related Disclosure Requirements
Cariforum	Caribbean Forum
CBD	Convention on Biological Diversity
COP	Conference of the Parties
CSIR	South African Council for Scientific and Industrial Research
EFTA	European Free Trade Area
EPA	Economic Partnership Agreement
EU	European Union
FAO	Food and Agriculture Organization
FTA	Free Trade Agreement
GIs	Geographical Indications
GLMC	Group of Like Minded Countries
GRs	Genetic Resources
ICTSD	International Centre for Trade and Sustainable Development
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IGC	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
IP	Intellectual Property
IRCC	Internationally Recognized Certificate of Compliance
ISWG	Inter-sessional Working Groups
MAT	Mutually Agreed terms
MEAs	Multilateral Environmental Agreements
NCAB	National Commission Against Biopiracy of Peru
NGO	Non Governmental Organization
PCT	Patent Cooperation Treaty
PLT	Patent Law Treaty
PIC	Prior Informed Consent
PVP	Plant Variety Protection
R&D	Research and Development
SCP	Standing Committee on Patents
TCE	Traditional Cultural Expressions
TK	Traditional Knowledge

TRIPS	Agreement on Trade-related Aspects of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
UNDRIP	United Nations Declaration on the Rights of Indigenous Peoples
US	United States
USDA	US Department of Agriculture
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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## FOREWORD

The relationship of genetic resources and traditional knowledge to intellectual property protection has been one of the most complex, controversial yet dynamic issues on the agenda of multilateral deliberations in the areas of biodiversity, trade and intellectual property during the past decade.

One of the important challenges it raises stems precisely from the fact that discussions have taken place simultaneously in a number of international forums such as the Convention on Biological Diversity (CBD), the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO), raising significant questions in terms of ensuring ‘coherence’ and ‘mutual supportiveness’ between processes responding to different mandates. While at the WTO the stalemate in the Doha round of negotiations has resulted in little progress on these and other matters, the adoption by the CBD of the Nagoya Protocol on Access and Benefit Sharing, in 2010, is an important milestone in the debate that has a bearing on deliberations in other forums.

At WIPO, the Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC) has been, since its creation in 2000, the main focus of deliberations with the active participation of a variety of stakeholders in particular indigenous groups. Throughout its existence, it has witnessed a rich policy dialogue and contributed to a better understanding of the issues at stake notwithstanding that important obstacles still lie ahead in generating concrete outcomes.

In 2009, an important step was taken when the WIPO General Assembly instructed the IGC to accelerate its work towards developing an international instrument or instruments to protect genetic resources, traditional knowledge and traditional cultural expressions. In addition, agreement was reached on the establishment of expert working groups for this purpose. Since then, WIPO members have made strenuous efforts to draft legal language to accommodate different views and perceptions in the arduous pursuit of possible new international norms in this area.

While divisions still remain on the legal nature of the final outcomes and on important substantive matters, progress has been made in discussions on traditional knowledge and traditional cultural exceptions/folklore. Nevertheless, genetic resources remain the item on the IGC’s agenda where the gap in positions remains the widest particularly on the proposal to include a mandatory disclosure requirement of the origin genetic resources in patent applications. This key issue as well as other relevant modalities and mechanisms for protection, such as databases, are the focus of this new ICTSD issue paper by David Vivas-Eugui, an international expert who has actively followed and taken part in these discussions during the past decade.

The study examines at length issues raised in the IGC’s deliberations on intellectual property and genetic resources in particular biodiversity disclosure requirements and databases. It also considers the binding or non-binding nature of the instrument(s) to emerge from the IGC and their different implications. In connection to all these aspects, the study makes recommendations regarding processes, substantive contents and identification of existing research gaps.

In this regard, the study emphasizes that a binding instrument is the surest way to see biodiversity-related measures in the IP system implemented by user countries, taking into consideration the need that the solutions it provides will have an effect in practice. It further points out that soft law solutions should not be ruled out, provided they address issues in an effective manner. Furthermore, it underlines the important fact that WIPO deliberations on disclosure requirements should be seen as complementary to WTO outcomes which could be enforced more effectively through the WTO’s dispute settlement system.



Finally, the author highlights that an international instrument comprising disclosure requirements, databases and model clauses for genetic resources protection is not a substitute for an effective access and benefit sharing mechanism at the national level. Besides proactive attention by competent authorities, direct notification of companies using genetic resources or associated traditional knowledge, engagement in post-access negotiations, utilisation of certificates compliance and exploration of litigation options within and outside the national jurisdiction, can also effectively contribute to curb potential biopiracy cases. At this very critical juncture of the work of the IGC, this analytical piece of work should constitute in our view an important contribution to better grasp the complexities of the issues at stake and to facilitate the emergence of a wider choice of options that Members would need to take into consideration to find lasting solutions to these questions.

The adequate consideration of genetic resources and traditional knowledge issues in the international intellectual property architecture has been a long-standing demand by developing countries. A central tenet of ICTSD's Innovation, Technology and Intellectual Property programme, launched in July 2001, has been that in a knowledge-based economy, a better understanding of IP related issues is imperative for informed policy making in virtually all areas of development. This is certainly the case of genetic resources and associated traditional knowledge. Our focus has been on ensuring a proper balance between the different interests at stake in designing appropriate intellectual property regimes that are supportive of sustainable development objectives and compliant with international commitments. An additional central objective has been to facilitate the emergence of a critical mass of well-informed stakeholders in developing countries - including decision-makers and negotiators as well as actors in the private sector and civil society - able to define their own sustainable human development objectives in the field of intellectual property and effectively advance them at the national and global levels.

I sincerely hope you will find this issue paper a useful contribution to efforts aiming at ensuring a concrete and tangible outcome of the work undertaken at WIPO on intellectual property, genetic resources and associated traditional knowledge.



Ricardo Meléndez-Ortiz  
Chief Executive, ICTSD

## EXECUTIVE SUMMARY

The Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC) of the World Intellectual Property Organization (WIPO) was created, in 2000, against the backdrop of an increased recognition of the economic value of genetic resources (GRs) and associated traditional knowledge (ATK) and the expansion of IP protection over biotechnological inventions including life forms. Biodiversity-rich countries and traditional knowledge (TK) holders had become concerned about the presumed lack of respect for national access and benefit-sharing (ABS) legislation and the misappropriation of their genetic patrimony and TK by some intellectual property (IP) applicants.

More than a decade after its creation, the IGC has a historic opportunity to contribute towards providing meaningful responses to concerns relating to biodiversity and IP. But while the IGC has generated significant research and analysis and resulted in some technical measures, it has yet to deliver with respect to international norm setting as significant disagreements persist on fundamental issues among user and provider countries, businesses and indigenous peoples. Overall, the IGC process has been encumbered by difficulties in ensuring users of GRs and ATK abide by national ABS and TK legislation. In addition, discussions on these matters which originated in the Convention on Biological Diversity (CBD) have been pursued in other forums, such as the World Trade Organization (WTO) and in bilateral trade negotiations, generating challenges for ensuring a coherent approach.

While the concept of ABS is integral to the CBD, only around 60 of its 193 parties have adopted national regulations to that effect. Of these, only a few user countries have done so, such as Australia and Norway. In the limited number of ABS contracts that have been signed, non-monetary benefits, such as training and knowledge transfer, have featured more prominently than monetary benefits. There is a clear need for better data on ABS contracts, which could be organized by setting up a notification system through the CBD Clearing-House Mechanism stipulated in the Nagoya Protocol (2010).

The Protocol is a new international instrument that advances the ABS obligations under the CBD and that can give higher levels of confidence, clarity, and legal certainty to both users and providers. It generates new definitions; clearer standards for ABS; obligations on providers and users; measures to address legal access across borders; and monitoring, cooperation and enforcement mechanisms. It raises the level of protection of ATK at the multilateral level. The Global Multilateral Benefit Sharing Mechanism under the Nagoya Protocol, which may be established in the near future, could address ABS in transboundary situations or where it is not possible to grant or obtain prior informed consent (PIC). The Protocol also introduces country checkpoints and an internationally recognized certificate of compliance (IRCC) that will facilitate the legal and legitimate utilization of GRs.

Despite the regular examination, since 2001, of the relationship between the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) and the CBD, no clear consensus has yet emerged. *Demandeurs*, for their part, have sustained their efforts, as most recently manifested in a revised joint proposal by a coalition of African, Asian, Caribbean and Latin American countries. For all intents and purposes, it is important that the content and language of proposals in the IGC show coherence with those advanced in the WTO.

Beyond the WTO, the incorporation of biodiversity- and TK-related IP provisions in free trade agreements (FTAs) is a more recent phenomenon. In several FTAs, user countries have already subscribed to new biodiversity and TK-related standards that appear to go beyond the CBD and the Nagoya Protocol, as well as the TRIPS Agreement. For instance, the European Free Trade

Association (EFTA) agreed to a mandatory disclosure requirement in FTAs with Colombia (2008) and Peru (2010). As a consequence, those user countries should in principle be more receptive to similar provisions at the multilateral level.

In 2009, the WIPO General Assembly gave the IGC a renewed mandate towards the elaboration of an international instrument or instruments to protect GRs, TK and traditional cultural expressions (TCEs). Since then, members, with the support of a “friends of the Chair” group, have made efforts to reduce the number of textual options on the table. However, divisions remain that are reminiscent of the status quo at the start of the process: a proposal to begin negotiations on a mandatory disclosure requirement was roundly rejected by some user countries at the IGC 19 meeting in July 2011.

Several delegations in the IGC have mentioned the need to achieve progress in discussions on GR protection commensurate with progress in deliberations on TK and TCE protection. A recent proposal by the Group of Like-Minded Countries (GLMC) gave more focus to the IGC's list of draft objectives and principles on GR protection and offered fresh draft proposals. The GLMC proposal, because of its comprehensiveness and the weight of its sponsorship, is analysed and compared in detail with the current draft text on objectives and principles in Annex I of this paper.

The incorporation of biodiversity-related disclosure requirements (BRDRs) is likely to be a deal breaker in the IGC process. BRDRs include: ATK, evidence of PIC, mutually agreed terms (MAT) and other ABS arrangements in addition to disclosure of the geographical and country origin of GRs used in an invention. Around 50 countries have some form of BRDRs in their national legislation but much more research on practical national experiences of BRDRs is needed.

Proposals in the IGC on the design of BRDRs have been wide in scope and strong in potential legal effect, while allowing for considerable policy space for their national implementation, which can be used to address the concerns of user countries and business groups. Important questions in the IGC are whether BRDRs should be voluntary or mandatory, and what form potential sanctions should take (patent revocation, suspension of the processing of the patent, administrative, civil, or criminal sanctions). Countries that lack the capacity to administer BRDRs could consider introducing a horizontal biodiversity conservation tax, applicable to sales of biodiversity-derived products and inventions.

BRDRs benefit user countries and business as well as provider countries by shielding them from claims of “biopiracy”, improving trust, and incentivizing providers to take a more investment-oriented approach. Concerns over the lack of effectiveness, burden, and costs of BRDRs are overstated, especially since ABS considerations should already have been internalized. A way for countries implementing BRDRs to ensure legal certainty is by applying the Nagoya Protocol standards of clarity and cost-effectiveness. An *ex post* legal restoration mechanism could also be put in place so that IP applicants who did not comply with ABS legislation can seek to do so rather than be sanctioned.

Databases are complementary to BDRs, though some user countries have proposed them as alternatives to BRDRs. They can help in prior art searches and reduce the burden on patent examiners, as well as play a role in the preservation of TK. An option for the IGC is to take a rights-based database approach for GRs and TK, whereby titleholders depositing them retain certain *sui generis* rights over their content and utilization.

An international instrument comprising BRDRs, databases, and model clauses for GR protection is not a substitute for an effective ABS mechanism at the national level. Besides, proactive attention

by competent authorities (e.g. Peru's National Commission Against Biopiracy), direct notification of companies using GRs or ATK, engagement in post-access negotiations and exploration of litigation options within and outside the national jurisdiction can curb potential biopiracy and misappropriation cases. Countries can consider outsourcing monitoring and litigation to civil society and consulting and law firms on a *pro bono* basis.

A binding instrument is the surest way to see biodiversity-related measures in the IP system implemented by user countries taking into consideration that the solutions it provides will have an effect in practice. Soft law solutions should not be ruled out, provided they address the issues effectively. Furthermore, WIPO deliberations on disclosure requirements should be seen as complementary to WTO outcomes which could be enforced more effectively through the WTO's dispute settlement system. The subsequent sections provide a summary of the main recommendations made in this report in terms of processes, content, and research.

### Process recommendations

- The Nagoya Protocol's new ABS standards should be supported in the IP system and addressed in ongoing negotiations in the IGC, the TRIPS Council, and FTAs.
- *Demandeurs* should mirror the language and content of proposals made in the TRIPS Council for the list of options and the text on principles and objectives under discussion in the IGC to ensure consistency.
- The biodiversity-related IP provisions in some recent FTAs (notably the EFTA agreements with Colombia and Peru) offer options for dealing with erroneous patents, insufficient patent examination and the promotion of legal access to GRs and ATK and benefit-sharing. These should be examined at the multilateral level as several user countries have already accepted them in a number of trade agreements.
- Additional trust-building measures are needed for both indigenous peoples and business groups. These could include a heightened role for the "friends of the Chair", appointing a special indigenous peoples' facilitator, supporting regional coordination groups and facilitating business roundtables and stakeholder dialogues parallel to the IGC process.

### Substantive recommendations

- A set of operational provisions should be added to the current IGC draft of objectives and principles in order to advance the process and facilitate their implementation.
- Definitions that already exist in other agreements (e.g. of "GRs", "utilization" and "derivatives") should contribute to better outcomes and clarity in the deliberations. The introduction of additional definitions (e.g. of "biopiracy", "misappropriation" and "misuse") could be included in order to provide clarity as to the type of acts that need to be addressed.
- The substance of the recent proposal by the GLMC could provide a suitable basis for negotiations in the IGC. As well as objectives and principles, it provides a new set of proposals and mechanisms and contains text seeking to improve transparency, reduce transaction costs, and ensure coherence with the CBD and Nagoya Protocol.
- The introduction of BRDRs at the multilateral level should be complemented by other policy developments. These include an ex post ABS restoration mechanism and a biodiversity linkage, ensuring proper treatment of confidential disclosed information, and making use of the Global

Multilateral Benefit Sharing Mechanism and certificates of compliance under the Nagoya Protocol. *Demandeurs* should evaluate the use of an enabling clause for BRDRs and carefully calibrate legal effects of non-compliance.

- A prior art cooperation mechanism could allow contributions from provider countries and indigenous groups (including from GR and TK databases) on prior art to IP offices in user countries, but would require incorporation in their examination procedures.
- BRDRs, databases, and prior art contributions are complementary and mutually supportive measures. A rights-based approach to GR and TK databases in the IGC could provide a positive as well as defensive role. There is a need to discuss whether databases could have not only declarative effects but also constitutive ones in relation to certain aspects of protection (i.e. confidential information and original organization of contents/expressions).
- Countries without the capacity to adequately implement ABS or BRDR systems might consider a horizontal biodiversity conservation tax on biodiversity-derived products and inventions. This tax could be low and exempt companies contributing to the Global Multilateral Benefit Sharing Mechanism.
- While a binding instrument is favourable, soft law solutions should not be ruled out provided they address concerns effectively.

#### Further research

- Better data is needed on the number and content of ABS contracts. This could be gathered by setting up a notification and database system through the CBD Clearing-House Mechanism.
- An independent commission on biopiracy and misappropriation (along the lines of the UK Commission on IPRs) could make an important contribution to the debate.
- Additional research on practical national experiences of BRDRs is urgently needed, which could be undertaken by IGC members directly or requested of the WIPO secretariat.

## 1. INTRODUCTION

The origin of the Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC) goes back to the negotiations and diplomatic conference that led to the adoption of the Patent Law Treaty (PLT) in 2000. At the time, Colombia presented a submission,<sup>1</sup> later supported by various members of the Group of Latin American and Caribbean Countries (GRULAC), in the World Intellectual Property Organization's (WIPO) Standing Committee on Patents (SCP) seeking to ensure that industrial property protection guaranteed the protection of the country's biological and genetic heritage. This proposal highlighted for the first time in WIPO that the granting and registration of relevant patents should be subject to the legal acquisition of genetic resources (GRs) and that patent applications should mention the registration number of the contract affording access to GRs by the country of origin. Several developed country members rejected that proposal in the SCP and the diplomatic conference that finally adopted the PLT. The main arguments against it were that the SCP was not the right forum for such discussions and that they did not fully understand the intent and purpose of the submission. In order to avoid a political impasse, and after various bilateral and regional grouping negotiations, a deal was struck by which Colombia would withdraw its proposal in exchange for the creation of a governmental body that would broadly address intellectual property (IP) issues that arise in the context of access to GRs and benefit-sharing.

Later on in the context of the twenty-sixth session of the WIPO General Assembly of 2000, and as a consequence of a GRULAC submission titled "traditional knowledge and the need to give it adequate intellectual property protection",<sup>2</sup> the mandate of a newly created body, namely the IGC, was adopted and extended so as to also include the protection of traditional knowledge (TK) and expressions of folklore.

Since its inception, the IGC has proven to be an open forum for discussion on the concerns expressed by biodiversity-rich countries and TK holders in relation to the IP system. It has generated a much higher level of awareness of key concerns and solutions proposed. The IGC has also generated a significant amount of research and analysis in the form of fact-finding missions, technical studies and toolkits (e.g. toolkit for TK documentation). It has further allowed for the introduction of technical reforms, such as the inclusion of some TK journals within the Patent Cooperation Treaty (PCT) minimum documentation, and the integration of TK classification tools and technical standards for TK documentation in order to contribute to the defensive protection of GRs and TK. The IGC has also provided guidance on IP-related clauses in access and benefit-sharing (ABS) agreements. Contributions have also been made through a series of documents that could culminate in an international instrument(s) such as a list of principles and objectives on GRs and draft articles on TK and Traditional Cultural Expressions (TCEs).

Nevertheless, even if advances have been made, the normative outcomes of the IGC seem to be quite modest compared to the actual expectations of *demandeurs* and the level of investment made so far. There are several reasons for this. The first reason is that while the objectives of avoiding the granting of erroneous patents and other IP titles and of improving examination quality have received significant attention, another important objective, which is to ensure that those using genetic information or associated traditional knowledge (ATK) in patent applications comply with national ABS legislation in the country of origin, has been fiercely resisted. Second, the level of disagreement and to some extent the mistrust on these issues between different actors (including user and provider countries as well as indigenous peoples and business groups) remains high, leaving little space for bridging proposals that would make the IP system more responsive to sustainable and equitable imperatives.

The third reason is that there were and still are several international processes dealing with similar issues. These processes include discussions on the relationship between the World Trade Organization's (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) and the Convention on Biological Diversity (CBD) taking place at the WTO and the negotiations that led to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization. This has made forum management and the generation of coherent policy outcomes more challenging, bearing in mind the varying policy dynamics in the respective forums.

Overall, in all related discussions, the main question remains: to what extent the IP system can introduce effective measures to support the objectives, principles and specific obligations under the CBD, and more recently the Nagoya Protocol, as well as national implementing legislation. This protracted debate, not only in WIPO but also in the WTO, the Conference of the Parties (COP) of the CBD, the Food and Agriculture Organization (FAO), and also recently under the World Health Organization (WHO) Meeting on Pandemic Influenza Preparedness, shows that the interface between intellectual property, genetic resources and associated traditional knowledge has complex ramifications. The debate is part of an international exercise of coherence where full international recognition and protection of several layers of rights, which go from basic sovereign rights over GRs to collective and customary rights of TK holders, is still in the making.

In order to provide relevant stakeholders participating in the IGC with a deeper understanding of existing and additional policy options, this study provides a critical review of the key issues at stake and proposes options for the defensive protection of GRs and ATK while ensuring that benefit-sharing arises from their utilization. The study also discusses recent policy trends, the implications of several measures proposed within the draft objectives and principles applicable to GRs and ATK, and a set of additional complementary measures that could assist WIPO members in advancing benefit-sharing objectives under the CBD and the Nagoya Protocol.

With the aim of further advancing the IGC process and bridging differences among parties, the study makes various proposals on processes, content and research gaps. The task of reaching consensus on the complex issues before the IGC is neither simple nor without risks, as it implies the need for stakeholders to depart from their traditional and sometimes dogmatic positions, among others.

In circumscribing the analysis to GRs-related questions, the paper does not address issues related to the positive protection of TK and Traditional Cultural Expressions (TCEs) being considered under the IGC due to their different natures and levels of complexity.

For the purposes of this paper, *user countries* refer to countries where "utilization" takes place in light of the Nagoya Protocol. *Provider countries* refer to countries where GRs are found *in situ*. It is important to note that in many cases countries can be both providers and users.<sup>3</sup>

## 2. THE EVOLVING INTERFACE BETWEEN GENETIC RESOURCES, ASSOCIATED TRADITIONAL KNOWLEDGE AND INTELLECTUAL PROPERTY

### 2.1 Revisiting the Economic Value of GRs

The debate on GRs, ATK and IP has emerged as a consequence of both an increased recognition of their economic value and a series of judicial decisions and laws that enabled the patenting and protection of life forms, allowing the capture and addition of value to those resources and knowledge through a series of technologies.<sup>4</sup> The potential economic value of GRs has been central to the IP-related debate and there are several estimates regarding the economic value of their utilization. In general terms, biodiversity provides a great range of ecosystem services, such as local water, food provision, materials for sustaining livelihoods and climate regulation. For example, it has been estimated that conserving forests avoids greenhouse gas emissions worth about USD 3.7 trillion.<sup>5</sup> Early estimates indicated that the value of products derived from GRs worldwide was USD 500-800 billion.<sup>6</sup> During the period 2002-03, about four-fifths of new chemicals introduced globally were derived from natural products.<sup>7</sup> More recent estimates indicate that three-quarters of the world's population depend on natural traditional medicines and that approximately half of synthetic drugs have a natural origin, including 10 of the 25 highest selling drugs in the United States (US).<sup>8</sup> So it is clear that GRs linked to ATK can in many cases reduce R&D costs and prove to be essential inputs in product development. There is also a great range of both economic and non-economic values attached to biodiversity, such as cultural values embodied in TK and practices that allow many indigenous and local communities to survive.

In practice, it has been extremely problematic for provider countries to capture the economic value of their GRs due to their intangible nature, wide variety and difficulties in controlling them outside national jurisdictions. Also, there seems not to be yet clear markets for GRs and when they exist they are highly imperfect.<sup>9</sup>

In addition, many estimates have been subject to over-expectation as to the capacity to extract value from domestic GRs, especially from bioprospecting.<sup>10</sup> For example, thus far, bioprospecting activities have not generated significant revenues for provider countries.<sup>11</sup> One reason for this is that a considerable part of the added value in bioprospecting projects accrues outside the country where it takes place.<sup>12</sup>

In this regard, it has been proposed that for the purposes of benefit-sharing, it could be more effective to base economic expectations on the potential commercial value of individual GRs,<sup>13</sup> focusing on and monitoring those that have the highest potential. This situation also points to the need for provider countries to add value to their own GRs through biotechnology and other technological developments in order to ensure that original value is effectively captured, reduce asymmetries in potential research and development (R&D) partnerships, and develop useful products and processes. When GRs are accompanied by ATK, the potential value is higher as indigenous and traditional communities have already found practical applications and uses that have maintained and evolved over generations.

One of the big difficulties for provider countries in seeking to generate value from their GRs has been how to ensure control when genetic information travels with biological resources and such movement could have occurred at different times (e.g. before or after the signature of the CBD in 1993). The fact that biological materials move does not mean that the utilization of genetic information contained in those materials has been authorized. Many industries intensive in GRs are still not used to questioning where, when and from whom they obtained a particular sample when undertaking R&D-related cooperation activities, even if they keep records about them. In some cases they are not even aware that the use they are giving



to biological materials implies a utilization of GRs. Asserting rights over GRs in cross-border activities and in other jurisdictions has become an important objective for provider countries in international ABS and IP-related negotiations. The same is occurring on the side of ATK-holders but with a broader remit as to the rights they want to be guaranteed. After the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing arising out of their Utilization (2002) and the Nagoya Protocol (2010), the recognition that ABS systems need to be developed and implemented in provider countries, but also supported in user countries, has become clearer.

## 2.2. Patents, Biopiracy and Misappropriation

One of the reasons that patent filing and granting have become sources of debate is that in many cases, and due to the nature and description of an invention, it becomes evident that there has been access to and utilization of GRs originating from other countries and/or ATK from an indigenous or local community. The question is whether this access and utilization has fulfilled national ABS and/or TK legislation. When looking at most cases reported, the response is in most cases negative. To this problem, we would also have to add the aggravating factor that IP may grant rights over genetic materials or components that are already subject to sovereign rights or the rights of indigenous and traditional communities. In these situations the concept of "biopiracy" has emerged as a vehicle to explain this phenomenon.

Reports on biopiracy cases continue to surface, with different levels of intensity and notoriety, from media sources, non-governmental organizations (NGOs) and individual reporting. The concept has proven to be useful for campaigning purposes but has not provided much clarity in the GR, TK and IP debate. The term "biopiracy" was coined by the North American advocacy group, Action Group on Erosion, Technology and

Concentration (ETC Group) - formerly known as Rural Advancement Foundation International - to refer to the uncompensated commercial use of biological resources or ATK from developing countries, as well as the patenting by corporations of claimed inventions based on such resources or knowledge.<sup>14</sup> Dutfield (2003) compiled a list of potential biopiracy actions regarding GRs and TK that illustrates some of the common situations.<sup>15</sup> Correa and Sarnoff (2006) have provided more precise legal definitions by considering biopiracy to mean obtaining access to genetic resources without authorization, and added the concept of "misappropriation" meaning the use of GRs in violation of access conditions and/or deriving benefits from GRs without equitable benefit-sharing.<sup>16</sup> These definitions can also, to a certain extent, be applied to ATK when accessed and used without authorization but with the difference that ATK implies an intellectual value addition that could have more important implications in a patentability examination. While not mentioned in these definitions, biopiracy also has important cultural and ethical implications as reported cases of problematic patents generate a great deal of controversy and a sense of inequity and indignation in provider countries and their indigenous and local communities.

Robinson (2010) has proposed a wider but simple categorization of biopiracy that could be used to understand different practical situations, including:

- a) Patent-based biopiracy, which applies mostly to cases of the patenting of inventions based on biological resources and ATK without authority;
- b) Non-patent biopiracy, which applies to other types of IP control of biological resources and TK, including plant breeders' rights and trademarks; and
- c) "Misappropriation", which implies the appropriation of the value and extraction of biological resources or TK without benefit-sharing.<sup>17</sup>

To this latter categorization we can add the concept of “misuse”, which refers to situations where utilization has gone beyond the access conditions and mutually agreed terms (MAT), e.g. requesting a patent or entering into commercialization when the access conditions and MAT only apply to non-commercial research. Additionally, the concept of “biofraud” has been used to define situations where the conditions of ABS arrangements bring very low monetary or non-monetary benefits.<sup>18</sup>

Most of the content of what could be termed biopiracy and misappropriation has been

illustrated by reported cases. Not all the cases are the same, have the same clarity, or have been addressed in the same manner. Neither can all cases be fully considered biopiracy, as access rules were not in place in several jurisdictions at the time of access. There have been dozens of high profile cases of potential and actual biopiracy and/or misappropriation over the last 20 years, including açai, ayahuasca, Artemisia judaica, basmati rice, Hawaiian taro, jamu, Kwao Krua, neem, numa bean, maca, Sacha Inchi, turmeric and Plao-noi.<sup>19</sup> In order to provide some illustrative examples, Box 1 describes some relatively recent cases and some lessons learned from them.

**Box 1. Illustrative cases of alleged patent- and breeders’ rights-related biopiracy and/or misappropriation**

**Yellow “Enola” bean**

In some cases and jurisdictions, revocation of patents due to lack of the fulfilment of patentability criteria has occurred. A recent example is the nullification of a patent on the **yellow Enola bean** (US Patent 5’894’079) by the US Court of Appeals (2009) on the grounds that the patent did not fulfil the criterion of non-obviousness. However, this only occurred after more than 10 years of litigation that was financed and supported by the International Centre for Tropical Agriculture. Since in this case the litigation focused on whether the patent fulfilled the patentability criteria, important questions, such as whether the patent applicant had authorization or an access contract/material transfer agreement could not be raised. During the period of litigation, the holder of the patent maintained a monopoly, which allowed him to exert his power over farmers and bean importers and exporters through countless lawsuits, threats and customs inspections. And despite these obvious abuses resulting in significant losses for farmers, there was no compensation. This type of situation shows that revocation in foreign jurisdictions can occur but only when effective action is taken by relevant stakeholders, placing the burden on those that consider the current level of patent examination and information available in the hands of examiners to be insufficient. Revocation actions also tend to be very expensive and not all actors or countries can undertake it. That is why invalidation or revocation actions initiated have been limited.

**Hoodia**

The South African Council for Scientific and Industrial Research (CSIR) filed a patent application for Hoodia gordonii as an appetite suppressant in 1995 (patent number 983170). A specific group of the San people in Southern Africa has been known to traditionally use hoodia as an appetite suppressant during long hunting trips. There is also ethnobotanical documentation on hoodia dating back to the 17th century. In 1998, CSIR signed an exclusive licensing agreement with a UK company, Phytopharm, and filed additional patents in other countries. After several waves of criticism from indigenous peoples and NGOs, CSIR responded by negotiating an *ex post* access/license memorandum of understanding in 2001 and by establishing a “San Hoodia Benefit Sharing Trust” in 2003. Later, Phytopharm engaged in joint development agreements with Unilever to develop active ingredients from the plant.

CSIR made some milestone payments to the trust fund, as licensed companies undertaking the research were about to release the clinical trial results from hoodia-derived products. However, Unilever recently pulled out of the agreements, as results of transferring the properties of hoodia into final products were not as promising as expected in 2008. As a consequence, shares in Phytopharm plunged in 2009, making clear the link between the need to have patents over certain profitable products and companies' financial sustainability. This case makes evident the difficulty of implementing ABS regulations in practice, the importance and challenges of obtaining prior informed consent (PIC) from indigenous communities by both national and foreign institutions, and the possibility of undertaking *ex post* access agreements to restore legality. It also shows that not all biodiversity-derived products will ultimately end in fully profitable marketable products and that there are always risks involved in R&D activities when trying to develop a commercial product. Also, a resulting "hoodia craze" has nearly led to the extinction of the plant in certain parts of the Kalahari - showing that the link between benefit-sharing and conservation and sustainable use does not automatically fall into place but also has to be managed.

#### **"TAM" mild habanero pepper**

A recent case of potential biopiracy and/or misappropriation has been identified in relation to the US Plant Variety Protection Office's issuing a certificate (number 200400329) to the Texas Agricultural Experiment Station, part of Texas A&M University (TAM), for the 'TAM Mild Habanero Pepper' in 2007. The main biopiracy concern in this case is that the pepper (*Capsicum chinense*) cultivar was bred from a cross between an orange habanero pepper from the Yucatán Peninsula and a pepper from a US Department of Agriculture (USDA) gene bank (PI 543188) collected from Bolivia. Due to the mildness of the tam mild habanero pepper, the breeder has indicated their excitement about the possibility of selling them to salsa companies and as a fresh product at USD 3-4 per pound; while the comparable jalapenos peppers fetch around 50 cents per pound. Despite tampering in Texan laboratories, much of the uniqueness of this mild habanero can likely be put down to the variety collected in Bolivia. There are long lists of documenting and archaeological evidence that indicate the extent of breeding and use of cultivars of the *Capsicum chinense* species, including the habanero pepper in South and Central America since 2000 BC.

The US Genetic Resources Information Network database record indicates that the original variety is 'not piquant' and that it is 'said to be grown locally' in Bolivia. A USDA official purchased the original variety from a Brazilian vendor in the Cobija market of Nicolas Suarez Province (Pando Department), which borders Brazil, on 13 November 1988. The plant material was then transferred to the USDA Plant Genetic Resources Conservation Unit in Georgia where the Texan breeders appear to have obtained the germplasm (PI 543188). This case raises concerns over how some germplasm has been collected, stocked and distributed without the existence of authorization from the country of origin, especially by institutions that should be fully aware of rights over those materials and international process and regulations on the matter. As of yet there has not been national or international action but the Permanent Mission of Plurinational State Bolivia to the UN in Geneva has been notified of the case and an investigation of relevant facts seems to be underway.

Besides these illustrative cases, there are situations where a significant number of patents and a wide range of claims within them are linked to the utilization of particular GRs or ATK, as shown in the Peruvian submission to the IGC on potential cases of biopiracy.<sup>20</sup> In this submission, Peru identified a number of patent applications and claims linked to inventions utilizing Peruvian GRs such as Camu Camu, Hercampuri, Yacon, Caigua and Chancapiedra. The submission contains detailed information about the number of patents, where they have been filed and in providing relevant information on prior art that could defeat some of the patents and claims. Several of these patent applications have ultimately been abandoned, withdrawn or rejected as a consequence of action by relevant Peruvian authorities (see Box 3, *infra*, on the recent experience of Peru's National Commission Against Biopiracy).

In response to this submission, a recent communication by the Biotechnology Industry Organization (BIO) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)<sup>21</sup> to the IGC stated, "the resources at issue in [the Peruvian submission] were made widely and freely available by sources in Peru at that time. It is likely then, that the uses at issue resulted from materials obtained through legitimate channels of commerce with no restrictions". This statement shows some confusion with regard to the distinction between different uses of GRs in the context of ABS regulations. Genetic resources can be made available and sold as commodities for construction or food use (e.g. export of timber or tropical fruits) outside ABS regimes but this does not mean that those commodities can be utilized for purposes of R&D without the authorization of the competent authority and/or from TK holders when there is ATK involved. In this regard, it is important to note that this differentiation is clear in Decision 391 of the Andean Community (1996) with regards to setting rules for access to GR and ATK. Along the same lines, Decision 391 requires the existence of access contracts and/or ATK licenses before GRs or ATK can be accessed

or utilized. More specifically, complementary provision number four of Decision 391 stipulates that health certificates for the export of biological resources must indicate that "use of this product as a genetic resource is not authorized".

Clear statistics on biopiracy and misappropriation do not exist but compilations of selected cases prepared by different NGOs and research centres are available and often updated. For example, a report by two research centres<sup>22</sup> recorded 36 cases of potential biopiracy cases in Africa up to 2006, including 12 cases related to medicine, six to cosmetics, seven in agriculture and another six in other biotechnology applications. These types of reports are becoming very specific on the GRs in question, their utilization, patents requested and filing place.

It should be noted that, regarding reported cases of potential or actual biopiracy, ABS contracts and material transfer agreements by competent authorities have rarely been presented as legal or political defences by IP applicants. In this regard, it seems that besides the issue of erroneous patents, the lack of benefit arrangements is widely spread in cases reported so far. So claims over the lack of benefit-sharing arrangements seem to be solid unless IP applicants in those cases start showing evidence to the contrary.

The need for more accurate information on cases and statistics over the last 20 years is becoming an imperative in order to make clearer affirmations and evaluate the actual size of the problem. In this regard, it is recommended that an independent commission (e.g. the UK Commission on IPRs) prepare a **factual report on the state of GR and ATK biopiracy and misappropriation** based on the best information available. To be useful, this report should not only look at the fulfilment of patentability and other IP criteria in selected cases but also address the problem of the lack of authorization, access contracts and benefit-sharing in light of the CBD, the Bonn Guidelines and the Nagoya Protocol. Such a report could

also look at the actual cost of defending GRs and ATK in foreign jurisdictions, as well as benefits not received as a consequence of the lack of ABS arrangements in IP filings and commercialization.

When considering possible solutions to address cases of biopiracy and misappropriation, one alternative could be to take a two-fold approach. The first aspect of the problem is **low patent quality, insufficient patent examination and the granting of so-called "erroneous patents"** in cases where GRs and ATK have been accessed and utilized. The second aspect is **the need to verify and comply with national ABS legislation, CBD and Nagoya Protocol requirements including PIC, the existence of MAT and other benefit-sharing arrangements in relevant IP filing and granting.** These two aspects of the problem have been incorporated in different manners in IGC documents on draft objectives and principles relating to IP and GRs and future options, which will be discussed in more detail in the following sections.

User countries and business groups<sup>23</sup> in the IGC are becoming more sensitive to concerns regarding erroneous patents and insufficient patent examination. Situations where patents are granted for products of nature or where inventions are not new or do not encompass an inventive step do not seem to be part of an effective innovation policy or provide a good image on the functioning of the patent system. However, the same level of interest

is not necessarily shared with respect to situations, seemingly, of low quality patents, such as the patentability of discoveries or the simple isolation of biological components.

Also, the proposals on extended disclosure requirements raised in relevant patent harmonization processes at WIPO,<sup>24</sup> and the momentum gained in TRIPS Council discussions and negotiations on disclosure requirements, have generated awareness of the need to find solutions to these concerns. It could even be said that addressing erroneous patents and insufficient patent examination might be the main objective that some user countries and business groups are ready to address in IGC negotiations. Some political will to address this aspect of the problem does not mean, however, that there is an agreement on common technical solutions.

There is an important level of resistance regarding **the need to ensure the existence of PIC, MAT and benefit-sharing arrangements in IP filing and granting.** The main reasons for such a resistance are suspicions that these types of requirements can generate unexpected costs, burdensome procedures, and uncertainties over patents and other IP titles. Resistance to seeking collaboration on the cross-border utilization of GRs leading to IP filing and granting has also made provider countries believe that there must be a much wider utilization of GRs than expected and that the current lack of transparency helps obscure the actual level of utilization.

### 3. KEY POLICY TRENDS IN RELATION TO GRS AND ATK

Biodiversity-rich countries, especially developing ones, have been very interested in realizing the potential benefits that could arise from the ABS provisions in the CBD. Concerns over reported cases of biopiracy and misappropriation, internal and international public opinion, and the need to obtain supportive measures within IP systems have pressed these countries to open several processes and negotiations in multilateral forums and at the regional and bilateral levels. This section will review the evolution of the main commitments, negotiations and discussions related to GRs, ATK and IP in the key international forums, recent regional and bilateral trade agreements, and at the national level.

#### 3.1 Current Level of Implementation of ABS Obligations Under the CBD

The benefit-sharing concept is part of the third objective of the CBD but also a keystone in its implementing construct. More specifically, the ABS mechanism was introduced in the CBD with the assumption that the private sector and the research community - the “users of genetic resources” - would bear the primary burden of benefit-sharing.<sup>25</sup> This assumption is somehow a development of the biodiversity field of Principle 2 (sovereign right to exploit their own resources) and Principle 16 (internalization of environmental costs) of the Rio Declaration on Environment and Development of 1992, as key beneficiaries of GRs should be the ones bearing the cost of conservation measures. Advancing ABS objectives is also supportive of Principles 3 (right to sustainable development), 9 (improving scientific understanding through exchanges of scientific and technological knowledge) and 22 (participation of indigenous peoples) of the Rio Declaration. Implementing effective ABS mechanisms can also be a key instrument for achieving the seventh Millennium Development Goal, which is to ensure environmental sustainability, including by assisting in raising necessary resources to tackle biodiversity loss. Thus, ensuring that benefit-sharing actually

occurs is not only a concern of biodiversity-rich countries and TK holders but also the international community as a whole.

Since the signature of the CBD in 1992, the level of enactment of national ABS legislation and regulations remains relatively low. While 193 parties have ratified the CBD, about 60 countries have adopted ABS regulations, of which half have sufficient administrative capacity and regulations to govern negotiations effectively.<sup>26</sup> None of the countries where major user industries are located have introduced ABS legislation, with the exception of Australia and Norway. The introduction of ABS legislation has mostly occurred in biodiversity-rich developing countries, such as the Andean countries, Brazil, Costa Rica, India, Nepal, Panama, the Philippines, Thailand and South Africa. So at least in terms of geographical scope, it can be affirmed that a significant number of relevant jurisdictions, meaning countries with the highest levels of biodiversity, have adopted ABS regulations. About 20 countries have also incorporated specific laws and provisions to protect TK through a diverse range of options including defensive and positive forms of protection,<sup>27</sup> including Bolivia, China, Costa Rica, Panama, Peru and the Philippines. Also, some developed countries, like Portugal and Italy, have included some forms of protection for certain types of plant and medicinal TK.

Preliminary analyses of the state of implementation of ABS legislation indicate that their level of effectiveness has been modest and that the realization of benefits still needs to be materialized.<sup>28</sup> ABS contracts have been considered as a key instrument for the fulfilment of ABS legislation. There are no statistics on the total number of ABS contracts and/or access to biological resources permits agreed or granted worldwide. In the case of countries where information is available or partially available, their numbers can vary greatly. Table 1 below shows some data found on government websites, in country reports

and in other literature regarding ABS contracts and access permits in a selected number of countries. ABS contracts tend to include access conditions, clauses on benefit-sharing (monetary and non-monetary) and IP clauses. Access permits usually allow sample collection

for taxonomic purposes and sometimes allow for bioprospecting in protected areas. These permits may also include restrictions on sample transfers and benefit-sharing clauses, depending on the potential additional commercial objectives of the activity.

**Table 1. Status of approved ABS contracts and access permits in selected countries (2010)**

Country	Type of authorization	Total number	Non-commercial purposes	Commercial purposes
Australia	Access permits for biological resources	107	106	1
Brazil	ABS contracts	22	N/A	N/A
Bolivia	ABS contracts	1	0	1
Colombia	ABS contracts	41	40	1
Costa Rica	Access permits for GR basic research and bioprospecting	150	135	15
Ethiopia	ABS contract	1	0	1
Mexico	Access with benefit-sharing components	3	Both purposes	
Panama	Access permits	1	1	0
Peru	Bioprospecting/scientific cooperation agreements	1	Both purposes	
	Scientific bioprospecting permits	422	422	0
Philippines	Commercial and academic research agreements	6	N/A	N/A
South Africa	Benefit-sharing agreements	2	1	1
Venezuela	ABS contracts	10	10	0
US	Authorization for bioprospecting	1	1	0

Source: Compiled by the author from: *ABS Capacity Building Development Initiative (2011)*, *Martínez Parra (2011)*, *Australian government, Department of Sustainability (2011)*, *Cabrera (2010)*, *CBD Secretariat (2007)*, *Pastor and Siguenzas (2008)*, *US National Park Service (2006)*, *Velez (2010)* and interviews with governmental officials, academics, research centres and NGOs.

Note: This table does not cover Material Transfer Agreements under the FAO.

Several examples of ABS contracts have also been reported in India, Kenya and even in the US, but total numbers have not been compiled.<sup>29</sup> While the number of ABS contracts and permits granted remains limited, the number of requests to the above-mentioned countries is several times higher. In some cases requests have been abandoned due to a lack of interest, reluctance to provide additional information or the too slow processing of requests. The great majority of contracts and permits granted so far have been for non-commercial

purposes to national research institutions and individual researchers. ABS contracts between corporations and governments have been relatively uncommon, with the exception of Costa Rica, Mexico, Ethiopia and South Africa, where several access permits, benefit-sharing and research agreements have been made with transnational companies such as Merck, Bristol Myers Squibb, Eli Lilly, Sandoz, Givaudan-Roure Fragrances, and small companies such as Dutch Health and Performance Food International. In some countries, ABS

contracts with transnational corporations have never occurred.

In terms of benefits arising from these contracts, the literature and country reports to the COP of the CBD point at the fact that most benefits received under these contracts have been non-monetary, with only a few cases in which lump sum disbursements were agreed.<sup>30</sup> Monetary benefits in the form of lump sums arising from these contracts have gone from around USD 10,000 to about USD 4 million in the best of cases. For example, in Costa Rica, the total income from bioprospecting contracts between 1993 and 2000 was estimated at USD 2.7 million.<sup>31</sup> When royalties have been agreed, rates are usually below 5 per cent of total sales/benefit.<sup>32</sup> In an interesting government-to-government bioprospecting/scientific cooperation agreement between Peru and South Korea on medicinal plants, benefits were distributed on a 50/50 basis.<sup>33</sup> In some other cases the granting of a percentage of the cost of the research was agreed. However, when looking at the type of contracts signed so far, almost all monetary benefits have gone to cover administrative costs, support the participation of local researchers, sample collection and some direct conservation costs. Non-monetary benefits have been more important than monetary ones in many contracts. Non-monetary benefits obtained include the training of scientific personnel, transfer of knowledge, sharing of research results and equipment transfer. Cases where more constructive relations and significant non-monetary benefits have been obtained are those where research and scientific centres with absorptive capacity have been involved on the side of the provider country.

There is a clear need for better information and data regarding ABS contracts. Setting up a **notification system through the CBD Clearing-House Mechanism**, by which all parties should notify a non-confidential extract of subscribed ABS contracts, could be of assistance. This extract could include the scope, biological resources covered, parties to the agreement (including country of origin and the party

requiring access), the date, the profit or non-profit nature of the activity, and whether benefit-sharing arrangements have been agreed. Notified contracts could then be compiled in a **non-confidential ABS online database**.

When looking at the collected sample of ABS contracts in Table 1, one cannot avoid the question of why there are still such a limited number of contracts for commercial purposes. In practice, during the initial implementation phase of the CBD, both national competent authorities and users faced several challenges, including a lack of experience, complex ABS legislation, uneasy relationships with indigenous and local communities, and a level of mistrust and incomplete provision of information. In the view of the author, national competent authorities have faced in this context a number of obstacles such as: insufficient regulatory clarity and administrative experience; low level of administrative capacity to negotiate, implement and monitor contracts; weak inter-institutional coordination; lack of financial and human resources; difficulties in handling political sensitivities with diverse stakeholders; and complaints of insufficient PIC from indigenous communities.

The main cause of these difficulties was that the ABS provisions in the CBD were the result of a top-bottom approach and not of the consolidation at the multilateral level of state practice. By 1993 there were no comprehensive ABS systems for GRs in place and/or operational at the national level. At that time most countries would just grant permits for bioprospecting or research in protected areas without including benefit-sharing clauses. So parties to the CBD had to find the most suitable way to implement ABS provisions without much experience or legal precedent. However, based on practice and the evolution of the last 18 years, it could be affirmed that a great deal of experience has been gained, especially on ABS contracts and permits for non-commercial purposes. In interviews with national experts, it was affirmed that requests for ABS contracts are being much better managed and answered



by national authorities, especially among the most active countries. They also indicated that the stance of national authorities is changing towards a more cooperative and investment-driven one.

On the user side, problems relate to some level of resistance towards the use of ABS regimes and low engagement in direct bioprospecting activities, as they might be using GRs already stocked in their own private collections or acquired from intermediaries (e.g. botanical gardens or from providers of biological resources for direct consumption). Some industries may also be acquiring samples or derivatives from R&D centres in provider countries without entering into negotiations with the competent authorities. This latter type of outsourcing model may be based in some cases on framework agreements between the national R&D centre and national competent authorities; but in other cases R&D centres may not be authorized to transfer such samples. Many companies have also been reluctant to enter into ABS agreements as they may consider some national ABS regulations too burdensome, unclear or inconsistent with their R&D models and timeframes.

This relatively low level of implementation of ABS objectives, the limited number of ABS contracts and the need to improve legal certainty, clarity and cross-border cooperation from providers and user countries has led to a series of policy and legal developments, including the adoption of the Bonn Guidelines and the Nagoya Protocol.

These reflections on ABS implementation raise several questions that could have an impact on the IGC, including:

- Why is there a dichotomy between the policy priority given at the national level to advancing ABS objectives and the international process? Could this be attributed to the continuous push towards higher levels of IP protection in general?;
- What is the actual level of effectiveness of national ABS systems and how can IP

contribute to improving such effectiveness? How can the complementary options among proposals already on the table in the IGC, or additional proposals, be of assistance?;

- To what extent is the current use of GRs for commercial purposes actually based on authorized access? If the number of contracts is so low, it is probable that in many cases access to GRs *in situ* after 1993 was not authorized by competent authorities.

### 3.2 The Impact of the Nagoya Protocol

The Nagoya Protocol represents a fundamentally new piece of an increasingly complex multilateral system governing the rights over, access to and utilization of GRs and ATK. It is the result of more than eight years of negotiations under the CBD COP seeking to fulfil the mandate of the World Summit on Sustainable Development (2002), which called for the establishment of an international regime on benefit-sharing. The objectives of the Protocol are the fair and equitable sharing of the benefits arising from the utilization of GRs, including by appropriate access and transfer of technology, thereby contributing to the conservation and sustainable use of biodiversity. The Protocol is not intended to expand the scope of the CBD but to further develop its provisions, notably Article 15 of the CBD dealing with PIC and benefit-sharing obligations. Therefore, it may be argued that the Protocol does not create an independent legal framework but is rather an agreed interpretation, adaptation and further development of the ABS obligations under the CBD.<sup>34</sup>

The primary impact of the Nagoya Protocol will be on national ABS legislation but also on the development of a series of new multilateral mechanisms. At the time of writing, about 63 countries had signed the Protocol;<sup>35</sup> it needs fifty ratifications before entering into force. According to the CBD Aichi Biodiversity Target 16, it is expected that “by 2015, the Nagoya Protocol on Access to Genetic Resources and the

Fair and Equitable Sharing of Benefits Arising from their Utilization is in force and operational, consistent with national legislation”.<sup>36</sup>

While the Protocol is quite comprehensive, its main effects will be felt in terms of the generation of new definitions, clearer standards for access and benefit-sharing, obligations on providers and users, measures to address legal access across borders, and monitoring, cooperation and enforcement mechanisms. The new standards imply important implementation challenges in terms of regulatory and institutional reforms by biodiversity authorities, and also indirectly by trade authorities and IP offices.

### 3.2.1 New definitions

The Nagoya Protocol defines several key terms, such as “utilization” of GRs, “biotechnology”, and “derivatives”.<sup>37</sup> To a certain extent, these definitions set the scope of the application of the Protocol. Utilization is a fundamental definition in the Protocol, as the type of use is what triggers the Protocol’s application. “Utilization” means to conduct R&D on genetic and/or biochemical compositions, including through the application of biotechnology. R&D activities can be quite wide in today’s knowledge-intensive world and can lead to IP applications and commercialization depending on the case. The CBD’s definition of “biotechnology” has been repeated in the Nagoya Protocol and includes any technological application that uses biological systems, living organisms or “derivatives” thereof.

The Protocol’s definition of the utilization of GRs addresses the issue of what constitutes access based on the physical composition and the intended use of GRs. Accessing any samples of biological origin containing “functional units of heredity” needs to follow the Nagoya rules. Such samples can be whole organisms, parts of organisms, powders or raw extracts.

“Biochemical compounds” can be defined as any chemical compound naturally occurring in living organisms. Biochemical compounds may be utilized without separation from the biological resource to which it belongs (e.g. dried plants)

or isolated and even synthesized. Currently available R&D techniques allow researchers to precisely detect, isolate and structurally characterize bioactive natural compounds. This term has been considered wide enough to end the dispute over whether only the intended use of genes (“functional heredity units”)<sup>38</sup> would trigger the Nagoya obligations, or if the intended use of biochemicals, as another component of biological samples, also obliges the user to follow Nagoya standards. In this regard, the subject matter has been clarified with the understanding that “genetic material”, which is defined by Article 2 of the CBD as biological material that contain “functional units of heredity” (such as nucleic acid sequences and genes), also encompass “biochemical compounds” (such as natural proteins, e.g. enzymes, and metabolites, e.g. vitamins).

The Protocol defines “derivatives” as naturally occurring biochemical compounds resulting from the genetic expression or metabolism of biological or genetic resources.<sup>39</sup> In the field of chemistry, the term derivative comprises various semi-industrial products, such as chemically-altered natural compounds, extracts and essential oils. In cases where access is sought for extracts purified to such an extent that they no longer contain any “functional units of heredity”, there is no consensus yet among experts interviewed over whether they would be governed by the access rules under the Protocol. The incorporation of the definition of “derivatives” and its effects on the interpretation of other provisions in the Protocol has been highly controversial due to several ambiguities in the text.

While the term “derivative” is not found anywhere else in the Nagoya Protocol, the cumulative interpretations of all these definitions tend to generate a quite expansive interpretative effect, as it becomes highly improbable to arrive at a derivative, as defined by the Protocol, without engaging in R&D on genetic material. These provisions are of specific importance for the interpretation of Article 5.1 of the Nagoya Protocol on benefit-sharing

that includes the “subsequent applications and commercialization of GRs”, which is actually in many cases based on the use of derivatives (e.g. in phytopharmaceuticals, cosmetics and nutraceuticals). “Subsequent applications and commercialization” can of course also be based on using derivatives in the understanding of chemical sciences. In such a case it will be for national ABS legislation or CBD COP decisions to further define and clarify the issue.

For example, the Union of Ethical Biotraders<sup>40</sup> has already indicated that for companies working with biodiversity-based ingredients for food and personal care products, perhaps the most important development in the Nagoya Protocol is the clear incorporation of its activities into the scope of ABS requirements.<sup>41</sup> Research conducted on the biochemical composition of plants to determine beneficial properties, as well as the subsequent development and commercialization of bioactive compounds as ingredients, has also been considered a “utilization” of GRs.<sup>42</sup> For future parties to the Nagoya Protocol, it is also important to note that it does not preclude the right of states to go further and incorporate all these items and definitions (GRs, biochemical and derivatives) as part of the scope of their national ABS legislation.

For the purposes of the IGC, the incorporation in the Glossary of Key Terms related to IP and GRs<sup>43</sup> of references to the definitions found in the Nagoya Protocol should not be a problem for most WIPO members. The incorporation of these definitions is totally coherent since the Protocol is completely relevant for the matter in question and is also a UN treaty. The glossary of terms so far is a compilation of existing definitions by the WIPO secretariat for informational purposes. So their incorporation does not prejudge outcomes in the IGC and only seeks to inform the debate. Also, a potential incorporation of these definitions can provide additional legal certainty as to the scope of a future instrument(s) on GRs under the IGC. However, they have not yet been included. One reason could be that the Protocol has not yet entered into force. Another could be that some

members feel uncomfortable with such legal certainty. Recently, the IGC's Group of Like Minded Countries (GLMC) proposed the inclusion of several definitions (i.e. ATK, derivatives, genetic material, GRs and utilization) in the draft principles, objectives, and articles for GR protection.<sup>44</sup> Definitions found in the Nagoya Protocol should be taken into consideration in negotiations on the IGC draft texts, in order to avoid the duplication of work and contradictory outcomes.

### 3.2.2 Clearer standards for access and benefit-sharing

Due to difficulties found by both users and providers in making use of ABS mechanisms at the national level, the Nagoya Protocol has incorporated a series of provisions to facilitate and make these regulations clearer. In this regard, parties to the Protocol shall provide for legal certainty, clarity and transparency in their domestic ABS legislation, fair and non-arbitrary rules and procedures on access to GRs, and information on how to apply for prior informed consent.<sup>45</sup> Many user countries have continuously reiterated the need for these new standards in a multilateral ABS agreement.

It has been argued that such new multilateral standards would curtail the policy space to define ABS regulations. However, when looking at practical difficulties found in applying ABS legislation, there is a need to improve legal certainty and effectiveness. Also, fair and non-arbitrary rules are basic principles linked to due process so they should not be difficult to incorporate. It should also be noted that the term “non-arbitrary” does not imply a national treatment obligation, so provider countries can still set friendlier or fast-track procedures for nationals. The clearer the regulations are, the easier it is for users to fulfil them and therefore engage in legal access and, hopefully, more benefit-sharing.

### 3.2.3 Raising the level of ATK protection

The treatment of ATK in the Nagoya Protocol goes beyond the CBD in terms of scope and content. The CBD only required the

respect, preservation and maintenance of TK innovation and practices of indigenous and local communities.<sup>46</sup> The Protocol requires parties, according to domestic law and taking into account customary laws and community protocols, to take measures to ensure that ATK is accessed with PIC or approval and involvement of those communities, and that MAT is established.<sup>47</sup>

This obligation puts ATK at a similar level to GRs. However, it should be noted that without legal development at the national level it would be difficult to claim rights. The use of terms such as “PIC” or “approval” may imply the application of different standards. Traditionally, the legal interpretation of PIC under international human rights law and labour law practice is a higher standard. In this regard, PIC should in principle include information sessions, discussions on conditions and terms with relevant institutions or authorities, record keeping, and final approval. Also, depending on the case there may be a need to follow customary law procedures of the community in question.

Official interpretations of several international instruments, including the Convention on the Elimination of Racial Discrimination, the Inter-American Convention on Human Rights, and the International Covenant on Economic, Social and Cultural Rights, indicate that PIC of indigenous peoples is central to effectuating rights within these conventions, including the right to non-discrimination and the right to property.<sup>48</sup> An interesting recent example of the application of PIC regarding regulatory changes applicable to IP and TK is the response from the Costa Rican Constitutional Court (2008) to a consultation by several congressmen regarding an amendment to a draft biodiversity law.<sup>49</sup> The draft amendment excluded from patent protection “inventions derived primarily from associated knowledge, biological practices or in the public domain”. The court declared that the proposed amendment was unconstitutional, as the free trade agreement (FTA) with the US in the Dominican Republic - Central America Free Trade Agreement (DR-CAFTA) does

not allow such an exclusion, and that it was necessary to clearly establish the possibility of patenting inventions derived from TK as long as the requirements of the patent law were met.<sup>50</sup> The court also indicated in a clarification that such an amendment would directly affect the interests of indigenous peoples. As a result, the amendment must be consulted with indigenous communities and other relevant stakeholders in conformity with the 169 ILO Convention.<sup>51</sup>

### 3.2.4 Obligations of providers and users

According to the Nagoya Protocol, access procedures shall be clear, cost-effective, and provide a reasonable period of time for decision-making. These procedural standards will assist users in gaining confidence that their access requests will be answered. They represent a significant challenge for developing countries but also for the delivery of technical assistance, for which stronger institutional, administrative, and monitoring and enforcement capacities will be needed. If taken seriously, these challenges will assist in making national ABS regulations more effective and address concerns over burdensome procedures. Additional requirements also include the recognition of permits or their equivalent as evidence of PIC, criteria and procedures for the involvement of indigenous and local communities, and clear rules and procedures for requiring and establishing MAT. The lack of clarity regarding PIC and the involvement of indigenous peoples and communities has been one of the main reasons that many access negotiations have failed. More precise rules in this regard will assist those seeking access to evaluate the costs of fulfilling national ABS regulations. Requirements for MAT include the introduction of clauses regarding dispute settlement, terms for benefit-sharing (including in relation to IP), terms for third party use, and changes in intent. Changes in intent will be particularly important due to the fine line, in practical terms, between research for commercial and non-commercial purposes.

One instrument that would facilitate the assessment of legality and legitimacy over access

to and utilization of GRs is the new international certificate of compliance.<sup>52</sup> A permit fulfilling access requirements in Article 6.3(e) of the Nagoya Protocol (evidencing the existence of PIC and the establishment of MAT by a national authority) and notified to the ABS Clearing-House Mechanism constitutes an internationally recognized certificate of compliance (IRCC). This certificate will allow more clarity on the fulfilment of requirements, facilitate the provision of evidence to checkpoints, and allow freer movement of samples within MATs. The adequate implementation of this mechanism will address many of the concerns that user countries and businesses have voiced on the lack of clarity.

Benefits arising from the utilization of GRs as well as subsequent applications and commercialization must be shared with countries of origin. All parties shall take legislative, administrative and policy measures to ensure those benefits are shared.<sup>53</sup> Similar obligations exist for ATK. It can be observed that the Nagoya Protocol has somehow delinked benefit-sharing from access obligations. This would allow single benefit-sharing agreements even if the GRs have already been accessed.<sup>54</sup> Royalties, licensing fees, and the joint ownership of IP rights have explicitly been included in the Annex to the Protocol as monetary benefits. Non-monetary benefits include other relevant aspects, such as sharing the results of R&D, participating in product development, and strengthening capacity for technology transfer. While most benefits received so far under ABS contracts and access permits include mostly non-monetary benefits, there are contractual options to link them with licensing benefits and IP co-ownership.

Provisions on benefit-sharing and compliance are the most important gains for biodiversity-rich countries in the Protocol. Parties shall take appropriate, effective, and proportionate legislative, administrative, and policy measures to make sure that GRs and ATK have been accessed in accordance with PIC and that MAT has been established.<sup>55</sup> These measures could be established in environmental and

biodiversity legislation, in policy frameworks dealing with both public and private research, in IP laws and in trade, in labelling, and in customs regulations. Adopting “appropriate” measures implies that measures taken must be suitable for the particular circumstances. In this regard, measures may be different for GRs and ATK and may vary from sector to sector. “Effective” means that the measures should attain the expected results and “proportional” may be linked to the level of damage produced or benefit obtained from utilization, application, or commercialization. Measures could include the availability of civil damages and administrative sanctions inside and outside the IP system (fines, suspension of procedures, compensation for damages, etc.), but also policy measures such as bilateral cooperation schemes to deal with specific cases. The level of responsibility in cases of non-compliance may vary depending on the individual or enterprise involved. In this regard, obligations of “due care” in relation to the knowledge of the individual and the sizes of the companies should apply. Parties have weak obligations to cooperate in situations of non-compliance and in cases of alleged violations. Nevertheless, if these obligations are taken seriously by complainant parties, they may bring results as user countries may initiate investigations or assist in seeking mutually agreeable solutions.

### 3.2.5 Monitoring, cooperation, and enforcement mechanisms

In order to support compliance measures, parties shall monitor and seek to enhance transparency on the utilization of GRs. One or more checkpoints shall be designated to collect or receive information on compliance with PIC and MAT.<sup>56</sup> The Protocol does not mention what to do with the information but its results seem obvious in that it will be used to ensure compliance with CBD and Nagoya obligations in the transfer and exchange of GRs. How to use, process, and assess the information, as well as any legal consequences, are left to parties for national implementation. Checkpoints will be relevant to all stages of utilization and for benefit-sharing, including in R&D, IP filing,

and commercialization, but this needs to be addressed at the national level. Developing countries should carefully explore options for appointing these checkpoints and clearly set their functions in ABS, TK, IP, and customs procedures.

In the negotiations leading to the Nagoya Protocol there were proposals for an explicit list of checkpoints including patent offices but also biodiversity and customs authorities. Such a list did not make it into the final Nagoya text due to opposing views by some user countries. Nevertheless, proposals for the designation of patent offices as checkpoints have been recently made in the WTO TRIPS Council by developing countries and in recent submissions by the GLMC<sup>57</sup> to the IGC. Such a designation is seen as a concrete opportunity for coherence and mutual supportiveness. For example, linkages between sanitary offices and patent enforcement already exist in some countries in the process for marketing approval of drugs. Therefore, it is not surprising that other authorities seek similar cooperation from IP authorities in advancing other relevant policy objectives.

An innovative idea in the Nagoya Protocol is the Global Multilateral Benefit Sharing Mechanism. This could to a certain extent be inspired by the benefit-sharing model of the FAO International Treaty on Plant Genetic Resources. If finally established, it is supposed to address equitable and fair benefit-sharing in transboundary situations or in cases where it is not possible to grant or obtain PIC.<sup>58</sup> Benefits shared through the mechanism shall be used for conservation purposes and sustainable use. This mechanism has not yet been designed and it up to future CBD COPs to devise its institutional structure and modalities. Such a mechanism can be an important premise for expanding the benefit-sharing base. Once such a mechanism is agreed and put into practice, arguments related to diverse jurisdictions, the lack of control after GRs have left the borders of the country of origin, the impossibility of obtaining PIC retroactively, and the lack of sufficient knowledge on the legality and legitimacy of the

transfer chain would not stand. In the case of inventions that have utilized GRs or ATK, such a mechanism can contribute to easing tensions and finding solutions. The incorporation of incentives and measures to notify utilization and share benefits needs to be effective enough to incentivize voluntary compliance and avoid circumvention.

In summary, new ABS standards in the Nagoya Protocol should generate higher levels of confidence, clarity, and legal certainty for both users and providers. Additional measures to support these new standards in the IP system need to be explored and addressed in ongoing IP negotiations in the IGC, TRIPS Council and even in FTAs.

### **3.3 The Ongoing TRIPS Discussions and the Doha Stalemate**

Since 2001, the TRIPS Council has been examining the relationship between TRIPS and the CBD, as well as the protection of TK and folklore.<sup>59</sup> In doing so, the TRIPS Council has to take into account the provisions of Article 27.3(b) (review of exceptions to patentable subject matter and plant variety protection); Article 71.1 (full TRIPS review); and its work under paragraph 12 of the Declaration dealing with negotiations on implementation issues. The list of Outstanding Implementation Issues includes a text indicating that in the interim - during the Article 27.3(b) review - there should be a suspension on granting patents that do not fulfil Article 15 of the CBD.<sup>60</sup> While there has been a great deal of discussion, several proposals on the table, and various technical documents prepared by the WTO secretariat on the main points raised by members, no outcome has been reached in the TRIPS Council yet.

Several developed countries have continuously indicated that the right forum to address these concerns is not the WTO but the WIPO IGC. The response by various developing countries was that the WTO was a more appropriate forum for dealing with disclosure issues due to the mandatory nature of the TRIPS

Agreement and the availability of a dispute settlement system at the multilateral level. Developing countries have been quite precise in their demands, the central point being a request for the incorporation of a disclosure mechanism for determining the country of origin of any biological material and ATK in patent applications and evidence of PIC and benefit-sharing. This was made clear in 2006, when six countries, including Brazil, India and Peru, proposed amending the TRIPS Agreement to incorporate such disclosure requirements through a new Article 29bis.<sup>61</sup>

At the WTO Mini-Ministerial Conference in July 2008 not much had changed. However, the interests of the European Union (EU), Switzerland and some Eastern European countries in the finalization of negotiations on a multilateral register for Geographical indications (GIs) for wines and spirits, and the extension of the higher level of GI protection to other products, converged with those of countries supporting the introduction of the extended disclosure mechanism in the TRIPS Agreement. A "Draft text on TRIPS negotiation modalities" covering the three issues was presented and supported by a large coalition of more than 110 developing and developed countries. Under this proposal, the three TRIPS issues were to be moved forward as a single undertaking negotiation item in the Doha Round. However, this proposal was strongly rejected by some members who contended that the three issues did not have the same level of mandate and that they were artificially linked. One critic also indicated that the gains for developing countries in this trade-off remain elusive, as benefits for the *demandeurs* of a multilateral GI register and extended protection would have more immediate effects than those arising from a potential disclosure mechanism.<sup>62</sup> However, this proposal showed the importance of the incorporation of a disclosure mechanism in the TRIPS Agreement to many developing countries and their willingness to engage in "trade-offs" if necessary. The fact that the proposal on IP negotiation modalities has not gone further also shows the strength of the principle of consensus in the WTO, even if a

significant coalition is able to identify potential trade-offs.

The Doha negotiations have been subject to repeated setbacks and prospects for successful conclusion seem to be low. Nevertheless, a recent revised proposal in the TRIPS Council on a "Draft Decision to enhance the mutual supportiveness between the TRIPS Agreements and the CBD",<sup>63</sup> by a coalition of certain developing countries from Asia and Latin America plus the African, Caribbean and Pacific (ACP) Group and the Africa Group, reflects the level of constancy of biodiversity-rich countries in pursuing their interests in the Doha Round. The new proposal introduces a more comprehensive mandatory disclosure mechanism that builds on many of the legal outcomes arising from the Nagoya Protocol. Certain aspects of the proposal are not only "TRIPS-plus" but even "Nagoya-plus". Under the new proposal, members would be required to disclose in patent applications the following information:

- a) Providing country (meaning the country of origin of such resources or a country that has acquired the GRs and/or ATK in accordance with the CBD);
- b) The source in the country providing the GRs or ATK; and
- c) Members shall also require that applicants provide a copy of an IRCC.

If an IRCC is not applicable in the providing country, the applicant should provide relevant information regarding compliance with PIC and fair and equitable benefit-sharing as required by the national legislation of the providing country. This proposal covers, for the first time in a developing country proposal, "the source" of GRs and ATK, a concept mostly proposed by Switzerland that includes both country of origin and the immediate provider of the genetic material, which is valuable for determining the legality of the GR transfer chain. However, there is a difference between the Swiss approach and that proposed by the GLMC to the IGC, which includes "source" in

addition to other requirements. Under the Swiss proposal source is an “alternative” and not a “cumulative” concept.

Links to obligations under Article 17 of the Nagoya Protocol to monitor and enhance transparency about the utilization of GRs, including designating effective checkpoints, have been cited as one of the supporting motives in the proposal’s preamble. They point at an incipient linkage between the new protocol and the TRIPS Agreement. Additional measures on enhanced transparency have been included by requiring the publication of the information disclosed, whether at the time of the application or at the granting of the patent.

But the proposal does not end there; it includes for the first time a request for the incorporation of appropriate, effective, and proportionate measures against non-compliance. Precise measures are also proposed in relation to specific situations of non-disclosure, submission of false or fraudulent information in patent applications and, in the case of violation, of national ABS legislation. In these cases, sanctions against a lack of compliance may be administrative, civil, or criminal, such as compensation for damages, fines, and potential revocation of the patent, depending on the particular case.

This latest proposal on a Draft Decision conveys a message of a coherent and evolutionary approach in parallel to the Nagoya Protocol. It incorporates higher levels of ambition, which signifies that the lack of success in negotiations so far is not going to diminish interest. On the contrary, continuous opposition to the disclosure mechanism might be creating incentives to develop a wider defensive protection regime within the IP system. Some of the new elements included in this proposal are also found in the list of options and the text on objectives and principles on GR protection.

The TRIPS Council has so far been considered by developing countries the most suitable forum for introducing an expanded disclosure mechanism due to the enforceability of its

provisions under the WTO dispute settlement system. Switzerland and the EU have in parallel proposed modifying certain PCT regulations.<sup>64</sup> The Swiss proposal seeks to modify certain PCT regulations to “explicitly enable the national patent legislation” to require the declaration of the source of GRs and TK in patent applications. It would allow that disclosure could take place at the national level or later during the international phase of the PCT examination process. Proposals under the PCT have not received broad support, particularly from developing countries, as they leave the introduction of disclosure as merely an option under national law or as part of the international examination phase. Developing countries still consider the WTO to be the principal forum to address this issue. Nevertheless, the current context suggests that *demandeurs* are also starting to propose the introduction of these type of measures in other forums, including the IGC, the CBD COP, and in regional and bilateral FTA negotiations. If a multiforum approach becomes more evident, it might be worth reassessing the value of the IGC and PCT proposals as complementary measures to any potential TRIPS amendment designed to introduce disclosure requirements.

In order to avoid contradictions and differences in scope and content, it is advisable that *demandeurs* in the IGC mirror the language and content of proposals made so far in the WTO in the list of options and in the text on principles and objectives under discussion in the IGC. This will also facilitate moving the level of negotiations on GRs and disclosure mechanisms in the IGC closer to those in the WTO discussions. It could even be argued that the current mandate of the IGC is more specific than the one given by the Doha Declaration in paragraph 19 and 12, as it clearly mandates negotiations on an international instrument(s).

### 3.4 Developments in Bilateral Free Trade Agreements

The incorporation of biodiversity- and TK-related provisions in FTAs is a recent phenomenon that started in the early



2000s. This is the case of FTAs between the Caribbean Forum (Cariforum), Colombia, Peru and Panama with developed country partners including the US, EU and European Free Trade Association (EFTA) countries, as well as Taiwan. Such provisions can also be found in recent FTAs between China and Costa Rica, and Peru and Korea.<sup>65</sup>

The incorporation of these provisions has usually been the consequence of demands by biodiversity- and TK-rich partners in these negotiations (i.e. Colombia, Costa Rica, China, Peru, Panama and Taiwan). However, they did not come for free, especially in the case of FTAs with the US, EU and EFTA. In those cases, biodiversity-related provisions were part of a trade off which included very wide and deep TRIPS-plus agreements. It could even be argued that these agreements are among those offering the highest level of IP protection today.

Biodiversity-related provisions tend to be quite different between FTAs, especially in terms of scope and ambition. Most of the provisions found are of exhortative nature or best endeavour clauses. In all these FTAs there is a general recognition of the importance and value of preserving and protecting GRs and TK but there are few operational provisions to guarantee such protection. In some cases, some binding provisions subject to the dispute settlement section under the particular FTA have been incorporated.

Two biodiversity-TK understandings have been annexed in US FTAs with Peru and Colombia (2006).<sup>66</sup> Understandings attached to a treaty, depending on their content and language, can have an effect on the interpretation of the treaty in question in light of Article 31(2) a of the Vienna Convention of the Law of the Treaties. The understandings attached to the US FTAs with Peru and Colombia recognize the importance of obtaining PIC before accessing GRs, of benefit-sharing arising from the use of GRs and TK, and of the need to promote quality patent examination. Proposals on disclosure were made during the negotiations but they did not make it into the final text, as they were

considered too controversial by the US. These understandings also mention that ABS issues can be adequately addressed through contracts. This latter affirmation has been criticized by civil society actors and several experts, as it does not take into consideration situations where there is no contract and GRs or TK have been accessed and utilized across borders without authorization. They also include a best endeavour clause by which parties will share information that has a bearing on patentability, including information found in accessible databases. This clause could prove useful as it can have an effect on prior art searches and patent examination. However, it remains to be seen how additional information can be provided during examination processes without the national authorities of provider countries or TK holders being made aware of the use of their GRs or TK in patent applications.

The 2008 EU-Cariforum Economic Partnership Agreement (EPA) incorporates an article within its section on IP titled "Genetic Resources, Traditional Knowledge and Folklore". This article recognizes the importance of taking measures to respect, preserve, and maintain TK, as well as the need for a wider application of PIC and benefit-sharing arising from their utilization. This EPA includes for the first time an enabling clause by which:

"Parties may require, as part of the administrative requirements for a patent application concerning an invention that uses biological material, that the applicant identifies the sources of the biological material used by the applicant and described as part of the invention".<sup>67</sup>

This clause, however, does not require the EU to set such an administrative requirement to disclose sources. It just allows parties to consider the introduction of such a requirement within the national context. This is not necessarily negative for Cariforum countries, as most of them have not yet incorporated such a requirement in their own legislation.

The EU's FTA with Colombia and Peru has incorporated a special section on biodiversity-

related provisions within its chapter on IP. In this FTA, provisions related to defensive protection become more precise and binding. It acknowledges the usefulness of requiring the disclosure of the origin or source of GRs and ATK in patent applications, considering that this contributes to transparency about their uses. Furthermore, parties are required to provide, in accordance with their domestic law, applicable effects of any such requirement. This is the first time that an EU FTA requires giving legal effect to disclosure requirements. This obligation would require amending the current EU Directive on Biotechnology (1998) in order to determine such effects.<sup>68</sup> Given a lack of compliance, no effect at all would undermine the objective's mechanism, including increased transparency. Possible effects to be given upon lack of compliance can be diverse and could include consequences in patent law (e.g. non-enforceability of the patent) but also civil, administrative, or criminal sanctions. The effects of a lack of fulfilment should be strong enough to ensure that disclosure and other requirements are respected, transparency is addressed, and compensation is provided when there has been unauthorized access to and utilization of GRs and TK.

The EFTA FTAs with Colombia (2008) and Peru (2010) go even further in their level of commitment. This is not surprising, as both Norway and Switzerland have shown a great deal of support for addressing biodiversity concerns in the IP system by already introducing mandatory disclosure mechanisms of the country of origin or source in their own national legislation. For the first time in an FTA, parties shall require, "according to their own national law, that patent applications contain a declaration of the origin or source of a genetic resource, to which the inventor or the patent applicant has had access".<sup>69</sup> These FTAs also recognize links between the use of GRs in patent applications and access requirements in the CBD by requiring the fulfilment of PIC. These provisions also apply to TK.

This mandatory disclosure requirement is backed with an obligation to provide for

administrative, civil, or criminal sanctions if the inventor or the patent applicant wilfully makes a wrongful or misleading declaration of the origin or source. The agreement does not mention effects within the patent system. The EFTA FTAs with Colombia and Peru also incorporate some benefit-sharing provisions that require parties to take policy, legal and administrative measures, with the aim of facilitating the fulfilment of terms and conditions for access. This type of provision would later be included in the Nagoya Protocol.

In both the EU FTAs and EFTA FTAs, biodiversity-related provisions are subject to the agreements' dispute settlement provisions. Parties might raise specific cases or lack of national implementation of FTA obligations by making use of these procedures. However, it has yet to be seen how effective this will be. So far litigation in FTAs has been quite uncommon, with the exception of NAFTA, where a wide body of jurisprudence already exists.

In the case of the EU FTAs, they are not subject to IP enforcement measures, as they have not been considered an IP category within the FTA.<sup>70</sup> The enforcement provisions explicitly indicate that they only apply to the IP categories linked in the section on general obligations, which incidentally do not include the protection of GRs or TK.

The biodiversity provisions in these FTAs also show different degrees of openness towards the incorporation of specific provisions to protect biodiversity. In the case of both EU and EFTA FTAs, the type of language used and additional measures included so far are supportive of the general objectives of the Nagoya Protocol and could be further developed in current IGC negotiations.

The most direct implication of new biodiversity-related provisions in FTAs for the IGC is that several user countries have already agreed with these types of provisions and they should not oppose, in principle, their incorporation at the multilateral level. Vivas-Eugui and Oliva (2010) provide more details and analysis on this matter.

## 4. THE IGC PROCESS

### 4.1 Mandates, Thematic Approach, and Key Documentation

Two years ago, the WIPO General Assembly adopted a new mandate for the IGC that pointed towards more solid and specific international outcomes. The 2009 mandate indicated that:

“Without prejudice to the work pursued in other forums, the IGC will, continue its work and undertake text-based negotiations with the objective of reaching agreement on a text of an international legal instrument (or instruments), which will ensure the effective protection of GRs, TK and TCEs”.<sup>71</sup>

In this mandate the sentence “to ensure the effective protection of GRs, TK and TCEs” is of great importance. “Protection” in an IP system usually implies granting economic/market rights, which go from protection against unfair competition to exclusive rights. In some cases moral rights can also be recognized. Protection needs to be differentiated from “preservation” which in the case of GRs and TK would imply the conservation of ecosystems and the traditional context. The term “effective” means that the system actually fulfils its purpose (in this case protecting GRs, TK and TCEs) and that there are available means to ensure this protection (usually enforcement measures). The text also mentions an “agreement on a text of an international instrument(s)”. International instruments could include a variety of options, such as binding international treaties but also different sorts of soft law such as understandings, recommendations, guidelines, declarations, and resolutions.

The 2009 mandate led to a higher level of engagement by all parties in the IGC and increased attention to the texts of specific proposals that could end in a binding or at least in a soft law type of instrument. The recent adoption of the Nagoya Protocol has also clarified many aspects of the national and incipient international ABS regime, inspiring some impetus to consolidate outstanding reforms in the IP system in response

to concerns over erroneous patents, the low quality of patent examinations and a lack of benefit-sharing.

The IGC is currently taking a thematic approach to GRs, TK and TCEs. The last three IGC sessions have been dedicated to each of these themes separately. An innovation introduced in 2010 was to hold additional inter-sessional working groups (ISWGs) in order to gather and make comments, observations and proposals regarding draft articles on the table. ISWGs are composed of experts from Geneva permanent missions, relevant ministries, IP offices, business groups, indigenous representatives, and civil society organizations. IGC sessions have been holding the political dialogue and setting the direction of the process while the ISWGs have become a vehicle in which to undertake technical discussions and advance draft texts. The value of the discussions in the ISWGs, in cleaning and facilitating the evolution of the draft texts, has been widely recognized.

In July 2011, the IGC adopted a consensual recommendation for the extension and strengthening of its mandate. The recommendation indicates, “the Committee will during the next biennium (2012-13), and without prejudice to work pursued in other forums, expedite its work of text-based negotiations with the objective of reaching agreement on an international legal instrument(s) which will ensure the effective protection of GRs, TK and TCEs”. Additionally, the IGC “will submit the text of an international legal instrument, which will ensure effective protection for GRs, TK and TCEs”.

The IGC recommendation further provides that the “General Assembly in 2012 will take stock of, consider progress made, and decide on convening a Diplomatic Conference, and consider any additional meetings”. The WIPO General Assembly adopted this IGC recommendation in September 2011.<sup>72</sup> The reference to convening a Diplomatic Conference leaves the option of an international binding treaty open.<sup>73</sup>

In substantive terms, the WIPO secretariat has compiled, produced and updated a series of documents that reflect members' responses to the mandate given by the General Assembly. The most important documents in relation to GR protection issued so far are the draft objectives and principles on IP and GRs<sup>74</sup> and the options for future work for GR protection.<sup>75</sup> These documents represent the basis of what could be a future instrument(s) on GR protection. In principle both documents also apply to ATK with respect to defensive and ABS aspects of IP filing and granting.

The idea of setting clear objectives and principles for the IGC process and developing an instrument for GRs, TK, and folklore expressions initially came from the GRULAC and Zambian submissions in the early 2000s.<sup>76</sup> The first stand-alone text of draft objectives and principles was initially proposed by Australia, Canada, New Zealand, Norway and the US in the context of IGC 2 and IGC 3. Some have wondered why these countries were the first to present such texts. The main reason seems to be that at that time the main *demandeurs* were putting all their stakes in relation to GRs in the TRIPS Council, so their level of engagement on the matter in the IGC was quite low. The second is that the proponents of the initial stand-alone text on objectives and principles seemed to be seeking a non-binding list of objectives and principles that provide some recognition of concerns expressed without having to make any modifications to the IP system as we know it today. Since then the document has benefited from proposals, inputs, and comments from all members. In the draft principles and objectives, there are so far five objectives proposed, along with their respective principles.

Not all three themes (GRs, TK and TCEs) are advancing at the same pace. The TCEs draft articles seems to be advancing with fewer

difficulties. The TK draft articles are starting to show some areas of consensus. However, divergence over key basic provisions regarding scope, subject matter, and titleholders has hindered faster results. Draft objectives and principles on IP and GRs are lagging behind and still need further work in order to streamline current and new options and make them operational and effective. One of the reasons why the advancement of the text on GRs is lagging is because most of the *demandeurs* were quite optimistic about generating positive precedents regarding some proposals on disclosure requirements and IP checkpoints in the Doha Round and in the Nagoya Protocol negotiations. But these expectations were not realized in the Nagoya Protocol and may still find difficulties in the seemingly never-ending Doha negotiations. Therefore, the IGC has been seen today under a new light as a potential forum to address these and other proposals related to GRs. Other relevant documents on the table at the IGC include glossaries related to IP and GRs, TK, and TCEs and the list of Options for Future Work on IP and GRs.

Over the last two years the IGC Chair, the friends of the Chair, and members have all made efforts to clean and reduce the number of options in the draft objectives and principles document. However, in many areas the gap between different options is still wide. Recently, the GLMC presented an important set of changes to this document and inserted a series of draft articles in order to reduce options, make them more precise and potentially more effective.<sup>77</sup>

The document on options for future work, which was formerly titled "Options on IP and GRs", incorporates comments and proposals by experts gathered and reviewed since IGC 3 on potential alternatives for GR protection within the IP system. The document is organized in clusters as shown in Table 2 below:

Table 2. Clusters of options on IP and GRs identified by the IGC (up to mid-2011)

Cluster	Options covered
Cluster A: Options for defensive protection of GRs	<ul style="list-style-type: none"> <li>• Inventories of databases and information on GRs</li> <li>• Information systems on GRs for defensive protection</li> <li>• Guidelines or recommendations on defensive protection</li> </ul>
Cluster B: Options on disclosure requirements	<ul style="list-style-type: none"> <li>• Mandatory requirements</li> <li>• Further examination of issues relating to disclosure requirements</li> <li>• Guidelines or recommendations on disclosure</li> <li>• Alternative mechanisms</li> </ul>
Cluster C: Options on IP issues in mutually agreed terms for fair and equitable benefit-sharing	<ul style="list-style-type: none"> <li>• Online database of IP clauses in mutually agreed terms on ABS</li> <li>• Draft guidelines for contractual practices</li> <li>• Study on licensing practices for GRs</li> </ul>

At IGC 19, it was decided that the document on options for future work would be revised and reissued by the WIPO Secretariat,<sup>78</sup> as most activities under Cluster C have been accomplished and discussions exhausted. So in the future, IGC meetings will focus on Clusters A and B.

#### 4.2 Building Trust Among IGC Stakeholders

As a forum that witnesses an inclusive and active participation of relevant stakeholders, the IGC has allowed for greater dialogue and exchanges of views. More efforts, however, are needed among states (including provider and user countries),<sup>79</sup> business groups and indigenous and local communities to build the trust necessary to reach an agreement. Differences in expectations and agendas are the key sources of disagreement. For many provider countries, such as the GLMC or regional groups like the African Group, the Asian Group and GRULAC, addressing in parallel problems related to erroneous patents, low patent quality, insufficient examination, and ensuring benefit-sharing for the utilization of GRs is of paramount importance. These countries tend to see the protection of GRs, TK and TCEs as a potential source of income for conservation and other purposes, as a means to improve the livelihoods of indigenous and local communities, and as a basis for building sustainable and responsible biotechnology and cultural industries.

On the user countries' side, the US, Japan, and Australia have been sceptical about many of the proposals made so far. However, they are becoming more engaged and constructive in several specific issues. They seem to be more willing to contribute solutions to the problem of erroneous patents, provided that it does not affect the integrity of the patent system. These actors view objectives seeking to ensure PIC, MAT and benefit-sharing with reluctance, as it is perceived that the IGC process may only lead to costs and little or no economic benefit for them. They also tend to strongly oppose discussions on a disclosure mechanism. Some other user countries, such as Norway, Switzerland and the EU member states, have been constructive in putting forward potential solutions that are closer to the interests of provider countries, and therefore actively seeking a common ground. The EU tends to favour non-binding outcomes more than binding ones.

Business groups and indigenous and traditional communities are quite special actors in the IGC. The participation of representatives of indigenous groups in the IGC process has been encouraged and facilitated as reflected in the creation of a voluntary fund to that effect. An important number of indigenous groups also have observer status in the IGC. While wider participation is still limited, active indigenous experts and representatives have been present in the IGC. The main source of tension between indigenous and local communities with other

stakeholders in the IGC process is related to the scope and content of their expectations. The level of expectation has proven to be much wider than what the IGC process can offer. Most indigenous and local communities have not really been demanding a *sui generis* system to protect GRs in their territories, their TK and TCEs, but rather a clear recognition of a wider set of rights, including self-determination, human rights, customary law, and land rights. Also, policies for ensuring the preservation of TK and their livelihoods are high on their agenda. Benefit-sharing arising from the utilization of TK and TCEs only comes after these first two priorities.

Some of these expectations have been embodied in international instruments such as the UN Declaration on the Rights of Indigenous Peoples (UNDRIP) (2007)<sup>80</sup> and ILO Convention 169 (1989). UNDRIP stipulates that “states shall provide redress through effective mechanisms, which may include restitution, developed in conjunction with indigenous peoples, with respect to their cultural, intellectual, religious and spiritual property taken without their free, prior and informed consent or in violation of their laws, traditions and customs”. It also indicates that, “they also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions”. While UNDRIP is of a non-binding nature, it represents an important precedent and source of standards already recognized. The use of words like “maintain, control and protect” and access standards, such as free PIC in UNDRIP, leaves little doubt as to indigenous peoples’ expectations regarding access to TK. Also, links to their laws, traditions and customs reflect their expectation that consent must be given under their conditions and customary law frameworks. It is therefore clear that for indigenous groups, ensuring their consent and maintaining their cultural system is much more important than any potential benefit-sharing, at least at this stage. Indigenous groups have also expressed their opposition to patents over life forms, for religious, cultural and moral reasons. Some indigenous peoples’ statements

expressing this opposition include: the Kari-Oca Declaration on Indigenous Peoples (1992), the Global Indigenous Forum (1992), the Mataatua Declaration on Cultural and Intellectual Property Rights (1993) and the Call of the Earth (2003), among many others.<sup>81</sup>

The private sector, both national and foreign, is seen as the main user of GRs and ATK. Indigenous and traditional communities are considered as titleholders of ATK but also of any potential rights arising from a future instrument(s) for TK and TCEs. Business groups tend to consider that legally-binding outcomes in the IGC might lead to legal uncertainty and additional R&D costs. They also believe that certain proposals made so far will affect the current functioning of the patent system and their business models. Some of these concerns would need to be addressed in the IGC in order to establish common ground. Business groups have usually taken quite a defensive stance in the IGC. This is similar to that taken by developing countries, civil society and consumer groups in processes leading to higher levels of IP protection, as they perceive that costs would be borne by them. This is evidence of the limits that mercantilism poses to multilateral IP processes. It also shows how those that usually benefit from the IP system will think or act when they are on the other side of the equation.

The IGC has already implemented some trust-building measures, such as the appointment of the figure of friends of the Chair and the creation inter-sessional working groups. WIPO has also allowed and organized side events, experts’ panels, and technical assistance missions, as well as covering developments through press releases.

In the case of indigenous and local communities, **additional trust-building measures** could include entrusting the friends of the Chair to go further and produce bridging text proposals under their responsibility; appointing a special indigenous peoples’ facilitator to ensure their views are taken into consideration; supporting the holding of regional coordination groups to build common positions (e.g. this was used in

the WHO process leading to the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property); and facilitating stakeholder bilaterals in parallel to the IGC process in order to reduce tensions.

Due to current levels of disagreement, the IGC has not been able to provide a platform for incentivizing legal access and benefit-sharing for GRs and ATK utilization within the IP system and creating business opportunities. One possibility for building business confidence could be to organize parallel business roundtables where countries, business associations, interested indigenous representatives, and fair trade organizations could exchange views on business opportunities, regulatory frameworks and investment incentives. Such roundtables could also showcase best practices and actual examples of legal ABS arrangements with relevant IP clauses where benefits have arisen for both provider and user countries. Good institutional partners for experimenting with such roundtables could be the United Nations Conference on Trade and Development (UNCTAD) Biotrade Unit and the Union for Ethical Biotrade, which have several years of experience in building sustainable business on biological and genetic resources.

#### 4.3 Recent Developments in the IGCs

Discussions in the IGC and ISWGs during 2010 and the first part of 2011 have shown important levels of engagement but also some disagreements among members. The adoption of the Nagoya Protocol is already framing certain aspects of the discussion and posing new challenges on coherence in the IGC. Proposals on disclosure requirements and a set of proposals made by

a group of developing countries incorporating some indigenous groups' ideas reflect such disagreements. Controversy arose in ISWG 3 and IGC 19 over a proposal by the African Group<sup>82</sup> to start negotiations on a mandatory disclosure requirement with a view to amend the PCT and PLT to reflect a mandatory disclosure of the origin of GRs and the incorporation of an international certificate of compliance as stipulated in the Nagoya Protocol. Also, a recent proposal by the GLMC is seeking to bring the negotiations on GR protection to the same level as those on TK and TCEs.<sup>83</sup>

The adoption of the Nagoya Protocol has brought new impetus to the IGC. Most members consider the protocol to be a fundamental piece in the biodiversity governance puzzle but also a new legally binding treaty that clarifies several aspects related to the subject matter of protection, clear ABS rules and standards for ABS and higher levels of ATK protection. The CBD secretariat presented the main purpose and new features of the Protocol in IGC 17.<sup>84</sup> Several delegations from both provider and user countries have welcomed the new Protocol and consider it to be a step forward in advancing CBD objectives. The African Group in particular has emphasized that the work of the IGC should be mutually supportive and not run counter to the CBD, the Nagoya Protocol and their objectives (specifically Article 3 bis of the CBD Nagoya Protocol).<sup>85</sup> Statements like these clearly point to the need that any outcome of the IGC be CBD and Nagoya compatible and that it should not undermine any commitments already agreed under those treaties. Links made between the Nagoya Protocol and a future WIPO instrument for GR, TK and TCE protection in IGC 17 and 18 are described in Box 2 below.

**Box 2. Main links made by WIPO members so far between the Nagoya Protocol and the IGC's work**

- The protocol has been considered as a valuable treaty for addressing issues of transparency, compliance and monitoring;<sup>86</sup>
- It is necessary to make the IP system and the new IGC instrument compliant with the Nagoya Protocol;<sup>87</sup>
- It is important to make clear links between the Protocol and the IGC's list of options for future work as a means to ensure that GRs associated with TK, and derivative products, had been accessed in accordance with PIC and other relevant principles;<sup>88</sup>
- The appointment of checkpoints, including IP offices, are a contributing factor to the IGC's work;<sup>89</sup>
- The international certificates of compliance will be useful in monitoring the utilization of GRs, including in the IP system;<sup>90</sup>
- It is imperative to start negotiations on a mandatory disclosure requirement for GRs in light of the Protocol;<sup>91</sup>
- It is important to address aspects of the Protocol related to ATK protection that have not been covered by the IGC;<sup>92</sup>
- The need to facilitate customary use and the exchange of GRs and ATK within and amongst indigenous and local communities;<sup>93</sup>
- A proposal to add an agenda item in the IGC on the relationship between the CBD, the Nagoya Protocol and WIPO treaties.<sup>94</sup>

*Source: WIPO reports for IGC 17 and IGC 18 in 2010 and 2011 respectively. Documents WIPO/IGCGRTKF/IC/17/10 and WIPO/IGCGRTKF/IC/18/11.*

In addition to these links, the recent proposal by the GLMC on draft articles on GRs explicitly indicates, “that future contracting parties to a WIPO instrument shall support the implementation of the Convention on Biological Diversity and the Nagoya Protocol”.<sup>95</sup> Obviously, all stakeholders in the IGC do not support these linkages and proposals, especially because the Protocol is not yet in force. Nevertheless, it is undeniable that the Protocol is already impacting discussions, even though it does not directly address IP issues. Even before entering into force, the Nagoya Protocol is considered to be a fundamental reference point and a building block in the IGC negotiations.

At IGC 18, entering into discussions on a mandatory disclosure requirement was firmly opposed by some IGC members. During the

meeting, the US indicated that “the objective of the IGC was to ensure that the system does not grant erroneous patents and not to discuss such mandatory requirements”.<sup>96</sup> The African Group, supported by Brazil, made clear in this debate that “they were not prepared to discuss clusters A and C if it did not come with a strong disclosure proposal”.<sup>97</sup> India backed this statement by indicating that “a mandatory disclosure is a must, everything else can follow”. These statements were followed by emotional replies by both the US and Namibia on the need “to take a break from negotiations if a mandatory disclosure requirement is what needs to be discussed”. Additional studies on disclosure systems were proposed by Australia and New Zealand but rejected by the African Group on the grounds that the necessity for disclosure requirements has already been proven.



This situation leaves a sense of *déjà vu* reminiscent of the IGC's creation, when a lack of understanding and political will from similar actors led to the withdrawal of the Colombian proposal on disclosure in exchange for the creation of a WIPO body where this and other issues such as TK and folklore protection could be discussed: the IGC. After more than 10 years of discussions and clarifications in the IGC, political will does not seem to have significantly improved on the issue. In this regard, it must be recalled that the same opponents have been avoiding discussions in the WTO and CBD by indicating that WIPO is the right forum. Now that a proposal on disclosure has been tabled in the WIPO IGC, having a discussion on the matter is again being rejected.

Difficulties and confusion when addressing indigenous concerns have been evidenced by a recent impasse in IGC 18. During this session, proposals by certain WIPO members (e.g. Bolivia, Ecuador, Guatemala and Venezuela) incorporating some indigenous groups' ideas were taken out of the draft text due to the lack of capacity by proponent countries to participate in subsequent negotiating sessions in light of the rules of procedure. Proposals were later brought back as a consequence of a strong statement by indigenous peoples<sup>98</sup> expressing their lack of support for a process where their views were not being taken seriously. In the same statement, indigenous groups were very clear on what they want from the IGC process. They indicated the need to recognize and protect indigenous peoples' rights over their TK, TCEs and GRs and ensure that any future international instruments shall not diminish their rights and that there should be clear recognition of their status as "peoples". This statement also put a great emphasis on the principle of free PIC and the need for repatriation of any TK, TCE and GRs taken without consent. It also contains an explicit rejection of any WIPO member(s) asserting rights over indigenous peoples' TK, TCEs and GRs. Proposals were brought back to the table due to a constructive attitude by several developed and developing country

members, regardless of the rules of procedure. As a consequence of this impasse, the IGC Chairman recognized that there might be a need to revise the current rules of procedure, which were adopted more than 10 years ago.

An important question that remains is the extent to which WIPO members can respond to these types of demands. Many of these requests seek to use the IGC process to reaffirm self-determination and sovereignty claims. This generates significant problems for many WIPO members as they might enter into conflict with several constitutional principles and national laws, depending on the case. More precise proposals on means to protect and promote indigenous peoples' TK, TCEs and GRs and on the recognition of free PIC and repatriation mechanisms could find their way into the process. PIC is already recognized in several international instruments. "Free" PIC in this context means without external pressures, which should already be subsumed in the existing PIC concept. The repatriation of indigenous GRs and TK embodied in those GRs or compiled in databases has already been done in a few cases. Examples of repatriation already exist, such as agreements and projects by the International Potato Center with several indigenous groups and farming communities since the mid-2000s to repatriate hundreds of potato varieties.<sup>99</sup> In this regard, the compilation of experiences and development of modalities for additional repatriation agreements could be part of the work of the IGC or could be left to the FAO or the CBD, depending on the GRs in question.

Regardless of these divergences, discussions on the text are advancing and the number of alternatives has been reduced. Discussions have been characterized by a generally positive atmosphere and constructive engagements. However, most of the core issues on the table are still unresolved, requiring more time and effort by all members.

Efforts by developing countries to advance in Clusters A and B under the list of options on IP and GRs are manifested in the recent

submission by the GLMC of a text with a more focused list of objectives and principles and a new section on preliminary draft articles.<sup>100</sup> This submission puts the text on GRs at a similar level to the texts on TK and TCEs. There have not yet been substantive reactions to the GLMC text as it was only introduced halfway through the last IGC meeting; they will certainly come in the next IGC session dedicated to GRs. Based on texts to be provided by the IGC, the General Assembly will then take stock, consider progress made and decide on convening a WIPO Diplomatic Conference and/or any other additional meetings. One issue that has explicitly arisen regarding a potential call for a Diplomatic Conference is if such a call prejudices the

nature of the instrument(s). Most developing countries are seeking to generate a binding instrument, while many developed countries would like to see a soft law type of approach, including recommendations, guidelines or general objectives and principles.

Also, with a view to enhancing the positive contributions by observers, especially from indigenous and local communities, the IGC requested a study to be prepared outlining current practices and potential options for expanding indigenous groups' participation. For this study, practice and experience in other forums such as the CBD (including working groups), UN human rights bodies, the FAO and the UN Permanent Forum on Indigenous Issues will be of relevance.

## 5. ADDRESSING KEY SUBSTANTIVE ISSUES IN THE IGC: DISCLOSURE REQUIREMENTS, PRIOR ART AND DATABASES

The two main mechanisms proposed so far in the IGC to protect GRs are disclosure requirements and databases. These two mechanisms seemingly represent the core of the discussion in both technical and political terms. As mentioned above, for provider countries disclosure requirements are a “must” in the negotiations. For user countries, databases are the most suitable option. This section will analyse these substantive issues in light of the recent literature, the Nagoya Protocol, and interviews undertaken. The main message of this section is that the two mechanisms are not contradictory but, on the contrary, complementary and could be designed and built in a mutually supportive way.

### 5.1 Biodiversity-related Disclosure Requirements in Patent Applications

In general terms, disclosure is an in-built conditionality in patent applications and examination procedures. The general disclosure requirements oblige applicants to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.<sup>101</sup> In some national laws the obligation goes even further and requires the best mode to carry out the invention known to the inventor. The information required has a direct connection to the examination of patentability criteria as set out in Article 27.1 of the TRIPS Agreement, and to the need of being able to replicate the invention. Disclosure of the geographical origin of GRs has been included voluntarily in many patent applications in order to complement the description of the invention. The same applies with regards to relevant ATK, as it can be a pertinent part of the analysis of prior art in patent examinations. This is so much the case that most reports of biopiracy and misappropriation are usually based on references to GRs and ATK in existing patent applications.

Disclosure requirements, as a mechanism to create synergies between international IP agreements and the CBD, were initially proposed in the TRIPS Council and in the negotiations leading to the PLT under WIPO in the late 1990s. These proposals initially focused on the geographical and country origin of GRs, but have been continuously expanded so as to include ATK, the source and evidence of PIC, MAT, and other benefit-sharing arrangements (for the purpose of this analysis these types of disclosure requirements will be called **biodiversity-related disclosure requirements - BRDRs**). Links with general disclosure requirements have been made clear in the proposals by a coalition of developing countries with the introduction of an Article 29*bis* to the TRIPS Agreements. Proposals to incorporate narrower variations of BRDRs for international applications under the PCT have been made by Switzerland and the EU. As mentioned above, these proposals could be complementary to those made in the TRIPS Council and in the IGC. Alternatives for BRDRs are also found within the options proposed in the draft objectives and principles and draft articles for GR protection and in recent proposals by the GLMC.

Resistance by certain countries and business groups towards BRDRs has generated higher levels of cohesion on the provider countries' side and an expansion of the original scope of the proposals. It has also fuelled a wider perception of imbalance in the IP system against development concerns that triggered, among others, the WIPO Development Agenda. In this regard, Recommendation 18 of the Development Agenda urges the acceleration of the IGC process on the protection of GRs, TK and folklore, without prejudice to any outcome, including the possible development of an international instrument(s).<sup>102</sup>

One could easily argue that the incorporation of BRDRs in the international IP system is more

than a controversial issue. It can be considered a dealmaker in the IGC process, and a bargaining chip in any potential trade-offs regarding a wider range of IP negotiation in the TRIPS Council and WIPO.

#### 5.1.1 Evolution in national legislation and practical experiences

The number of national laws incorporating BRDRs has greatly increased and their content has evolved since the late 1990s. Today about 50 countries already have different forms of BRDRs in their national legislation (biodiversity laws, patents and breeders' rights, etc.).<sup>103</sup> Countries with such requirements include the Andean countries, Brazil, Belgium, Costa Rica, China, Denmark, EU members, India, Kyrgyzstan, Norway, the Philippines, South Africa, Switzerland, Thailand, and Vietnam. This list includes both provider and user countries, showing the commitment by some countries toward the implementation of the CBD as well as user country measures. The scope of the requirements, material, or information to be disclosed, the binding nature of the mechanism, and potential consequences for non-compliance vary greatly from country to country.<sup>104</sup>

BRDRs are usually applied to patents and to a lesser extent to breeders' rights. Materials to be disclosed include biological and/or genetic material (usually plant, animals and microorganisms) but also ATK. In some cases, the requirement only applies to material found within the jurisdiction of the country (e.g. Costa Rica, Brazil and South Africa). Requirements to only disclose TK are found in only a few cases (e.g. New Zealand). Requirements to disclose the origin and source, or evidence of PIC (by both competent authority and TK holders), MAT or evidence of benefit-sharing arrangements are also included in many legislations. Almost all countries incorporating BRDRs require the disclosure of either countries of origin or source or both. About a quarter of the countries incorporating BRDRs require the disclosure of evidence of PIC and MAT, ABS contracts, licenses from TK holders, and other relevant certificates. In terms of legal effect, in about a third of these countries BRDRs are mandatory

and have legal effect whether in the IP system or outside it. Most provider countries with BRDRs in their legislation also have national ABS or TK legislation in place, showing that BRDRs do not usually work in isolation.

There are only a few reports analysing national experiences with BRDRs. There are two interesting reported experiences in Brazil and Costa Rica. A study by the Social and Environmental Institute (Instituto Socioambiental, Brazil) and the Initiative for the Prevention of Biopiracy (Peru)<sup>105</sup> on the implementation of the Brazilian Provision Measure 2.186-16 of 2001 gives some idea of their experience with BRDRs. The study indicates that in the case of 110 patents where there was a high probability of utilization of Brazilian GRs or ATK, 18 patents disclosed the origin of the genetic material and 27 mentioned ATK in references to the efficacy of the claimed invention. Interestingly, patent applicants were almost entirely nationals. These patent applicants included national research centres, universities, foundations, authorities at the sub-federal level, and state-owned biotechnology companies. In one example given by the study, the applicant was a sub-federal biodiversity reserve that had developed its own products and sought to reinvest the derived benefits in its conservation activities. In the case of ATK, most of the TK identified was linked to "popular medicine" and not to a particular community. In one application, the use of stevia by Guaraní people was mentioned. In the case of Costa Rica, no patent application making use of national GRs has yet been identified.<sup>106</sup> Local authorities once reviewed a patent application in order to determine the origin of specific GRs, but the result was that the strains of material were originated in the US, Germany and the Netherlands.

These two experiences provide some lessons. The first is that even if a country has a BRDR it also needs to have the administrative and monitoring capacity to assess the information disclosed. Second, it seems that national entities are making important efforts to

fulfil national BRDRs but also national ABS legislation, as discussed above. This might also be the consequence of limiting BRDRs to GRs or ATK within the national jurisdiction. Finally, transnational and foreign companies seem not to be utilizing local GRs or are afraid to disclose such information. There are no reports in any of these countries so far on legal cases brought for lack of disclosure. Further research on **practical national experiences on BRDRs** is urgently needed in order to be able to make better assessments regarding their effectiveness, but also to find possible problems and solutions regarding their practical implementation.

#### 5.1.2 Design and functioning of BRDRs

Key questions regarding the design and functioning of BRDRs will greatly depend on the national implementing legislation. Proposals made so far in the IGC on BRDRs are wide in scope and strong in relation to potential effects but they leave a great deal of policy space for their design within the national context. There are several references to disclosure requirements in various places in the IGC's draft principles and objectives and in the recent proposal by the GLMC. The recent proposal by the LDCs also contains specific language on BRDRs in its draft Article 3. Proposals made so far have put emphasis on:

- a) What type of material is subject to the requirement? (i.e. GRs, biological material<sup>107</sup> derivatives and ATK; only national resources or all);<sup>108</sup>
- b) What type of information needs to be disclosed? (i.e. origin, source, evidence of PIC, MAT and other ABS arrangements);
- c) What type of information is most useful for enhancing transparency, improving patent examinations, and ensuring ABS compliance? (Some requirements might be more useful for certain purposes than others);
- d) What is the legal nature of the mechanism? (e.g. mandatory or voluntary for states to implement and/or for IP applicants to fulfil);
- e) What type of information can IP applicants actually disclose? (Sometimes IP applicants may not have all the information required at hand);
- f) Possible effects for non-compliance (e.g. revocation, prevention of further processing of IP applications, administrative civil sanctions).

Many other important aspects of future BRDRs are not proposed for international regulation. Aspects that are not covered are:

- National treatment;
- Mutual recognition of systems;
- Treatment of information; and
- Incentives for compliance.

Many of these issues have already been analysed under CBD discussions on disclosure and consistency with WIPO administrative treaties. A submission by UNCTAD (2006), titled "Analysis of options for the implementation of disclosure requirements in intellectual property applications" and prepared by Sarnoff and Correa, proposed a variety of policy options for BRDR design as well as modalities for implementation. More recently, a short report of the "International workshop on the application of disclosure of origin and legal access in intellectual property regulations" (2009) organized by WIPO, PSEL, NCAB and IFPB<sup>109</sup> provides an illustration of the practical functioning of BRDRs and interesting proposals, based on experience, on how best to implement them. Documents from ISWG 3 also cover a wide variety of arguments (in favour and against), technical positions and potential options regarding BRDRs. These documents also show significant levels of disagreement regarding BRDRs.

All these studies and documents show that there is ample leverage for national implementation and policy space to address many of the concerns expressed by user countries and business groups.

### 5.1.3 Objectives of BRDRs, type of information to be disclosed, and impacts over patentability and ABS compliance

The objectives of BRDRs have already been quite well developed in the literature.<sup>110</sup> They include:

- Transparency;
- Traceability;
- Improvement of the examination process for patents and other IP rights;
- Better assessment of patent claims;
- Generation of mutual trust and support for ABS legislation compliance; and
- Implementation of the CBD, Bonn guidelines, and Nagoya Protocol.

BRDRs have a general impact on transparency, traceability, and the generation of mutual trust as they give information on what GRs and ATK are actually being accessed and utilized in patent applications, who is utilizing them and for what purposes. With this information countries and TK holders can initiate investigations regarding the legality and legitimacy of access and utilization.

The effects of BRDRs over patentability vary with the scope of the requirements. When looking at what type of material is subject to the requirements, relevant *biological material* utilized in the R&D process leading to the invention should be disclosed. The biological material utilized is usually included in the description of many biotechnological patents (i.e. GMOs) but also in applications for breeders' rights protection. The disclosure of biological material in the context of the implementation of CBD and Nagoya obligations makes full sense as such material contains units of heredity and biochemicals of natural origin. They are also the raw material for producing derivatives. Disclosure of GRs can also apply but it is more difficult to determine their origin.

The relevance of the utilization of different biological materials may vary according to the

invention in question. One option to assess the level of relevance is to apply a causal link test. If the invention would not have been achieved without the utilization or incorporation of the biological material in question then it is relevant for the purposes of disclosure. An additional option is to disclose biological material/GRs directly used in the R&D process. The question here is how to differentiate direct and indirect use in practice.

The *disclosure of geographical origin of biological material* has a limited effect on patent examination and the assessment of patent claims of biotechnological inventions. Information about the origin of GRs can complement the description of the invention based on endemic GRs, certain microorganisms (e.g. extremophiles and pathogens), GRs difficult to reproduce outside the original environment and/or when the invention has reproductive purposes. In all these cases, information on the geographical origin will be of assistance for replicating the invention (e.g. to understand environmental conditions) and understanding the particular properties contained in the biological/genetic material. This reasoning is also applicable to breeders' rights applications as reproductive purposes are obvious.

In the case of inventions involving the use of microorganisms or other biological materials, deposits of the biological material can be required to complement the description since repeatability often cannot be ensured by means of a written description alone. The WIPO Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure already recognizes the value of additional requirements, such as the depositing of biological material to complement the description of the invention for the purposes of patent examination procedures. In cases where such a deposit has occurred, additional information regarding the geographical origin will be of little relevance for patentability purposes, as the material deposited can be used to clarify questions regarding replication of the invention or evaluate its particular properties.<sup>111</sup> Nevertheless, some experts have proposed

the introduction of a requirement to disclose origin and legal provenance of the biological/genetic material in the Budapest Treaty, as an alternative to generating synergies between the two mechanisms.<sup>112</sup>

In the context of patent examination, *disclosure of the country of origin* has no impact unless it complements information on the geographical origin and source. The greater value of disclosing the country of origin is the determination and affirmation of sovereign rights over utilized GRs. It also supports transparency, monitoring, and compliance obligations under the CBD and Nagoya Protocol, especially in cases where the IP offices have been appointed as a checkpoint. In general terms, the disclosure of origin (geographical and country of origin) has been considered the less complex aspect of BRDRs to be operationalized.<sup>113</sup>

*Disclosure of source* usually includes the country of origin but also the providers involved in the GR and TK knowledge supply chain. The source can also include information on the TK holders and information found in specialized GR and TK databases and relevant scientific or TK journals. Information on the direct sources can allow provider countries to examine the legality of the sample, the supply chain, and links with additional relevant prior art information. In principle, information on the source should refer to known information by the applicant in order to avoid burdensome supply chain research exercises. While the disclosure of source was originally conceived as an alternative to information on the country of origin, both are relevant for ensuring ABS compliance. After Nagoya, certifying the legality of samples will become easier as IRCCs will facilitate the flow and exchange of information.

The *disclosure of existing ATK* is in principle part of the prior art<sup>114</sup> and can have significant effects in both patent examinations and assessments of potential claims over inventorship and/or misappropriation in courts. A clearer understanding of relevant ATK can assist a patent examiner in making better decisions on the fulfilment of the novelty and non-obviousness criteria. The provision of relevant ATK infor-

mation will reduce the research burden on examiners and the scope for mistakes. Knowing the origin of ATK would allow TK holders to make claims over the access and utilization of their knowledge where authorization has not been granted.

Disclosure of *PIC, MAT, and other ABS arrangements* has a strong impact on ensuring compliance with ABS standards but none on patentability examinations. This information will be particularly relevant in countries where IP offices have been appointed as **checkpoints** under the Nagoya Protocol. In this regard, the GLMC has proposed appointing IP offices as checkpoints. So it must be clear that in this case patent quality examinations are not the main objective, but rather ensuring the legality and legitimacy of access to and utilization of GRs and ATK in the invention.

Presenting evidence of PIC, MAT, and other benefit-sharing arrangements should be less of a problem after the Nagoya Protocol as obligations have been set out to clarify and reduce the cost of ABS requirements. Also, IRCCs can facilitate the gathering and production of evidence in multiple jurisdictions. In this regard, IP offices can verify the presentation of PIC, MAT and/or IRCCs but they have neither the capacity nor the authority to assess their authenticity or whether benefit-sharing has actually occurred in practice.<sup>115</sup> In this regard, a patent examiner interviewed proposed requiring applicants to send this information directly to biodiversity authorities in order to evaluate any potential rights or misconduct related to the material.<sup>116</sup> There is also the possibility of IP offices publishing this information or making it available to the national biodiversity focal point of the country of origin for its factual evaluation under environmental law and the assessment of potential administrative or judicial actions (a kind of **biodiversity linkage**). This information can also be sent to the CBD Clearing-House Mechanism in order to facilitate monitoring of the utilization under Article 17(iii) of the Nagoya Protocol.

Additionally, patent examiners could also benefit from **national or regional guidelines**

to assess all the information arising as a consequence of BRDRs in light of patentability criteria and patent law in general. Additional measures to reduce these claimed burdens, not only for users but also for examiners, is to introduce an obligation to fully consider any additional information provided by IP and/or biodiversity authorities in third countries. There have been positive experiences in this regard as a consequence of prior art reports sent by the National Commission Against Biopiracy (NCAB) of Peru to several patent offices around the world.<sup>117</sup>

#### 5.1.4 The legal nature of BRDRs and effects of non-compliance

One of the big questions in the IGC is whether BRDRs should be voluntary or mandatory. Voluntary requirements would not provide enough incentives for compliance and would only allow those acting in good faith to do so. Voluntary disclosure is also already encouraged by the Bonn Guidelines. This has not, however, generated any significant policy changes in key users such as the US, the EU, and Japan. So the effect of voluntary requirements is basically the status quo and does not imply any political concession. Mandatory requirements would definitely assist in giving an actual picture of the level of utilization of GRs and ATK in patent applications. They would also give a better idea as to the potential market value of GRs and ATK. Without mandatory obligations, national disclosure of origin requirements may not be recognized and enforced by other countries in which patents are applied for, and information provided pursuant to such requirements may not be employed to prevent the improper issuance of IPRs and to ensure benefit-sharing.<sup>118</sup>

One alternative between these two options is to introduce an **enabling clause**<sup>119</sup> by which any WIPO member may introduce BRDRs in national IP laws with freedom to set the scope, content, and legal effects. This option will protect existing BRDRs in national legislation from challenge, limit contradictory outcomes in bilateral free trade/IP agreements, and pave the way for wider use of the mechanism and further policy development. Such an enabling clause

may be accompanied by a mechanism designed to facilitate mutual recognition of relevant judicial and administrative decisions that would strengthen cooperation among interested parties. The weak point of this proposal is that it addresses neither the main concerns of key user countries nor cross-border situations of unauthorized access and utilization and the lack of benefit-sharing.

In the cases of non-compliance with BRDRs, proposals have been put on the table for potential sanctions, including **revocation, procedural suspension, administrative, civil, and criminal sanctions**. Revocation has been proposed as a strong means to ensure compliance. The main argument made in favour of revocation is that it will be the only way to ensure effective compliance by patent applicants. The main limitation of the revocation approach is that in cases where GRs and ATK have been utilized there will be little or no benefits to share. The revocation option would be relevant in cases where the patentability criteria have not been fulfilled, where a fraudulent declaration has been made regarding the information required by BRDRs, or where the applicant is not the actual inventor. Revocation or suspension of the patent holder's rights could also arise as a consequence of anticompetitive practices investigations. If mistakes were made in the applicant's declarations, opportunities for amendments should be allowed without effects on the patent. In the case of incomplete or inaccurate declarations or disclosure, preventing further processing of the application could also be an option. In these situations there should be a reasonable period of time for the applicant to comply with relevant ABS legislation and priority rights should be preserved. Suspension of further processing of a patent or an IP application could be an interesting middle ground between revocation and administrative and civil sanctions, as it could allow for preservation of patent holder rights and at the same induce compliance. In countries with a civil law tradition this option is referred to as "partial nullity".

In cases where there has been access or utilization of GRs and ATK without PIC, MAT



and ABS, administrative and civil actions could be the most suitable ones to compensate the state, TK holders or any other interested party. For example, Brazil has levied more than BRL 100 million (USD 59 million) in fines since July 2010 on companies charged with not paying fair compensation for the use of genetic material native to Brazil.<sup>120</sup> This amount clearly surpasses any benefit provided by existing ABS contracts. But this is not the end of the story. Many of the companies under investigation may also face patent revocation. This case shows how avoiding multilateral solutions to address provider countries' concerns will not necessarily stop action at the national level, adding even more uncertainty.

Another option that could be explored by countries without the capacity to implement effective ABS systems or BRDRs is to set up a **horizontal biodiversity conservation tax** applicable to sales of biodiversity-derived products and inventions. This tax could be quite low but at the same time more effective (e.g. 1 per cent of the sales). The tax could also apply to GR-intensive industries, as they are the main beneficiaries. Companies contributing to the future Global Multilateral Benefit Sharing Mechanism under the CBD could be exempted from such a tax, in order to create incentives for compliance at the multilateral level.

#### 5.1.5 Benefits, concerns, and complementary measures

The BRDRs can bring significant benefits for user countries and GR-intensive industries or those that have utilized ATK. They can shield user countries and business groups from public campaigns and biopiracy and misappropriation claims. It is important to bear in mind that not all industries have the same level of sensitivity vis-à-vis these claims. The food and cosmetic industries, for example, as they directly incorporate biological material in their final products and are closer to consumer oversight, can be more affected than others. They have understood this and generated alternative fair trade models with ABS components. For example, one cosmetic company in the business of producing argan oil has offered

local communities that it exclusively source all its inputs from them as a form of benefit-sharing.<sup>121</sup> In this regard, BRDRs will bring higher levels of trust and therefore improve the business environment and opportunities for new agreements.

Continuous claims by provider countries seem to be taking more of a political profile, not less. This is not good for the general governance and image of the IP system. Allowing provider countries to make some benefits (which at the end might be much lower than expected) would generate a positive stance towards the IP system. BRDRs will also reduce the burden on patent examiners and provide additional information for patent examination. Recognizing BRDRs at the multilateral level could allow a less defensive stand and a more investment-oriented implementation of this type of requirement by competent authorities.

Some user countries and industries have expressed several concerns regarding BRDRs.<sup>122</sup> Their *lack of effectiveness* is a common one. While this should be the problem of providers and not users, the lack of effectiveness concern seems to be addressed by the fact that most claims so far made on the lack of legal access and utilization in IP filing and granting have arisen because some patents already disclose information on the origin/country of origin, leading to the supposition that access to and utilization of a GRs is already happening (authorized or not). However, there is not much empirical evidence yet to support either claims as to the effectiveness or ineffectiveness of the mechanism and additional evidence-based research is in order.

Claims have been made that gathering information required by BRDRs can be *burdensome*. This type of claim needs to be addressed seriously in order to encourage wider support. All scientific bioprospecting activities since the 18th century start with the collection of the material and the preparation of so-called collecting/ethnobotanical labels and protocols. These labels and protocols indicate the name given to the living organism, who collected the sample, the date of collection, geographical

coordinates, the description of the living organism, the assigned biological classification, and sometimes information about known uses by local populations and the surrounding environment. Today they are even more precise

and most research centres compile this plus additional information on barcodes attached to each sample (see picture 1 below). So in principle providing this information should be not considered burdensome.

#### Barcode tracking utilized by the National Biodiversity Institute (INBio) of Costa Rica



Source: INBio (2010) from the ICTSD, BMZ and GTZ visit there.

Recent research by Oldham (2011)<sup>123</sup> suggests that countries and regions of origin of GRs and TK routinely appear in patent documentation by key patents offices. This becomes particularly evident when focussing electronic patent searches on the following criteria: “family”, “genus”, “species”, “plant extract”, “natural extract”, “genome”, “synthetic biology”, “synthetic genomics” and “metabolic engineering”. Oldham suggests that the main difficulty in undertaking searches on the use of GRs and TK in patent applications relates to a problem of design.<sup>124</sup> In this regard, he considers that there is a need to redesign patent search systems to facilitate such tracking and monitoring. This has been done, for example, to retrieve information on Bayh-Dole Act<sup>125</sup> disclosure requirements on the use of government funding for R&D leading to patents in certain patent databases.<sup>126</sup> Oldham

proposes a new **ABS patent index** that would cluster the main search criteria and retrieve most relevant patents in order to evaluate the actual utilization of GRs and TK.<sup>127</sup> He has also indicated that such a new tool would make monitoring, tracking, and disclosure of GRs and TK cost-effective and feasible. He is already running scenarios of different search methodologies, showing surprising results.

When we talk about biological material already in trade, the situation is different as there might be too many actors in the supply chain. Here, the important issue for users is that they need to be aware of the difference between acquiring material for biological resource uses and utilizing genetic resources for R&D purposes. In the latter situations it will be necessary to ensure the fulfilment of ABS requirements and/or the legality of the sample. Requiring IP applicants

to provide, in good faith, the best information known to them regarding the country of origin and source of the material may address this problem and avoid overly burdensome searches.

Requirements to provide information on PIC and evidence of benefit-sharing arrangements should be less burdensome once Nagoya is implemented, as it offers the possibility of using IRCCs. Also, diverse authorities appointed as checkpoints under the Nagoya Protocol will collect relevant information related to PIC, to the source of the GR, to the establishment of MAT, and/or to the utilization of GRs.<sup>128</sup> So even if there is not a BRDR, there will be a need to produce the same information for other checkpoints. The effort of producing this information could be similar to that needed to fulfil other certification requirements under environmental law.

Costs have also been raised several times as an important problem. Here we have to make a distinction between the cost of fulfilling ABS requirements and the cost of fulfilling BRDRs. In principle, the costs of ABS requirements should already be internalized. While there might be more complicated ABS laws in one country, users can always go to the country that offers less “costly” and “burdensome” procedures. Also, as mentioned above, Nagoya already requires access procedures to be clear and cost-effective, and that decisions should be made within a reasonable period of time.

When looking at existing ABS contracts, the costs seem to be fairly low as the benefits shared so far are quite small. Even if the cost becomes higher it can always be translated to the consumers, which incidentally are found in both user and provider countries. The Nagoya Protocol also offers the potential development of a future Global Multilateral Benefit Sharing Mechanism, which allows users to make contributions in cases where it is not possible to obtain PIC, or in transboundary situations.<sup>129</sup> Once this mechanism is in place, it will be difficult to argue any complication regarding national ABS legislation. Responsible businesses would then be able to inform the Global Multilateral Benefit Sharing Mechanism about access and utilization and make a reasonable contribution.

With regard to BRDRs, if a business has already fulfilled ABS requirements it should not be concerned about costs, as they were already assumed and it just has to produce the available information. Also, the existence of patents does not necessarily imply benefits. Benefits arise with the commercialization of the invention. Only about 10 to 15 per cent of biotechnology patents bring economic benefits and usually after they were granted.<sup>130</sup> Therefore only in these cases will there be a need to share benefits.

It has been indicated that BRDRs may *hinder non-commercial research*. This argument seems to apply more to ABS legislation than to BRDRs. Patenting and IP filing occurs after the R&D process is finished and new inventions or products have been developed. It is also important to mention that most access permits granted and ABS contracts agreed apply to non-commercial bioprospecting and R&D activities, so they do not seem to be a great barrier at this stage. One option for addressing this type of concern is to allow fast track ABS procedures for non-commercial research activities in order to facilitate access.

Concerns over *lack of legal certainty* have been repeated not only in ABS discussions but in relation to BRDRs. This claim has some merits as in many cases ABS legislation has been too complex to fulfil and competent authorities have been inefficient in negotiating and granting permits and contracts. In the case of BRDRs, this situation may occur if such requirements are not precise and clear and administrative guidelines for IP offices on their application have not been designed. Countries implementing BRDRs should be required to apply the same Nagoya standards of clarity and cost-effectiveness, and undertaking legal assessments within a reasonable period of time can address this concern.

Making use of IRCCs under the Nagoya Protocol will be the most effective way to respond to BRDRs or requests by any checkpoint. **Certificates** have been seen as the suitable way to ensure the fulfilment of BRDRs as they can improve transparency and clarity, and to a certain extent contribute to justice and equity.<sup>131</sup>

The simplification of procedures and capacity building for IP offices and national biodiversity focal points, on both the implementation of BRDRs and negotiation of ABS contracts and IP-related clauses, would also help in generating higher levels of certainty.

There might be situations where BRDRs are already in place under national legislation and IP applicants do not comply with ABS legislation. In such cases, an *ex post* legal restoration mechanism could be put in place to allow those interested in fulfilling national ABS requirements to do so even if access has already occurred. Such a mechanism should not sanction IP applicants and other users but seek that negotiations to restore legality go smoothly. Incentives to encourage the use of the restoration mechanism could be to fix a reasonable benefit-sharing royalty rate (e.g. 2.5 per cent of total sales, the average royalty rate paid in most ABS contracts) for governments or TK holders on any potential benefits arising from the commercialization of the invention or the relevant IP titles.

Business groups have also mentioned that BRDRs will expose them to possible attacks targeting their *patent portfolio and will affect their business models*. Rights over IP have always been litigious. In practice, there are three categories of actors that might initiate a legal action as a consequence of the lack of fulfilment of BRDRs and/or ABS legislation: authorities from provider countries, indigenous groups and competitors. Claims by the first two actors will be a natural consequence of this type of requirement. Businesses that do not utilize GRs or that have fulfilled national ABS legislation have nothing to fear. Initiating litigation might not be easy as it is costly and evidence needs to be gathered. Also, we find that no litigation has yet been triggered by the application of BRDRs in any country so far. However, governments, research centres and indigenous communities have often requested patent reviews and engaged in invalidation procedures in several jurisdictions (e.g. ayahuasca, maca, Enola bean, basmati and turmeric). Legal actions by competitors will have to prove legitimate interest and produce evidence of non-fulfilment of the patentability

criteria. In these situations, the legal actions that are sustained by the court will assist in improving patent quality. An option to reduce risks of over-exposure to litigation might be to produce a **non-confidential declaration that fulfils basic BRDRs** and accompany such a declaration with confidential extracts to be given only to the IP office, and sent later to the competent biodiversity authority of the providing country or relevant checkpoints under the Nagoya Protocol.

Many pharmaceutical and biotechnology companies seek credit and investors by improving and expanding their patent portfolio. Litigation and having patents questioned weakens the value of these portfolios, as well as the financial capacity and business sustainability of these companies. However, in this situation the best answer is to play clean. A business model based on free riding on others' rights over GRs or ATK does not seem ethical or likely to be uncontroversial in the long run. An important missing element for any future agreement in the IGC is a clear understanding that conservation and ABS costs need to be internalized by users.

## 5.2 Prior Art Issues, Databases and Registers

Databases have been considered a valuable mechanism by the literature and by many provider and user countries to address problems of erroneous patents and insufficient patent examination. Databases can be designed to compile, reference, and make easily accessible unlimited amounts of information. Databases could apply to GRs, known uses of GRs, biochemicals, derivatives and almost any form of TK, with the exception of sacred knowledge. They can incorporate scientific and layman's terminology, specialized literature and scientific articles, but also codified TK including translations into different languages. Databases can facilitate the compilation of different terms for biological resources and link scientific and layman's terms. They can complement prior art searches, reduce the burden on patent examiners and assist them in making determinations of novelty

and inventiveness more accurate.<sup>132</sup> They can also play a role in the preservation and management of TK rights.

Some of the most enthusiastic proponents of databases are the same countries that reject BRDRs. One can easily see some level of contradiction in this position. How is it possible that additional information arising from databases is useful and information arising from BRDRs is not? Both mechanisms provide relevant information. The main difference is that in the case of BRDRs, the obligation is borne by those utilizing GRs and ATK. In the case of databases, the cost of setting up and operating the database, the protection of the information/rights, and the management of potential information-sharing arrangements mostly falls on provider countries and indigenous and local communities - exactly those suffering from situations of biopiracy and misappropriation. Databases and registers may be able to provide a wider range of information than BRDRs. However, it is highly improbable that they can provide information on who, where, and how IP applicants have utilized GRs or ATK in the R&D process leading to an invention or assisting in the determination of legal access and utilization. In this sense, BRDRs and databases are not contradictory options but complementary ones. If both options are incorporated into a future IGC instrument(s), they would allow for a division of the burden of the implementation of new obligations among users, providers and indigenous and local communities.

GRs and TK databases can operate under different modalities. They can be compiled and held by states, research centres, or indigenous and traditional communities. They can be informal or institutionalized. Information can be recorded through written reports, and audio and video recordings. They can also include samples and seeds, as in the case of the ANDES potato park.<sup>133</sup> They can be publicly available or restricted. They can cover all forms of TK or specific ones such as agriculture, medicinal TK or folkloric expressions.

Databases do not work in isolation. National TK legislation needs to clarify key issues, including the recognition of rights, ownership, who provides the PIC, the type of rights recognized, and their limits. To be legitimate and effective, databases need to be solidly built on PIC, MAT, and other benefit-sharing arrangements. Some databases have already faced problems and criticism from indigenous groups when they did not fully comply with these requirements and did not enjoy clear indigenous authorization and support (e.g. Biozulua database).<sup>134</sup>

A case that illustrates the value of TK databases for the purposes of avoiding erroneous patents and improving patent examinations is that of the TKDL database. Part of a project developed over a ten-year period, it documented knowledge about traditional medical treatments and the curative properties of plants, which was contained in ancient texts and languages, and classified the information in a searchable database.<sup>135</sup> The TKDL now contains 34 million pages in five international languages. The TKDL makes this information available, via Access and Non-Disclosure Agreements that seek to ensure confidentiality to key patent offices.<sup>136</sup> An example of its effectiveness is given by the use of the TKDL database by the EPO, which has identified 36 patents making use of Indian TK.<sup>137</sup> In some cases, the EPO has set aside its intention to grant the patent, while in others applicants have withdrawn their applications. In this case, however, it is important to note that most of the information is based on ancient codified TK that is generally common patrimony of the Indian nation. In this regard, the database was not the consequence of compiling "living TK" and obtaining PIC and MAT from relevant indigenous and traditional communities. In the case of databases constructed on "living TK", the time necessary for obtaining PIC can be much longer and the transaction cost for compilation can be much higher. A better example of a database built on "living TK" would be the Honeybee Network, also in India.

Japan<sup>138</sup> has proposed in the IGC a “one step database” that would address the erroneous grant of patents using GR and ATK when they do not comply with the requirements of novelty and inventive step, such as the cases of turmeric and neem. Japan argues that it is extremely difficult for examiners to review all of the available documents since there are countless documents referring to GR and associated TK. For Japan, an access-friendly database would facilitate the search function and reduce risks for error in patent examination. The main limitation of this proposal is that it seems to disregard the importance of obtaining PIC and ABS and the need to preserve the “secrecy” of certain types of TK. The proposal does not either resolve the issue of respecting existing rights over GRs and ATK. Due to the constructive nature of this proposal, it would be appropriate to clarify how this approach would ensure the fulfilment of national ABS and TK regimes in line with international obligations. Others aspects that would require further clarification are: What happens when the IP applicant uses a particular GR or ATK originated in a third country without fulfilling the above obligations? Who ensures that ABS requirements are fulfilled in the IP examination process? How the confidentiality of the information included in the database could be safeguarded?

More broadly, the main criticism regarding databases is that they can contribute to placing TK -that has been held in secrecy or is unknown outside the traditional context- into the public domain. It has also been pointed out that databases do not directly contribute to benefit-sharing, unless additional protection measures are put in place. Databases have also been considered intrusive and inadequate to capture the diversity and richness of GRs and TK.<sup>139</sup> TK databases might also have limitations in addressing the evolving nature of TK.

For TK databases, the main means of protection so far has been confidentiality. In some cases, TK registers have been used as a vehicle to provide *sui generis* positive protection for TK, as in the case of registers under Panama's

Act 20 on the collective rights of indigenous peoples and the Peruvian collective regime on TK. In the case of Panama, there are already 10 specific protected TK practices belonging to the Kuna, Ngobe, Bugle, Embera and Wounaan communities. The knowledge so far protected falls under the realm of TCEs and includes textiles and fibres works, woodcrafts and musical instruments.<sup>140</sup> So far indigenous communities in Panama have not finalized any contract or license of their collective rights.<sup>141</sup>

In the case of Peru, Law 27811 of 2000 on the Collective Knowledge of Indigenous Peoples created several parallel registers.<sup>142</sup> The law mandates the creation of a National Public Register to collect TK in the public domain (meaning knowledge that has already left the traditional context through mass communication such as publications), a National Confidential Register (subject to restricted access) and local registers basically made by indigenous communities following their own practices and customary rules. The type of collective knowledge protected under Law 27811 is quite wide and includes protection against revelation, acquisition and use without PIC or through unfair means. Access and utilization of protected collective knowledge, such as that deposited in the National Confidential Register or local registers, are subject to PIC and the approval of a collective knowledge license. There is also special protection for collective knowledge that fell into the public domain in the last 20 years. There is already a web portal,<sup>143</sup> which lists entries in the National Public Register. Peru's National Institute for the Defence of Competition and Protection of Intellectual Property offers access to registered information subject to specific requirements and terms of use. The National Public Register contains more than 1000 entries so far. Additionally, some 193 applications for collective knowledge protection under the Confidential National Register have been received since 2009.<sup>144</sup> So far 70 applications under the National Confidential Register and 19 under the National Public Register have been granted protection under the law.<sup>145</sup> Applicants include 29 native communities but also 63

farming communities.<sup>146</sup> Besides licensing, an innovative fund for the development of indigenous peoples was created to ensure and promote benefit-sharing. The experience of the Peruvian law shows that protection given can generate incentives for confidence, empowerment and use by titleholders. It also shows that it is possible to have parallel mechanisms for defensive and positive protection in a coherent manner and at different levels.

Due to the fact that there seems to be great interest in databases and registers for both defensive and positive protection, one option in the IGC is to take a **rights-based database approach** for both genetic information and TK. Under this approach, titleholders depositing their GRs or TK in the database could at the same time allow access to the information for defensive purposes but also enjoy certain *sui generis* rights over their content and utilization. In this regard, IP offices could obtain access to the information under confidentiality arrangements for defensive purposes in line with the TKDL experience. At the same time, positive protection for content and the organization of information could be granted following the experiences of Panama and Peru.

The justification for positive protection in this case includes:

- a) GRs are regulated by states and TK belongs to relevant indigenous and local communities;<sup>147</sup>
- b) Access and benefit-sharing requirements need in any case to be authorized and agreed with those title holders;
- c) The investment for the building of those databases in most cases comes from governments, philanthropic organizations and/or indigenous and local communities; and
- d) There will be important intellectual contributions by titleholders in collecting and organizing the information in a way

that fulfils multiple purposes, including preservation, ensuring legal access and benefit-sharing.

The beneficiaries of protection will obviously be governments for GR-related information and indigenous and local communities for TK. The subject matter of protection would be GRs as defined by the CBD, Nagoya Protocol and national ABS legislation; and TK and TCEs as defined by national TK/TCE legislation or by a future WIPO instrument(s) on TK and TCE protection.

The type of protection given under the rights-based database approach could be provided under a three layered approach:

- **Layer one:** In the case of GRs, the database would assist in having an inventory of GRs that could be subject to ABS regulations in line with international obligations including future WIPO instruments on GR. It could also provide additional information, such as vulgar and scientific names and known uses. In relation to TK, the database could further facilitate and complement TK protection regimes. Under this layer the database/register would have declarative effects over TK rights.
- **Layer two:** It should provide for a presumption that any unauthorized use of confidential information contained in the database should be considered an act of unfair competition or unjust enrichment. This presumption would operate unless the users can prove that they fulfilled ABS requirements, have a license from TK holders or have obtained the same information by honest/legitimate means (e.g. information was known or accessed before 1993).
- **Layer three:** Copyright protection for the original compilation and organization of information. This type of protection is already recognized for the original compilations of data, regardless of the type of content, under Article 10.2 of the TRIPS Agreement.<sup>148</sup>

Granting exclusive rights over the contents of the database and its utilization is also an option but would have to be based on a more complex set of rules under the draft articles on TK protection, which might also include exceptions. Under this scenario, measures to ensure confidentiality may not be needed. This approach could also assist in getting providers, TK holders, and users to move beyond their traditional positions. There is also the alternative of strengthening rights under future TK draft articles by extending those rights over information already compiled in existing or future GR/TK databases and registers.

One potential criticism that could arise in relation to this proposal is that GRs do not represent an intellectual value added and should not be protected through IP. It is important to recall that genetic information, depending on the case, can have economic value. Also, it is now very expensive to preserve biological resources *in situ*. One possible response to this criticism is that there are already IP categories in which protection is not based on the intellectual value added. For example, there are cases in national legislation where simple data is protected because it is costly to gather, such as the protection of test data for regulatory approval or of “non-original” database compilations.



## 6. THE IGC'S DRAFT OBJECTIVES AND PRINCIPLES ON IP AND GRS

This section provides an analysis of the main objectives and principles on IP and GRs and matches them with the proposed options under Clusters A and B where relevant. This involves a selection of key issues. The analysis is based on documents presented at the IGC 19 session in July 2011, which were the latest available at the time of writing. These documents were recently updated for the WIPO General Assembly of 2011.<sup>149</sup> It looks at the legal value and interpretation of current draft text on principles and objectives and offers a commentary on key proposals. The commentary is presented in a table in Annex I.

### 6.1 Legal Value and Interpretation

The draft text on objectives and principles so far contains a mix of exhortative language, objectives, principles and some specific provisions. However, all provisions are titled and numbered as objectives and principles. While it is fundamental to agree on common objectives and principles to further develop solutions, it seems important to understand the legal value of a document with such a title and content. The objectives and principles guide the interpretation and application of the treaty or instrument in question. In the case of international treaties, Article 31.1 of the Vienna Convention is very clear on the interpretive value of objectives and principles when indicating, "a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose". The interpretive value of the objectives and principles will greatly depend on the language. The use of words such as "shall or should" also have important implications in setting the scope of the specific instrument and operational provisions.

The WTO panel decisions on the TRIPS Agreements are illustrative of the interpretation given to principles and objectives so far. In the Canada-Patent Protection on Pharmaceuticals case, the panel decision made clear that both the goals and the limitations stated in Articles

7 and 8.1 must obviously be borne in mind, as well as those of other TRIPS provisions.<sup>150</sup> In this case, the panel upheld the European Commission approach by which the balancing of objectives had already taken place in specific provisions, but at the same time it recognized that Article 28 of the agreement (patent holder rights) would need certain adjustments in light of Articles 7 and 8.1.<sup>151</sup> In the appeal to this case, the WTO Appellate Body acknowledged that it has yet to determine the applicability of Article 7 or Article 8 of the TRIPS Agreement in possible future cases with respect to measures to promote WTO members' policy objectives that are set out in those Articles and that "those Articles still await appropriate interpretation".<sup>152</sup>

Principles and objectives can also play a bridging function between two international instruments.<sup>153</sup> For example, paragraph 19 of the Doha Ministerial explicitly stipulates that "the TRIPS Council should be guided by Articles 7 and 8 in its examination of the relationship between the TRIPS Agreement and the Convention on Biological Diversity and the protection of traditional knowledge and folklore". This process is still ongoing as part of the Doha Round of negotiations and the outstanding implementation agenda items (paragraph 12 of the Doha Declaration) and has generated several specific proposals to amend the TRIPS Agreement as mentioned above.

Agreeing on a set of objectives and principles is an important step to ensure that stakeholders share a common purpose by providing the necessary basis for further work. Moreover, they are an important source of interpretation of the instrument(s) to be agreed. What is more relevant in this context, however, is the need for operational provisions that would develop and implement such objectives and principles.

Operational provisions could include specific legal, policy, and administrative measures. A GR protection instrument with clear objectives, principles, and operational

provisions could become a common basis for additional adjustments in WIPO, such as further discussions on PCT disclosure proposals. It could also complement a more general agreement on an extended disclosure mechanism under a potential Article 29*bis* of the TRIPS Agreement.

This latter idea was understood by the GLMC when they inserted a new set of draft articles on the protection of GRs, including provisions on:

- a) The scope of the subject matter;
- b) Beneficiaries;
- c) Scope of protection;
- d) Complementary measures;
- e) The relationship with other international agreements;
- f) Transboundary cooperation;
- g) Sanctions and remedies; and
- h) Technical assistance.

The content of operational provisions, in this case called draft articles, does not preclude the binding or guiding nature of the outcome. Its content may evolve as negotiations advance and they could greatly benefit from

alternatives already identified by the views of members and experts in the IGC.

## **6.2 Commentary on Objectives, Principles, and Operational Provisions**

In order to provide more specific comments on WIPO's draft objectives and principles on GRs, as well as on the recent proposal by the GLMC, a separate table is included in Annex I to complement the analysis provided in this study. The table compares and analyses the current draft objectives and principles with the GLMC proposal. It is assumed that previous proposals have been incorporated in the current IGC text and filtered through the WIPO process. The analysis on the current IGC texts makes links to additional options proposed in this paper.

The GLMC proposal has been chosen as a point of comparison for several reasons. First, it is the most recent comprehensive proposal on the table at the time the research for this study was undertaken. Second, it represents an effort by several provider countries to develop a cross-regional coalition. Finally, it is the only proposal that has explicitly included specific articles on GR and ATK protection in addition to objectives and principles that could derive in a complete instrument(s) on GR protection.

## 7. MONITORING, ENFORCEMENT MEASURES, AND DISPUTE SETTLEMENT

Monitoring, enforcement, and dispute settlement issues will be fundamental for providing clarity and legal certainty and ensuring compliance with any new potential instrument(s) for GR protection under the IGC. There is no reference in the draft objectives and principles on GR protection to enforcement or dispute settlement. However, there are references to the appointment of IP offices as checkpoints for disclosure and monitoring of the utilization of GRs, derivatives and ATK (see Annex I). This is not surprising, as this sort of proposal was already discussed in negotiations leading to the Nagoya Protocol. As mentioned above, the Protocol requires the appointment of one or more checkpoints to monitor and enhance transparency about the utilization of GRs. It is for parties to the Protocol to make such an appointment. Ministries of environment, biodiversity offices, IP offices, and customs

authorities may be appointed. Appointing IP offices as checkpoints would be fully coherent for a future instrument(s) on GRs protection that seeks to improve patent quality examination of inventions accessing or utilizing GRs and ensure benefit-sharing. Enhancing transparency and monitoring the utilization of GRs and ATK in IP applications is, in fact, expected of them. Obviously, not all members and actors agree with benefit-sharing objectives in the new instrument or support this approach.

Sometimes autonomous bodies can undertake the monitoring and prevention of biopiracy and misappropriation functions. The case of the National Commission Against Biopiracy (Comisión Nacional contra la Biopiratería) of Peru is the most advanced model on the matter today. Box 3 illustrates its experience so far.

### Box 3. The recent experience of the National Commission Against Biopiracy of Peru

The NCAB was created in 2004 as an interagency coordination and technical advisory body that directly reports to the Presidency of the Republic. The Commission is Chaired by the National Institute for the Defence of Competition and Protection of Intellectual Property and is composed of several public agencies (e.g. environmental, health, agriculture and tourist authorities), research centres and NGOs. The mission of the NCAB is to develop actions to identify, prevent and avoid potential cases of biopiracy<sup>154</sup> with the objective of protecting the interests of the Peruvian state. Among its functions we found the following:

- Create and maintain registers on biological resources originated in Peru as well of the collective knowledge of Peruvian indigenous peoples;
- Identify, assess and follow up patent applications filed abroad that have utilized Peruvian GRs or ATK;
- Initiate legal actions for the defence of Peruvian genetic patrimony and the TK of indigenous people, including within the IP system;
- Establish channels of contact and dialogue with IP offices abroad on these matters;
- Undertake consultations with all relevant stakeholders;
- Support the Peruvian state in multilateral negotiations.

Recently, the NCAB has also focussed on the simplification and review of ABS regulations in order to make them more user-friendly.

The NCAB has prioritized 35 Peruvian biological resources of significant utility and potential value. In response, it has prepared and sent various studies on potential cases of biopiracy and prior art dossiers to relevant IP offices in third countries. It has also provided contributions on the matter to the IGC. So far the NCAB has impeded the granting of nine controversial patents utilizing Peruvian GRs and ATK. Below is the list of controversial patents rejected, withdrawn or abandoned as a consequence of the NCAB action. In these cases it has been proven that without the action of the NCAB, these patents would have been granted, feeding the list of actual cases of biopiracy and potential misappropriation.

Resource	Patent or patent application	IP office	Status
Maca	Compositions and methods for their preparation from lepidium (WO 0051548)	PCT	Rejected
Maca	Functional food product containing maca (publicación N° 2004 000171)	Japan	Rejected
Maca	Ameliorant for sleep disturbance (JP2007031371)	Japan	Rejected
Maca	The manufacturing method and composition of a maca extract (Kr20070073663)	Korea	Rejected
Maca	Testosterona increasing composition (jp2005306754)	Japan	Rejected
Sacha inchi	An extract of a plant belonging to the genus plukenetia volubilis and its cosmetic use. (WO/2006/048158 )	PCT	Withdrawn
Sacha inchi	Utilisation essential oils and proteins of Plukenetia volubilis linneo seeds in cosmetic, dermatologic and nutraceutic compositions (FR 2880278)	France	Withdrawn
Camu camu	Preserves of fruit of myrciaria dubia (publicación N° 09 - 215475)	Japan	Abandoned
Pasuchaca	Inhibitor of glycosidase (P2005-200389 <sup>a</sup> )	Japan	Abandoned

Sources: Compiled by author from information from the NCAB website, official documents of the NCAB (2011) and interviews with governmental officials.

Something that provider countries need to understand is that none of the mechanisms proposed for inclusion in a future instrument(s) for GR protection are a substitute for a transparent, effective, and efficient ABS mechanism at the national level. BRDRs, databases and model clauses can support ABS implementation but cannot regulate access, issue ABS contracts and manage relations between users and providers. It is also evident from the TKDL and NCAB experiences that a proactive stand can curb the number of potential cases of biopiracy in the IP system. Besides these two experiences, direct notification of companies utilizing GRs or ATK, engagement in

post-access negotiations, and exploring options for litigation within and outside the national jurisdiction can produce results. Also, in many cases users may have assets in the provider country, making it easier to bring cases for violation of environmental law and the rights of TK holders within national jurisdictions. For TK holders, mechanisms under human rights conventions may also represent suitable options for establishing legal precedents and even for gaining compensation.

The fact that countries hold rights over GRs does not mean that states have the capacity to effectively seek enforcement outside their

border or to litigate. An option that states have at hand is to outsource monitoring and litigation to law or consultancy firms. Potential benefits or compensations may assist in sustaining the cost of legal defence. Also, some NGOs, such as the Centre for International Environmental Law, Public Interest Intellectual Property Advisors, the Bern Declaration and Natural Justice have already provided legal advice, support and representation on a *pro bono* basis in cases of biopiracy.

An additional option for seeking enforcement is to create a CBD/WIPO arbitration mechanism to resolve any disputes or interpretation difficulties among the parties regarding obligations under a future WIPO instrument. The mechanism could also apply to state-business disputes or to indigenous-business disputes regarding access contracts by including an arbitration clause. A compulsory jurisdiction of this mechanism in cases of a cross-border nature is also an

option. Situations that will definitely need a compulsory adjudication will be those in which there is no ABS contract and one of the parties alleges illegal access and/or utilization. In such situations, contracts and arbitration clauses are obviously useless, as they do not exist. To generate balanced outcomes, mandatory terms of reference for the WIPO/CBD mechanism should include in the determination of legal and factual consistency all CBD and WIPO conventions, as well as subsequent recommendations and decisions produced by relevant bodies in a mutually supportive manner.

Correa (2008) has also proposed an international regime for the recognition of national regulations on access to GRs.<sup>155</sup> Such a regime would include a mechanism for the recognition of foreign determinations made on the basis of national access legislation. This alternative could be expanded to also cover *sui generis* TK regimes.

## 8. BINDING OR NON-BINDING?

One outstanding question that remains is whether or not such an instrument(s) should be legally binding. To properly respond to this question it will be necessary to look at the content of the main proposals and their potential to address key concerns. It would be irrelevant to generate a binding instrument that would not change the current reality and provide solutions to low patent quality examinations, compliance with ABS requirements and ensuring higher levels of transparency and legal certainty. If solutions on the table have the capacity to tackle these problems in practice, then and only then could a binding instrument be of assistance.

A binding instrument would be the most direct and safest way to ensure that measures in the IP system are effectively taken in user countries. Without a binding instrument, the *status quo* will probably continue, especially among non-signatories of the Nagoya Protocol. Timing is also important: if a new WIPO instrument is adopted within the next two years it could be jointly implemented with the Nagoya Protocol, facilitating the emergence of coherent solutions and making policy changes in parallel.

If a binding instrument is politically unfeasible, soft law options should not be ruled out. A joint recommendation, guidelines, or declaration taken at the WIPO General Assembly level could have important interpretative effects. The case of the Doha Declaration on TRIPS and Public Health (2001) is a good example of the political and interpretative importance of such instruments. However, this is not always the case. An example can be found in the Bonn Guidelines regarding the consideration of measures to encourage the disclosure of origin of GRs and ATK, which did not have the expected effect on most user countries.

Soft law solutions can be considered as a potential incremental step toward a more solid incorporation of mandatory BRDRs, as well as specific measures in the TRIPS Agreement and

in the PCT. Soft law options might also have the potential to become stronger legal text, if they are later introduced as part of future TRIPS negotiations, WIPO treaty reviews or in the text of future FTAs.

A possible **joint understanding, recommendation, guidelines or WIPO declaration** on the protection of GRs and ATK could include a full recognition of the following aspects:

- Indicate that the acquisition of IP is subject to the respect of the genetic patrimony of states and of the rights of indigenous and local communities;
- Insert a clear understanding that IP applicants need to fulfil national ABS requirements and obligations under the CBD and the Nagoya Protocol (PIC, MAT and other benefit-sharing arrangements) for GRs and ATK;
- Insert a clear statement that nothing in WIPO treaties limits the rights of members to introduce requirements to ensure legal access and the existence of benefit-sharing arrangements in IP application and granting procedures;
- Require and/or encourage the incorporation and use of mandatory BRDRs in IP applications with clear legal effects;
- Introduce a follow up negotiating mandate for WIPO bodies to modify treaties such as the PCT, UPOV, and the Budapest Treaty, in order to introduce effective mandatory BRDRs with clear legal effects;
- Incorporate complementary measures such as different modalities for GRs and TK database protection (e.g. a rights-based database approach for GRs and ATK);
- Provide support to introduce user measures within the IP system as a consequence of obligations under the CBD and the Nagoya Protocol;

- Provide support to those members and/or indigenous and local communities to build their own databases under modalities to be determined by them;
- Require IP offices to be supportive of transparency, monitoring, and enforcement of ABS requirements and the Nagoya Protocol;
- Appoint and/or encourage members to designate IP offices as checkpoints under the Nagoya Protocol;
- Make a clear statement that WIPO treaties and bodies shall support the implementation of the CBD and the Nagoya Protocol and as well as CBD COP Decisions.

If soft law becomes an option, it should not be subject to political trade-offs, as it would not require any regulatory changes by user

countries or bring direct implementation costs. *Demandeurs* of such an approach should also be clear that the soft law option would just imply gaining time and it is highly probable the issue will continue to be raised at the multilateral level and be developed in national legislation, as the main concerns will not be solved. Also, under this scenario, proposals for the introduction of measures in IP to ensure legal access and benefit-sharing and address cross-border situations will keep its value as a defensive tool *vis-à-vis* other IP negotiations whether in WIPO or the WTO. So it is probable that many countries would also propose soft law solutions to address patent harmonization and enforcement concerns.

The question for many then becomes: do IGC members really want to find a solid and stable multilateral solution or just keep dragging their heels?

## 9. THE WAY FORWARD

While under the CBD COP several legal and policy outcomes have been achieved, results in IP-related forums such as the TRIPS Council and WIPO bodies, including the IGC, have been thin or non-existent so far. The IGC has an historical opportunity to deliver in an area where the need for equitable solutions is vast. While several international processes have failed to create synergies between IP and biodiversity concerns, the IGC has the potential to build trust, reduce policy gaps, and deliver a landmark multilateral instrument(s) on the protection of GRs, TK and TCEs.

In light of the analysis and evidence presented in this document, a number of process and content recommendations can be made, together with an identification of areas for further research.

### 9.1 On Processes

- The new ABS standards in the Nagoya Protocol can generate higher levels of confidence, clarity and legal certainty for both users and providers. Additional measures to support these new standards in the IP system need to be explored and addressed in ongoing IP negotiations in the IGC, the TRIPS Council, and FTAs.
- A TRIPS amendment is considered to be the most suitable and effective option for introducing BRDRs. However, if *demandeurs* continue to seek the incorporation of BRDRs not only in the TRIPS Council but also in the IGC, it is advisable to mirror and adapt the language and content of proposals made so far in the TRIPS Council in order to avoid contradictions and differences in scope and content. Proposals under the IGC and the PCT could be considered as complementary operational options.
- Biodiversity-related provisions in various bilateral FTAs already provide some incipient options for addressing concerns over erroneous patents, insufficient patent examination, the lack of legal access to GRs and ATK and to ensure benefit-sharing. Standards found in recent EFTA FTAs with Colombia and Peru are particularly valuable. It is advisable to draw on these provisions, as several user countries in the IGC have already accepted standards that go beyond TRIPS and WIPO agreements on these matters.
- There is a need in the IGC for additional trust-building measures, especially with indigenous groups and local communities. Measures could include entrusting the friends of the Chair to go further and produce bridging text proposals under their responsibility; appointing a special indigenous peoples' facilitator to ensure their views are taken into consideration ; supporting the holding of regional consultations to build common positions; and facilitating stakeholder dialogues in parallel to the IGC process in order to reduce tensions.
- Options for building business confidence should also be explored. Parallel business roundtables with the participation of countries, business associations, interested indigenous representatives and "fair trade" organizations could be organized in order to exchange views on business opportunities, regulatory frameworks and investment incentives. Such roundtables could also showcase best practices and actual examples of legal ABS arrangements with relevant IP clauses where benefits have arisen for both provider and user countries.

### 9.2 On Substance

- The addition of a set of provisions to the current IGC draft of objectives and principles on GR protection seeking their operationalization. Such operational provisions may include obligations for IP applicants to respect ABS regimes in line with international obligations; introduce mandatory BRDRs; and rights-based database protection.



- The incorporation of definitions that already exist in international agreements, such as those on “GRs”, “utilization” and “derivatives”, plus agreement on some specific ones such as “biopiracy”, “misappropriation” and “misuse”, could contribute to higher levels of clarity.
- The recent proposal by the GLMC could provide a suitable base for advancing negotiations in the new phase of the IGC. This proposal is explicit on what the main proponents want in terms of objectives and principles, providing also a new set of proposals and mechanisms designed to tackle key concerns. This proposal needs to be adjusted to address some additional concerns of indigenous peoples, user countries and industries. An added advantage of the proposal is that it seeks to improve transparency, reduce transaction costs, and ensure coherence and mutual supportiveness with the CBD and Nagoya Protocol.
- While minimum standards are proposed to introduce BRDRs at the multilateral level, there is ample space to design them in light of additional policy objectives. Introducing an *ex post* ABS restoration mechanism and a biodiversity linkage, ensuring the proper treatment of confidential disclosed information, developing the Global Multilateral Benefit Sharing Mechanism, and making use of certificates of compliance under the Nagoya Protocol could complement the efficacy and cost effectiveness of BRDRs. The main *demandeurs* should evaluate the use of an “enabling clause” for BRDRs. A careful selection of legal effects in the case of a lack of BRDR compliance and ABS regulations, by explicitly indicating cases where patent revocation could occur (e.g. fraud or anticompetitive practices) and introducing additional effective administrative or civil measures (e.g. fines or damages), could also give higher levels of certainty to users and providers.
- Allowing contributions on prior art by provider countries and indigenous organizations could facilitate search and examination by examiners. A prior art cooperation mechanism, by which IP offices in user countries could give full consideration to any prior art submission made by provider countries and other stakeholders such as indigenous organizations (including from GR and TK databases), could be of assistance. For this mechanism to be effective, a procedural opportunity to make such submissions should be introduced in IP examination procedures.
- Introducing a rights-based database approach could give GR and TK databases not only a potential defensive role but also a positive one. BRDRs, databases, and prior art contributions are not contradictory measures. They all provide different types of information that will ultimately benefit prior art searches, facilitate the work of patent examiners, allow transparency and traceability, and ensure the fulfilment of ABS requirements.
- One option available to countries without the capacity to implement effective ABS systems or BRDRs is to set a horizontal biodiversity conservation tax applicable to sales of biodiversity-derived products and inventions. This tax could be low but at the same time more effective (e.g. 1 per cent of sales). It could also apply to GR-intensive industries, as they are the main beneficiaries. Companies contributing to the new Global Multilateral Benefit Sharing Mechanism under the CBD could be exempted, in order to create incentives for compliance at the multilateral level.
- Options for monitoring, enforcement and dispute settlement would be of great importance in any agreed outcome. They could include good offices, an interpretative mechanism, a proposal for a CBD/WIPO arbitration service, mutual recognition

agreements, and setting up national monitoring and enforcement institutions. Different modalities could be agreed for state-to-state disputes and state-to-other stakeholders disputes.

- While a binding instrument would provide the most direct and solid solution, soft law solutions should not be ruled out at this stage. In this regard, it is important that the content of the instrument addresses concerns effectively. Specific content for a soft law approach is given in case efforts towards binding solutions do not progress. In any case, it is perceived that the incorporation of BRDRs will be a “deal breaker” in the current IGC process on GRs and ATK.

### 9.3 Further Research

- There is a need for better data on the existence, number, and basic content of ABS contracts. Setting up a notification system through the CBD Clearing-House Mechanism, by which all parties should notify a non-confidential extract of subscribed ABS contracts, could be of assistance. This extract could include the scope, biological resources covered, parties to the agreement (including country of origin and the party requiring access), the date, the profit or non-profit nature of the activity, and whether benefit-sharing arrangements have been agreed. Notified contracts could then be compiled in a non-confidential database.
- An important contribution to the debate could be to establish an independent international commission to prepare a factual report on the state of GR and ATK biopiracy and misappropriation based on the best information and evidence available. This report should not only look at claims related to the fulfilment or not of IP criteria but also address the problem of the lack of authorization and ABS contracts in light of the CBD, the Bonn Guidelines and the Nagoya Protocol. Such a report could also look at the actual cost of defending GRs and ATK in foreign jurisdictions, as well as the lost benefits resulting from the lack of ABS arrangements in IP filing and commercialization.
- Additional research on practical national experiences on BRDRs could shed light on their effectiveness but also on possible problems and solutions found in the practical implementation of BRDRs to address concerns by both user and provider countries. This work could be carried out directly by IGC members or undertaken by the WIPO secretariat. In this case, field missions and the compilation of statistical data might be in order.

## ENDNOTES

- 1 Submission by Colombia to the SCP, 6-14 September 1999. The text of the proposals indicated the following: "All industrial property protection shall guarantee the protection of the country's biological and genetic heritage. Consequently, the grant of patents or registrations<sup>18</sup> that relate to elements of that heritage shall be subject to their having been acquired legally. [...] Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof where the goods or services for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin".
- 2 Submission by GRULAC, 14 September 2000.
- 3 This is evident for example in the case of Australia, New Zealand, Russia, France, the US and the UK. All these countries are megadiverse and at the same time undertake important R&D activities. Australia and New Zealand have the highest level of endemic species. France and the UK have a wide range of overseas territories with high biodiversity. These countries also have indigenous and local communities in their territories and rich traditional cultures. So assumptions of a zero-sum game in the discussions on GRs, TK and IP are not fully accurate.
- 4 Pastor & Ruiz (2009).
- 5 TEEB (2010).
- 6 Ten & Laird (1999).
- 7 WWF, ZSL & GFPN (2005).
- 8 TEEB (2008).
- 9 Bifani (2005).
- 10 Correa (2005).
- 11 Cabrera (2003).
- 12 Ibid.
- 13 Bifani (2005).
- 14 Dutfield (2003).
- 15 Ibid.
- 16 Sarnoff & Correa (2006).
- 17 Robinson (2010a).
- 18 Vogel (2005).
- 19 Ibid., Robinson (2010).
- 20 Government of Peru (2005).
- 21 BIO & IFPMA (2010).
- 22 Macgow (2006).

- 23 BIO & IFPMA (2010) and ICC statement in IGC 18 meeting, paragraph 370 referring to IGC objectives, see WIPO/GRTKF/IC/18/11/ Prov. 2.
- 24 Dutfield (2005).
- 25 Bhatti et al. (2007).
- 26 Louafi & Tobin (2005).
- 27 See WIPO (2011).
- 28 See Pastor & Ruiz (2009).
- 29 See Laird & Wynberg (2008).
- 30 Pastor & Ruiz (2009).
- 31 Bhatti et al. (2007).
- 32 Ibid.
- 33 Santiago & Siguenzas (2008).
- 34 Ibid.
- 35 See the list of signatory countries to the Nagoya Protocol at <http://www.cbd.int/abs/nagoya-protocol/signatories/> (last accessed November 2011).
- 36 See Aichi at <http://www.cbd.int/sp/targets/>
- 37 See Article 2 of the Nagoya Protocol.
- 38 See Nijar (2011).
- 39 See Article 2 of the Nagoya Protocol.
- 40 A non-profit association that promotes the ‘Sourcing with Respect’ of ingredients that come from biodiversity.
- 41 Union for Ethical Bioproducts (2010a).
- 42 Ibid.
- 43 See WIPO/GRTKF/IC/19/INF/9, May 2011.
- 44 See WIPO/GRTKF/IC/19/11, July 2011. Some of the definitions in this text go beyond the Nagoya Protocol.
- 45 See Article 5 of the Nagoya Protocol.
- 46 See Article 8 (j) of the CBD.
- 47 See Article 7 and 12 of the Nagoya Protocol.
- 48 Pernault & Oliva (2005).
- 49 Cabrera (2010a).
- 50 Ibid. and see decision SC, No. 8-13832, 11 September 2008.
- 51 Ibid.

- 52 See Article 17 of the Nagoya Protocol.
- 53 See Article 5 of the Nagoya Protocol.
- 54 Comment made by an expert interviewed.
- 55 See Article 15 of the Nagoya Protocol.
- 56 See Article 17 of the Nagoya Protocol.
- 57 Participants in the GLMC include Algeria, Angola, Bangladesh, Colombia, Egypt, India, Indonesia, Malaysia, Myanmar, Namibia, Pakistan, Peru, South Africa, Tanzania, Thailand and Zimbabwe.
- 58 See Article 10 of the Nagoya Protocol.
- 59 WTO Doha Ministerial Declaration, document WT/MIN/(01)/DEC/W1, 14 November 2001.
- 60 See Job(01)/152/Rev.1.
- 61 See document WT/GC/W/564, 31 May 2006.
- 62 Correa (2010).
- 63 See document TN/C/W/59, 19 April 2011.
- 64 PCT/R/WG/9/5, March 2007 and WIPO/GRTKF/IC/8/11.
- 65 Lopez-Tarruella Martinez (2011).
- 66 The US-Colombia FTA was signed but has not yet been ratified by the US Congress.
- 67 See Article 150 of the EU-Cariforum Agreement.
- 68 See Vivas-Eugui & Oliva (2010).
- 69 See Article 6.5 of the EFTA-Colombia and Peru FTAs.
- 70 Vivas-Eugui & Oliva (2010). For further understanding, see Articles 196.5 and 234.1 of the FTA between the EU and Colombia/Peru.
- 71 See WIPO (2009).
- 72 See Assemblies of WIPO Member States. Decision on item 31, Matters Concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. September 26 to October 5 of 2011. See [http://www.wipo.int/export/sites/www/tk/en/documents/pdf/decision\\_assemblies\\_2011.pdf](http://www.wipo.int/export/sites/www/tk/en/documents/pdf/decision_assemblies_2011.pdf)
- 73 In WIPO's practice, Diplomatic Conferences are the last phase of negotiations toward the adoption and signature of a new international convention or treaty.
- 74 See WIPO/IGCGRTKF/IC/19/6, May 2011.
- 75 See WIPO/IGCGRTKF/IC/19/7, May 2011.
- 76 See WIPO/IGCGRTKF/IC/1/12, 2001.
- 77 See WIPO/IGCGRTKF/IC/19/11, July 2011.
- 78 See WIPO Decisions of IGC 19, 22 July 2011.

- 79 It also important to note that the utilization in this context of the term user and provider countries might be also somehow misleading as all countries may be both (for example the US and Australia are also megadiverse countries). However, this terminology is useful to represent the main positions in the IGC.
- 80 UN General Assembly Resolution 61/295, 2007.
- 81 Pastor & Ruiz (2009).
- 82 See WIPO/IGCGRTKF/IC/17/10, December 2010.
- 83 See WIPO/GRTKF/IC/19/11, July 2011.
- 84 See CBD Secretariat statement in IGC 17, document WIPO/IGCGRTKF/IC/17/10.
- 85 Submission by the African Group at IGC 17, document WIPO/GRTKF/IC/17/10 and reissued at IGC 20 in document WIPO/GRTKF/IC/20/INF/12.
- 86 See statement by Norway and Japan in IGC 17.
- 87 See statements by Norway, Brazil and Indonesia in IGC 17.
- 88 See statement by South Africa in IGC 18, document WIPO/IGCGRTKF/IC/18/11.
- 89 Statements by Brazil, Bangladesh on behalf of the Asian Group, Chile, the EU, Norway, Switzerland in IGC 17 and well as various experts on discussions of options for future work in ISWGs. See documents WIPO/IGCGRTKF/IC/17/10 and WIPO/IGCGRTKF/IC/19/7.
- 90 See statements by Brazil and the CBD Secretariat in IGC 17. See also statement by South Africa in IGC 18.
- 91 See statement by South Africa in IGC 18.
- 92 See statements by Norway in IGC 18.
- 93 See statement by South Africa in IGC 17.
- 94 See statement by Mexico in IGC 17.
- 95 See Article 5.2. WIPO/GRTKF/IC/19/11
- 96 See Bridges Trade Biores (2011). This section builds on ICTSD and IP Watch reporting in 2010-11. This is a reflection of the known position of the African Group since IGC 17 to primarily focus IGC's work on mandatory disclosure requirement option and on the need to ensure its incorporation in the draft text of GR objectives and principles.
- 97 Ibid.
- 98 Statement by indigenous people to IGC 18, 12 May 2011.
- 99 ANDES (2010).
- 100 See document WIPO/GRTKF/IC/19/11, July 2011.
- 101 See Article 29 of the TRIPS Agreement.
- 102 Recommendation 18 of the WIPO Development Agenda. See: <http://www.wipo.int/ip-development/en/agenda/recommendations.html> (last accessed November 2011).

- 103 See comparative analysis of BRDRs in these legislations in Henninger (2010). The compilation includes the EU Directives even if the BRDR in that case is voluntary.
- 104 The following analysis is based on the compilation made by Henninger (2010).
- 105 Ibanez de Novion & Baptista (2006).
- 106 Cabrera (2010a).
- 107 For the purposes of this paper, biological material is understood to be any biological derived material containing units of heredity but also naturally occurring biochemicals. It can take the form of cells, individual entities and parts of living organisms.
- 108 For example, certain countries such as Brazil, Costa Rica and China only require the disclosure of GRs originated in their territories.
- 109 See: <http://www.biopirateria.org/documentos/Informe%20taller%20FINAL.pdf>. It is recommended to translate this report and distribute it at the IGC.
- 110 See Chouchena-Rojas et al. (2005).
- 111 Comment made by an expert interviewed.
- 112 WIPO, PSEL, NCAB and IFPB (2009).
- 113 Ibid.
- 114 It should be kept in mind that the definition of prior art may vary from jurisdiction to jurisdiction. In some countries there are territorial limitations or prior art is restricted to recorded or codified information and not to practices or oral traditions.
- 115 See WIPO, PSEL, NCAB and IFPB (2009). This document also presents a series of interesting alternatives for the implementation of BRDRs.
- 116 Comment made by an expert interviewed.
- 117 Interview with Andres Valladolid. See section on monitoring, enforcement and dispute settlement.
- 118 Sarnoff & Correa (2006).
- 119 Proposals raised by one of the experts interviewed.
- 120 Ellsworth (2010).
- 121 See Lybbert Travis (2007).
- 122 See various statements and submissions by the US, Australia and Japan in the TRIPS Council and the IGC. ICC (2011), BIO & IFPMA (2010).
- 123 Oldham (2011).
- 124 Ibid.
- 125 US Patent and Trademark Law Amendments Act (1980).
- 126 Oldham & Burton (2010).
- 127 Oldham (2011).

- 128 See Article 17 of the Nagoya Protocol.
- 129 See Article 16 of the Nagoya Protocol.
- 130 WIPO, PSEL, NCAB and IFPB (2009).
- 131 Ibid.
- 132 Merle et al. (2003).
- 133 See: [http://www.parquedelapapa.org/eng/01visitanos\\_01.html](http://www.parquedelapapa.org/eng/01visitanos_01.html).
- 134 Merle et al. (2003).
- 135 WIPO (2010).
- 136 Ibid.
- 137 Ibid.
- 138 See WIPO/GRTKF/IC/20/5 of the 10 of October 2011.
- 139 Merle et al. (2003).
- 140 Arenas (2010).
- 141 Ibid.
- 142 See text of the law at: <http://www.concytec.gob.pe/infocyt/ley27811.html>.
- 143 See INDECOPI (2010a).
- 144 See INDECOPI (2010b).
- 145 INDECOPI (2010a).
- 146 INDECOPI (2010a).
- 147 In certain cases access to GRs may also be subject to PIC by indigenous and local communities in accordance with national law (e.g. GRs found within indigenous territories; see Article 6.2 of the Nagoya Protocol).
- 148 This protection should be differentiated from *sui generis* database protection where the organization of the information is non-original.
- 149 These documents were recently updated for the 2011 WIPO General Assembly. See WO/GA/40/7, 12 August 2011.
- 150 WTO (2000).
- 151 See Yu (2009).
- 152 WTO (2000), para. 101.
- 153 See Yu (2009).
- 154 See their definition of biopiracy at: <http://www.biopirateria.gob.pe/index2.htm>.
- 155 See Correa (2008).



156 Sarnoff & Correa (2006).

157 Ibid.

158 National law and requirements include customary norms.

159 Country providing is the country of origin or that has acquired the GRs/TK in accordance with the CBD.

160 WTO Appellate Body decision on US - Gasoline stated that the "general rule of interpretation", contained in Article 31(2) of the Vienna Convention, had attained the status of customary or general international law. The Appellate Body added that WTO law was not to be "read in clinical isolation from public international law".

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## ANNEX I: COMMENTARY AND COMPARATIVE TABLE ON IGC DRAFT OBJECTIVES AND PRINCIPLES AND RECENT GLMC PROPOSAL (JULY 2011)

Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<p>DEFINITIONS</p> <p>Providing country: Country providing is the country of origin or that has acquired the genetic resources/ with traditional knowledge in accordance with the CBD.</p> <p>National law and requirements: National law and requirements include customary norms.</p>	<p>DEFINITIONS</p> <p>For the purposes of this instrument:</p> <p>(a) “Associated Traditional knowledge” means knowledge which is dynamic and evolving, generated in a traditional context, collectively preserved and transmitted from generation to generation including but is not limited to know-how, skills, innovations, practices and learning, that subsist in genetic resources;</p> <p>(b) “Derivative” means a biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity;</p> <p>(c) “Genetic material” means any material of plant, animal, microbial or other origin containing functional units of heredity;</p> <p>(d) “Genetic Resources” are genetic material of actual or potential value;</p> <p>(e) “Utilization of Genetic Resources” means to conduct research and development on the genetic and/or biochemical composition of genetic resources, their derivatives and associated traditional knowledge including through the application of biotechnology.</p>	<p>The definition of “providing country” in the draft principles and objectives is based on the CBD definition. However, It clarifies that the acquiring country may also be a provider if the acquisition of the GRs in question was made in accordance with the CBD. This definition is also wider than the CBD one as it includes ATK.</p> <p>Inclusion of customary norms within national law may raise concerns among countries that do not recognize customary law sources within their legal systems.</p> <p>The GLMC’s definition of “associated traditional knowledge” is based on existing proposed definitions in IGC draft articles on TK. The incorporation of this definition will be essential as there will be a need to differentiate it from the general TK definition. A key element of this definition is that for TK to be “associated”, it must subsist in close relation with genetic resources. It could be advisable to expand this link to also cover <i>biological material</i> as well as <i>ecosystems</i> as ATK exclusively applicable to GRs is rare.</p> <p>Other definitions included in the GLMC proposal are based on terms found in the CBD and in the Nagoya Protocol. The term “derivative” does not include the term “naturally occurring”, so is wider and applies to any type of derivative (naturally or artificially occurring).</p>

Selected objectives and principles	Relevant section of the GLMC proposal	Comments
		<p>Stakeholders in the IGC may explore the need to introduce additional definitions such as “biopiracy”, “misappropriation” and “misuse” in light of definitions provided in the section on the evolving interface between GRs, ATK and IP in the study.</p> <p>“Biopiracy” could be defined as “means of obtaining access to genetic resources without authorization”.<sup>156</sup></p> <p>“Misappropriation” could be defined as “using GRs and/or to derive benefits from GRs and/or ATK without equitable benefit-sharing”.<sup>157</sup></p> <p>“Misuse” could be defined as “situations where utilization has gone beyond the access conditions and mutually agreed terms (MAT)”.</p>
<b>OBJECTIVE 1</b>		
<p><i>Objective 1 - Option 1</i></p> <p>Ensure those accessing genetic resources and associated traditional knowledge comply with specific conditions for access, use and benefit-sharing under national law.</p> <p><i>Objective 1 - Options 3 and 4 - NEW CONSOLIDATED TEXT</i></p> <p>Ensure that those accessing and/or using genetic resources, their derivatives and/or associated traditional knowledge in particular applicants for intellectual property rights comply with national law and requirements<sup>158</sup> of the country providing<sup>159</sup> for prior informed consent, mutually agreed terms, fair and equitable benefit-sharing and disclosure of origin.</p>	<p>Ensure that those accessing and/or using genetic resources, their derivatives and/or associated traditional knowledge in particular applicants for intellectual property rights comply with national law and requirement of the country providing for prior informed consent, mutually agreed terms, fair and equitable benefit-sharing and disclosure of origin.</p>	<p><i>Objective 1 - Option 1</i> is a more general objective. It reaffirms basic conditions of access and benefit-sharing under national law. This statement does not add much to existing CBD or Nagoya obligations and makes no links with the IP system, which is the core issue at hand.</p> <p><i>Objective 1 - Options 3 and 4 - new consolidated text</i> is much more precise. It builds on the Nagoya language and confirms that applicants for IPRs (and not only patent applications) need to comply with national law and requirements of the providing country. It lists basic access requirements that patent applicants need to fulfil including PIC, MATs and fair and equitable benefit-sharing. It even identifies one mechanism for compliance, which is the disclosure of origin. The incorporation not only of access requirements such as PIC and MAT but also of fair and equitable benefit-sharing is important. Such an incorporation makes evident that the objective is wider than simply addressing erroneous patents but to ensure that those</p>



Selected objectives and principles	Relevant section of the GLMC proposal	Comments
		<p>that utilized GRs, their derivatives and ATK fully comply with national ABS legislation and that benefits are effectively shared. This proposal also seeks to subject IP applications to legal access and provides a clear understanding that building IPRs without the consent of the rights holders over GRs and ATK should not be allowed.</p> <p>The proposal of the GLMC just takes a stand as to the preferred option among those mentioned in the existing IGC draft.</p>
<b>PRINCIPLES OF OBJECTIVE 1</b>		
<p><i>Principles of Objective 1 - Option 1</i></p> <p>Recognize the wide variety of ownership arrangements pertaining to genetic resources, their derivatives and/ or associated traditional knowledge, including the sovereign rights of States, the rights of indigenous peoples and local communities, as well as private property rights.</p> <p><i>Principles of Objective 1 - Option 3</i></p> <p>Sovereign states have the authority to determine access to genetic resources in their jurisdiction.</p> <p>Subject to national legislation, persons accessing traditional knowledge associated with genetic resources from the knowledge holder(s) and applying that knowledge in the development of an invention should</p>	<p>Recognize the wide variety of ownership arrangements pertaining to genetic resources, their derivatives and/ or associated traditional knowledge, including the sovereign rights of States, the rights of indigenous and local communities, as well as private property rights.</p> <p>ARTICLE 2</p> <p>BENEFICIARIES</p> <ol style="list-style-type: none"> <li>1. Measures for the protection of genetic resources, their derivatives and associated traditional knowledge shall be for the benefit of country of origin of genetic resources.</li> <li>2. Parties shall respect the rights of indigenous and local communities in the traditional knowledge associated with genetic resources,</li> </ol>	<p><i>Principles of Objective 1</i> include references to diverse ownership arrangements, reaffirmation of sovereign rights over GRs, the need for approval by indigenous and local communities with respect to their ATK, as well as a wider set of indigenous peoples' aspirational rights. When looking at <i>Principles of Objective 1 (Options 1 to 4)</i>, what seems to be important is to reaffirm that sovereign rights are what define subsequent rights of ownership in relation to GRs including ownership as a common patrimony of the Nation and/or as individual property rights.</p> <p>Indigenous and local communities' rights over their ATK precede those of the State in historical terms so it should be advisable to list them as separate rights. Reference to ensuring respect for the rights of indigenous peoples over their ATK, including principles of PIC, MAT, and effective participation, should not be questionable at this stage, especially after the adoption of the Nagoya Protocol and the UNDRIP.</p> <p>References to self-determination may be problematic to many States but at the same time they are the most</p>

Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<p>obtain approval from the knowledge holder(s) and seek their involvement.</p> <p><i>Principles of Objective 1 - Option 4</i></p> <p>States have the authority to determine access to genetic resources. Persons accessing traditional knowledge associated with genetic resources from the knowledge holder(s) and applying that knowledge in the development of an invention should obtain approval from the knowledge holder(s) and seek their involvement.</p> <p><i>Principles of Objective 1 - Option 5</i></p> <p>Ensure respect for the principle of self-determination of indigenous peoples and local communities, including peoples partially or entirely under occupation and their rights over genetic resources and associated traditional knowledge, including the principles of prior informed consent, mutually agreed terms, and full and effective participation, noting the United Nations Declaration on the Rights of Indigenous Peoples.</p>	<p>their derivatives in accordance with the domestic legislation.</p>	<p>members as this text was already approved as a Resolution of the UN General Assembly and there is clarity over its non-binding nature.</p> <p>The GLMC proposal takes a stand in relation to <i>Objective 1 - Option 1</i>. Recognition of competent authorities to determine access to GRs and TK under <i>Options 3 and 4</i> is advisable. This would make clear that intermediaries could not authorize access to and use of GRs or ATK unless they have explicit delegation/ authorization from the competent authority or relevant titleholders. Finding options to accommodate some of the concerns expressed by indigenous peoples will be needed to build trust and obtain their support and legitimacy.</p> <p>Instead of putting emphasis on “ownership arrangements”, the GLMC has taken a particular approach by proposing a new <i>sui generis</i> system of protection for GRs and ATK (see Article 2 of the GLMC proposal). In such a system the beneficiaries of the protection are the countries of origin and indigenous and local communities.</p>

Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<b>OBJECTIVE 2</b>		
<p><i>Objective 2 - Options 2 and 6 - NEW CONSOLIDATED TEXT</i></p> <p>Prevent intellectual property rights involving the access and utilization of genetic resources, their derivatives and/or associated traditional knowledge from being granted where there is no prior informed consent, mutually agreed terms and/or fair and equitable benefit-sharing, and disclosure of origin.</p> <p><i>Objective 2 - Option 3</i></p> <p>Prevent patents from being granted in error for inventions that are not novel or inventive in light of genetic resources and associated traditional knowledge.</p> <p><i>Objective 2 - Option 4</i></p> <p>Prevent intellectual property rights from being granted in error and/or bad faith for intellectual property applications relating to genetic resources, their derivatives and/or associated traditional knowledge that do not satisfy the eligibility conditions.</p> <p><i>Objective 2 - Option 5</i></p> <p>Ensure that no patents on life and life forms are granted for genetic resources and associated traditional</p>	<p><i>Objective 2 - Options 1</i></p> <p>Prevent intellectual property rights involving the access and utilization of genetic resources, their derivatives and/or associated traditional knowledge from being granted where there is no prior informed consent, mutually agreed terms and/or fair and equitable benefit-sharing, and disclosure of origin.</p> <p><i>Objective 2 - Option 2</i></p> <p>Prevent intellectual property rights from being granted in error and/or bad faith for intellectual property applications relating to genetic resources, their derivatives and/or associated traditional knowledge that do not satisfy the eligibility conditions.</p> <p>ARTICLE 3</p> <p>SCOPE OF PROTECTION</p> <p>1. Contracting parties shall provide in their national intellectual property legislation the following in the event that the subject-matter of an application involves genetic resources,</p>	<p><i>Objective 2</i> embodies the defensive aims regarding the granting of IPRs that involve the access and utilization of GRs, derivatives and ATK without fulfilling ABS requirements (PIC, MAT and benefit-sharing and disclosure requirements) but also the avoidance of erroneous patents. It should be noted that these two goals are not incompatible. Measures can be designed in parallel to address both problems without entering into contradictions.</p> <p>The language on <i>Option 5</i> is rather odd. While it seems at first glance to be including proposals on the non-patentability of life forms made by certain IGC members and indigenous organizations, what it actually does is to reaffirm that there should not be patents on GRs and ATK when they do not fulfil patentability criteria. This option, as currently drafted, does not mean that there should not be patents on inventions based on GRs and ATK.</p> <p>The GLMC have introduced a proposal to clearly exclude from patentability GRs that naturally occur <i>in situ</i> and <i>ex situ</i>. The aim of this proposal is to improve patent quality and examination by clearly excluding products of nature and naturally occurring phenomena from patentability. While it seems obvious they are not inventions, the patentability of discoveries and simple isolation of components found within biological material in certain jurisdictions and some cases</p>

Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<b>Objectives 2</b>		
<p>knowledge, because they do not comply with the requirements of novelty and inventive step.</p> <p><i>Objective 2 - Option 7</i></p> <p>Increase transparency in access and benefit-sharing.</p>	<p>their derivatives and associated traditional knowledge:</p> <p>(d) No intellectual property rights shall be granted to genetic resources that naturally occur in situ and ex situ.</p>	<p>of biopiracy and misappropriation of genetic material as such justify this type of proposal.</p>
<b>PRINCIPLES OF OBJECTIVE 2</b>		
<p><i>Principles of Objective 2 - Option 1</i></p> <p>Patent applicants should not receive exclusive rights on inventions that are not new or inventive. The patent system should provide certainty of rights for legitimate users of genetic resources.</p> <p><i>Principles of Objective 2 - Option 2</i></p> <p>The intellectual property system should provide certainty of rights for legitimate users and providers of genetic resources, their derivatives and/or associated traditional knowledge. The intellectual property system must provide for mandatory disclosure requirements ensuring that the intellectual property offices become key checkpoints for disclosure and monitoring the utilization of genetic resources, their derivatives and/or associated traditional knowledge.</p>	<p><i>Principles of Objective 2 - Option 1</i></p> <p>The intellectual property system should provide certainty of rights for legitimate users and providers of genetic resources, their derivatives and/or associated traditional knowledge. The intellectual property system must provide for mandatory disclosure requirements ensuring that the intellectual property offices become key checkpoints for disclosure and monitoring the utilization of genetic resources, their derivatives and/or associated traditional knowledge.</p> <p>Administrative and/or judicial authorities shall have the right to (a) prevent the further processing of the intellectual property applications or (b) prevent the granting of</p>	<p><i>Principles of Objective 2 - Options 2 and 7</i> in the draft objectives and principles are today the core of the discussion. As mentioned in the study, disclosure requirements will be a deal maker or breaker in the negotiations.</p> <p>The disclosure requirement proposed in <i>Objective 1 - Option 2</i> is mandatory and would cover not only GRs but also derivatives and ATK. Links with Nagoya are clear when indicating that IP offices are to become checkpoints. IP offices appointed as checkpoints would seek to ensure disclosure but also monitor the utilization of GRs, derivatives and ATK. Under this objective the disclosure mechanism is the main operational mechanism identified but it does not rule out other mechanisms such as databases or prior art submissions. The GLMC makes a clear choice in favour of the disclosure mechanism option.</p> <p>The GLMC proposal includes a more precise article on scope of protection (Article 3). It includes a clearer obligation for the incorporation of a mandatory disclosure requirement in a future instrument(s) as an operational provision and not just as an</p>

Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<b>PRINCIPLES OF OBJECTIVE 2</b>		
<p>Administrative and/or judicial authorities shall have the right to (a) prevent the further processing of the intellectual property applications or (b) prevent the granting of intellectual property rights, as well as (c) revoke intellectual property rights subject to Article 32 of the TRIPS Agreement and render unenforceable intellectual property rights when the applicant has either failed to comply with the objectives and principles or provided false or fraudulent information.</p> <p><i>Principles of Objective 2 - Option 6</i></p> <p>Intellectual property rights applicants should not receive exclusive rights where free, prior and informed consent and fair and equitable benefit-sharing requirements for accessing and using genetic resources have not been met.</p> <p><i>Principles of Objective 2 - Option 7</i></p> <p>Persons applying for intellectual property rights involving the use of genetic resources and/or associated traditional knowledge have a duty of good faith and candor to disclose in their applications all background</p>	<p>intellectual property rights, as well as (c) revoke intellectual property rights and render unenforceable intellectual property rights when the applicant has either failed to comply with the objectives and principles or provided false or fraudulent information.</p> <p><i>Principles of Objective 2 - Option 2</i></p> <p>Intellectual property rights applicants should not receive exclusive rights where free, prior and informed consent and fair and equitable benefit-sharing requirements for accessing and using genetic resources have not been met.</p> <p><i>Principles of Objective 2 - Option 3</i></p> <p>Persons applying for intellectual property rights involving the use of genetic resources and/or associated traditional knowledge have a duty of good faith and candor to disclose in their applications all background information relating to the genetic resources and associated traditional knowledge,</p>	<p>objective or a principle. The scope of obligation covers the origin and source of GRs, derivatives and ATK. It also encompasses PIC and evidence of MAT. Using IRCCs under the Nagoya Protocol can assist in fulfilling this latter set of requirements. It goes even further by also requiring the inclusion of not only written but also oral information of ATK applicable to GRs and derivatives and details of the ATK holder. This is a very wide obligation and could be burdensome to many applicants. This proposed obligation could be clarified by making reference to “all relevant” written information and to “relevant oral information known to the applicant”. This provision also shows an evolving level of ambition. The longer a possible agreement will take the more additions there will be to this type of proposal.</p> <p>As mentioned in the study, there are several additional mechanism that could be added in order to address concerns regarding BRDRs, such as an ex post ABS restoration mechanism, a biodiversity linkage, ensuring proper treatment of confidential disclosed information, developing the Global Multilateral Benefit Sharing Mechanism and making use of IRCCs under the Nagoya Protocol (see section on disclosure requirements).</p> <p><i>Principles of Objective 2 - Option 2</i> also includes a list of potential legal effects including the prevention of further administrative processing,</p>

Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<b>PRINCIPLES OF OBJECTIVE 2</b>		
<p>information relating to the genetic resources and associated traditional knowledge, including the country of source or origin.</p>	<p>including the country of source or origin.</p> <p>ARTICLE 3.1(a)</p> <p>SCOPE OF PROTECTION</p> <p>1. Contracting parties shall provide in their national intellectual property legislation the following in the event that the subject-matter of an application involves genetic resources, their derivatives and associated traditional knowledge:</p> <p>(a) Mandatory disclosure of information in the intellectual property application, of the following:</p> <p>(i) Country of origin and source of genetic resources, their derivatives and associated traditional knowledge;</p> <p>(ii) Prior informed consent, either by the certificate of origin or by any other document issued in accordance with the domestic law of country of origin. In case the country of origin is not identifiable even after making reasonable efforts, certificate of evidence issued in accordance with the domestic law of country providing;</p> <p>(iii) Evidence of benefit sharing under mutually agreed terms entered with the beneficiaries as define in Article 2 in accordance with their domestic legislation;</p> <p>(iv) Make available written and oral information regarding traditional knowledge associated with genetic resources, their derivatives for</p>	<p>the granting of IP rights and revocation. Many user countries in the IGC are concerned about these types of effects. A possible common ground for a potential trade off would be to include a mandatory requirement but limit the effects to further processing until ABS requirements are fulfilled, and a commitment to introducing civil and administrative measures to compensate countries of origin and ATK holders for any damage generated by acts of biopiracy, misappropriation, or misuse. See section of definitions.</p> <p>It is well known that these proposed requirements and legal effects are difficult items for many delegations. Something that could assist more proactive dialogue would be for user countries to indicate what type of disclosure obligation could be acceptable to them. For example, the limited disclosure obligation as somehow accepted in the proposed trade off between GI and biodiversity <i>demandeurs</i> in the TRIPS Council (the 110 Members proposal). This proposal included a mandatory disclosure of origin and/or source requirement plus PIC with no</p>

Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<b>PRINCIPLES OF OBJECTIVE 2</b>		
	<p>enabling search and examination of the intellectual property application including the details of the holder of the TK.</p> <p>ARTICLE 3.2</p> <p>SCOPE OF PROTECTION</p> <p>Contracting Parties shall appoint national intellectual property offices as a checkpoint for disclosure of the country of origin and source of genetic resources, their derivatives and associated traditional knowledge and for their monitoring.</p>	<p>effect in the patent system but with the availability of civil and administrative actions outside the patent system. So, in principle not all elements of a potential disclosure seem to be unacceptable to all Members. Therefore, starting a discussion on specific aspects of these requirements could reduce tensions and actually address the main concerns on all sides (see section on BRDRs of the study to have an overview of options for giving legal effects).</p>
<b>OBJECTIVE 3</b>		
<p><i>Objective 3 - Option 1</i></p> <p>Ensure patent offices have available the information needed to make proper decisions in granting patents.</p> <p><i>Objective 3 - Options 2 and 4 - NEW CONSOLIDATED TEXT</i></p> <p>Ensure that intellectual property offices have appropriate and available information on genetic resources, their derivatives and/or associated traditional knowledge needed to make proper and informed decisions in granting intellectual property rights. Such information shall include confirmation through the mandatory disclosure requirements that prior informed consent has been obtained and access has been granted on mutually</p>	<p>Ensure that intellectual property offices have appropriate and available information on genetic resources, their derivatives and/or associated traditional knowledge needed to make proper and informed decisions in granting intellectual property rights. Such information shall include confirmation through the mandatory disclosure requirements that prior informed consent has been obtained and access has been granted on mutually agreed terms which can be made through an internationally recognized certificate of compliance.</p>	<p><i>Objective 3 - Options 1, 2 and 4</i> make evident the differences regarding potential mechanisms to address the problem. On one hand, making available information is seen as the solution (a reflection of proposals on databases). On the other, a reaffirmation that information generated through a disclosure is considered as essential. As mentioned in the study, these two mechanisms are not incompatible and could be built in a complementary manner. In this regard, it just needs to be clear that additional information on the prior art will address concerns over erroneous patents but will not solve benefit-sharing concerns. In the case of disclosure requirements, the main objective is to ensure the fulfilment of national ABS legislation, CBD and Nagoya</p>

Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<b>OBJECTIVE 3</b>		
agreed terms which can be made through an internationally recognized certificate of compliance.		requirements in IP filing and granting and to facilitate legal action by titleholders over GRs and ATK. At the same time it can have some effects over patentability examinations (see section on BRDRs).
<b>PRINCIPLES OF OBJECTIVE 3</b>		
<p><i>Principles of Objective 3 - Option 1</i></p> <p>Patent offices must consider all relevant prior art when assessing the patentability of an invention.</p> <p>Patent applicants must indicate the background art, which, as far as known to the applicant, can be regarded as useful for the understanding, searching and examination of the invention.</p> <p>There is a need to recognize that some holders of traditional knowledge may not want their knowledge documented.</p> <p><i>Principles of Objective 3 - Option 2</i></p> <p>Intellectual property offices should consider all relevant prior art information relating to genetic resources, their derivatives and associated traditional knowledge when assessing the eligibility for grant of intellectual property rights.</p>	<p>Intellectual property offices should consider all relevant prior art information relating to genetic resources, their derivatives and associated traditional knowledge when assessing the eligibility for grant of intellectual property rights.</p> <p>Intellectual property applicants should disclose all background information of genetic resources, their derivatives and associated traditional knowledge relevant for determining the eligibility conditions.</p> <p>ARTICLE 3 (b) and (e)</p> <p>SCOPE OF PROTECTION</p> <p>(b) Put in place an adequate information dissemination system to enable an opportunity by relevant authorities from other contracting parties, indigenous and local communities or any other interested parties to submit information relevant to search and examination of an intellectual property application pending before national intellectual property offices in order to better assess compliance with the eligibility criteria for the grant of intellectual property rights.</p>	<p>The need to take into consideration all relevant information for prior art evaluations and the value of databases to improve patent and IPR examinations has been referenced in the <i>Principle of Objective 3 - Option 1 and 2 and in Article 4</i> on complementary measures as proposed by the GLMC. Proposals made reference to the obligation of applicants to consider all prior art and background information known to them regarded as useful to facilitate understanding and the examination of patents utilizing GRs on ATK. Proposals have also been made to allow countries to facilitate access to information placed in databases but subject to certain conditions, such as confidentiality in the treatment of information by the GLMC.</p> <p>One option that could be added in this regard is to include a <b>prior art cooperation mechanism</b> (see Article 3(b) of the GLMC proposal) by which IP offices in user countries will give full consideration to any submission on the prior art given by providing countries and other stakeholders such as indigenous organizations</p>



Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<b>PRINCIPLES OF OBJECTIVE 3</b>		
<p>Intellectual property applicants should disclose all background information of genetic resources, their derivatives and associated traditional knowledge relevant for determining the eligibility conditions.</p>	<p>(e) That the national intellectual property offices shall:</p> <p>(i) Consider all relevant written and oral information relating to genetic resources, their derivatives and associated traditional knowledge, regardless of the language, from all countries when conducting search and examination for determining the eligibility criteria for granting of intellectual property rights.</p> <p>(ii) Develop appropriate and adequate guidelines for the purpose of conducting search and examination of intellectual property applications relating to genetic resource, their derivatives and associated traditional knowledge considering existing and additional information provided by the applicants, as well as accessible to the examiners.</p> <p>ARTICLE 4</p> <p>COMPLEMENTARY MEASURES</p> <p>1. Contracting Parties may facilitate access to information, including information made available in databases, relating to genetic resources, their derivatives and associated traditional knowledge with the intellectual property offices of Contracting Parties to this instrument.</p> <p>2. Contracting Parties shall ensure that:</p> <p>(a) confidentiality of such information provided to the intellectual property offices as stated in clause 1.1 is maintained by the such offices and the applicants who have access to such information, in accordance with</p>	<p>(including from GR and TK databases). To be effective such a submission should be made quite quickly. Opportunities to make such a submission could be incorporated in national law.</p> <p>Proposals made on a <b>rights-based database approach</b> could be quite relevant for addressing proposals and concerns over information in GR and TK databases that is relevant for prior art searches (see section on prior art and database issues in the study).</p>

Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<b>PRINCIPLES OF OBJECTIVE 3</b>		
	<p>domestic legislation or contractual obligation;</p> <p>(b) any violation of the same shall be considered as an act of unfair competition and a violation of contractual obligations or an infringement of the protection provided in this instrument and be subjected to sanction as provided in this instrument.</p>	
<b>OBJECTIVE 4</b>		
<p><i>Objective 4 - Option 1</i></p> <p>Promote a mutually supportive relationship with relevant international agreements and processes.</p> <p><i>Objective 4 - Options 2 and 3 - NEW CONSOLIDATED TEXT</i></p> <p>Establish a coherent system and promote mutually supportive relationship between intellectual property rights involving the utilization of genetic resources, their derivatives and/or associated traditional knowledge and existing international and regional agreements and treaties.</p> <p><i>Objective 4 - Option 4</i></p> <p>Ensure consistency with international legal standards in the promotion and protection of the collective rights of indigenous peoples to their genetic resources and/or associated</p>	<p><i>Objective 4 - Options 1</i></p> <p>Establish a coherent system and promote mutually supportive relationship between intellectual property rights involving the utilization of genetic resources, their derivatives and/or associated traditional knowledge and existing international and regional agreements and treaties.</p> <p><i>Objective 4 - Option 2</i></p> <p>Ensure consistency with international legal standards in the promotion and protection of the collective rights of indigenous and local communities to their genetic resources and/or associated traditional knowledge by establishing a transparent, independent, accessible mechanism for oversight and dispute resolution, with associated rights to local communities.</p> <p>ARTICLE 5.1</p> <p>RELATIONSHIP WITH OTHER INTERNATIONAL AGREEMENTS</p> <p>Contracting Parties shall establish a coherent system and promote mutually supportive relationship</p>	<p>Calls for mutual supportiveness is a common feature in international agreements, especially in areas where the subject matter is regulated by various international treaties. The TRIPS/CBD relationship is one of the areas where lack of mutual supportiveness has been pointed out by several developing countries in the TRIPS Council. The main concern in this case, as it could also to some extent be in the IGC, is the lack of measures in the IP system to ensure the fulfilment of Article 15 of the CBD in IP filing and granting.</p> <p>There are no international standards that guide how mutual supportiveness should be addressed in cases of conflict or overlap. The only legal source at hand to deal with such situations is the rules on treaty interpretation of the Vienna Convention on the Law of Treaties. WTO jurisprudence when dealing with the relationship between WTO law and</p>

Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<b>OBJECTIVE 4</b>		
<p>traditional knowledge by establishing a transparent, independent, accessible mechanism for oversight and dispute resolution, with associated rights to local communities.</p>	<p>between intellectual property rights involving the utilization of genetic resources, their derivatives and associated traditional knowledge and existing international agreements and treaties.</p>	<p>Multilateral Environmental Agreements (MEAs) has clearly indicated that Panels cannot make interpretations in clinical isolation <i>vis-à-vis</i> international public law.<sup>160</sup></p> <p>There is not yet a case under WTO jurisprudence where a direct conflict between WTO law and an MEA has occurred. The WTO Committee on Trade and Environment is currently negotiating options and mechanisms to seek interpretation in cases where a specific trade obligation is found in a MEA. The Chairman has recently proposed a draft WTO decision to create a group of trade and environmental experts to provide specific advice to Members who have doubts on the interpretation or application of specific trade obligations.</p> <p>If a conflicting situation would arise, the interpretation of the Panel could be guided by the relevant rules of the Vienna Convention, specific interpretative rules within the treaties in question (whether WTO or not) and the principle that interpretation should be made to the extent possible in a mutually supportive manner.</p> <p>Even if in WIPO Conventions there are clauses to resolve disputes through the International Court of Justice, there is no case known yet, as the court cannot adjudicate cases without the consent of parties involved.</p>

Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<b>PRINCIPLES OF OBJECTIVE 4</b>		
<p><i>Principles of Objective 4 - Option 1</i></p> <p>Promote respect for and seek consistency with other international and regional instruments and processes.</p> <p>Promote cooperation with relevant international and regional instruments and processes.</p> <p><i>Principles of Objective 4 - Option 2</i></p> <p>Promote respect for and seek consistency with other international and regional instruments and processes.</p> <p>Promote cooperation with relevant international and regional instruments and processes.</p> <p>The work of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore should not prejudice the work pursued in other forums.</p>	<p>Promote respect for and seek consistency with other international and regional instruments and processes.</p> <p>Promote cooperation with relevant international and regional instruments and processes.</p> <p>The work of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore should not prejudice the work pursued in other forums.</p> <p>ARTICLE 5.2</p> <p>RELATIONSHIP WITH OTHER INTERNATIONAL AGREEMENTS</p> <p>Contracting Parties shall support, in particular, the implementation of the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention of Biological Diversity.</p>	<p>Promoting respect, and seeking consistency and cooperation with other international and regional instruments has little value if those instruments are not explicitly mentioned. In this regard it is recommended to mention the CBD, the Nagoya Protocol the Bonn Guidelines but also the Paris Convention and the UPOV Convention under WIPO.</p> <p>Not prejudicing the work in other forums is considered a positive feature as there are other relevant ongoing processes in the WTO and CBD.</p> <p>Calls made in Article 5.2 of the GLMC proposal are considered highly valuable, as they require parties to the future instrument to support the implementation of relevant MEAs on the relationship between GRs, ATK and IP.</p> <p>Transboundary cooperation under Article 7 of the GLMC proposal is also considered to be a positive feature, as ATK may be utilized across borders or their possession could be shared across regional borders. It is recommended to add GRs to the text. It is also recommended to add a sentence by which user countries will cooperate in gathering information and the resolution of specific cases of infringement of national ABS laws, the CBD and the Nagoya Protocol in IP filing and granting. This latter type of provision has already been included in FTAs between the EU and EFTA countries with some biodiversity-rich countries.</p>

Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<b>PRINCIPLES OF OBJECTIVE 4</b>		
<p><i>Principles of Objective 4 - Option 3</i></p> <p>Respect the decisions adopted by the United Nations treaty bodies pertaining to cases submitted by indigenous peoples.</p> <p><i>Principles of Objective 4 - Option 4</i></p> <p>Support, in particular, the implementation of the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention of Biological Diversity.</p> <p><i>Principles of Objective 4 - Option 6</i></p> <p>Promotion of awareness raising and information sharing among different relevant and related international and regional agreements, instruments and processes related to genetic resources.</p>	<p>ARTICLE 7</p> <p>TRANS-BOUNDARY COOPERATION</p> <p>In instances where traditional knowledge is located in territories of different Contracting Parties, those Contracting Parties shall cooperate by taking measures that are supportive of and do not run counter to the objectives of this instrument.</p>	
<b>OBJECTIVE 5</b>		
<p><i>Objective 5 - Options 1 and 10 - NEW CONSOLIDATED TEXT</i></p> <p>Preventing the adverse effects of the intellectual property system on the indigenous peoples' customs, beliefs and rights with the aim of recognize and protect the rights of indigenous peoples to use, develop, create and protect their knowledge and innovation in relation to genetic resources.</p>	<p><i>Objective 5 - Option 1</i></p> <p>Preventing the adverse effects of the intellectual property system on the indigenous and local communities' customs, beliefs and rights with the aim of recognize and protect the rights of indigenous and local communities to use, develop, create and protect their knowledge and innovation in relation to genetic resources.</p>	<p>It should be made clear in the political discussions that demands to introduce measures in the IP system to ensure compliance with national ABS legislations, the CBD and the Nagoya Protocol do not seek to undermine innovation, hinder new inventions based on GRs and ATK or the transfer of technology. These demands only seek to ensure the respect of pre-existing</p>

Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<b>OBJECTIVE 5</b>		
<p><i>Objective 5 - Option 2</i></p> <p>Maintain the role of the intellectual property system in promoting innovation.</p> <p><i>Objective 5 - Option 3</i></p> <p>Recognize and maintain the role of the intellectual property system in promoting innovation and transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, noting the relationship with genetic resources, their derivatives and/or associated traditional knowledge.</p> <p><i>Objective 5 - Option 4</i></p> <p>Recognize the role of the intellectual property system in the protection of traditional knowledge, genetic resources and traditional cultural expressions.</p> <p><i>Objective 5 - Option 6 - NEW TEXT</i></p> <p>Recognize and maintain the role of the intellectual property system in promoting innovation, transfer and dissemination of technology, to the mutual advantage of holders and users of genetic resources, their derivatives and/or associated traditional knowledge in a manner conducive to social and economic welfare, while contributing to the protection of genetic resources, their derivatives and/or associated traditional knowledge.</p>	<p><i>Objective 5 - Option 2</i></p> <p>Recognize and maintain the role of the intellectual property system in promoting innovation, transfer and dissemination of technology, to the mutual advantage of holders and users of genetic resources, their derivatives and/or associated traditional knowledge in a manner conducive to social and economic welfare, while contributing to the protection of genetic resources, their derivatives and/or associated traditional knowledge.</p>	<p>rights over inputs (GRs and ATK) used in R&amp;D leading to IP filing and granting. In this regard, mutual respect of rights can only benefit innovation and the creation of incentives for increased cooperation.</p> <p>In this sense, references to ensuring that the IP system supports the promotion of innovation and transfer and dissemination of technology to the mutual advantages of holders of rights over GRs and TK but also of producers and users of technology need to be made clear in order to ensure balance. This objective can only be achieved by introducing specific measures to ensure the respect of rights over GRs and ATK in the IP filing and granting.</p>

Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<b>PRINCIPLES OF OBJECTIVE 5</b>		
<p><i>Principles of Objective 5 - Option 1</i></p> <p>Maintain the incentives for innovation provided by the intellectual property system.</p> <p>Promote certainty and clarity of intellectual property rights.</p> <p>Protect creativity and reward investments made in developing a new invention.</p> <p>Promote transparency and dissemination of information by publishing and disclosing technical information related to new inventions, so as to enrich the total body of technical knowledge accessible to the public.</p> <p><i>Principles of Objective 5 - Option 2</i></p> <p>Recognize and maintain the role of the intellectual property system in promoting innovation, noting the relationship with genetic resources and associated traditional knowledge.</p> <p>Promote certainty and clarity of intellectual property rights, noting the relationship with genetic resources and associated traditional knowledge.</p> <p>Protect creativity and reward investments.</p> <p>Promoting transparency and dissemination of information</p>	<p><i>Principles of Objective 5 - Option 1</i></p> <p>Recognize and maintain the role of the intellectual property system in promoting innovation, noting the relationship with genetic resources and associated traditional knowledge.</p> <p>Promote certainty and clarity of intellectual property rights, noting the relationship with genetic resources and associated traditional knowledge.</p> <p>Protect creativity and reward investments.</p> <p>Promoting transparency and dissemination of information by publishing and disclosing technical information related to new inventions, where appropriate and when publicly available, so as to enrich the total body of knowledge accessible to the public.</p> <p><i>Principles of Objective 5 - Option 2</i></p> <p>Recognize and maintain the role of the intellectual property system in promoting innovation, noting the relationship with genetic resources, their derivatives and/or associated traditional</p>	<p>Calls for transparency and legal certainty are included in several parts of the draft objectives and principles. References can be found in <i>Objective 2 - Option 7 and Principles of Objective 5 - Options 1, 2 and 3</i>. Transparency is a minimum standard in any international instrument. In the particular case of GRs and ATK, due to the high levels of mistrust, it becomes a must in all the situations mentioned above. Transparency is not only important to facilitate the implementation of a future instrument(s) in WIPO but also for existing Agreements under WIPO and the CBD. In this regard, links and cooperation between WIPO dissemination instruments and the new ABS Clearing-House Mechanism need to be established and enhanced.</p> <p>Legal certainty is a general principle of law in most national constitutions. Problems usually arise as the consequence of administrative and judicial implementation but also because of too much regulation or a lack of regulation. In the IGC, perceptions as to legal uncertainty are found in both provider and user countries but also from other stakeholders. Provider countries feel their rights are not being supported and that few user measures have been implemented in key markets. On the users' side, lack of certainty has a lot to do</p>

Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<b>PRINCIPLES OF OBJECTIVE 5</b>		
<p>by publishing and disclosing technical information related to new inventions, where appropriate and when publicly available, so as to enrich the total body of knowledge accessible to the public.</p> <p><i>Principles of Objective 5 - Option 3</i></p> <p>Recognize and maintain the role of the intellectual property system in promoting innovation, noting the relationship with genetic resources, their derivatives and/or associated traditional knowledge and in the protection of traditional knowledge, genetic resources, their derivatives and/or associated traditional knowledge and traditional cultural expressions and fair and equitable sharing of benefits arising from their use.</p> <p>Promote certainty and clarity of intellectual property rights, noting the relationship with genetic resources, their derivatives and/or associated traditional knowledge and obligations with respect to the protection of traditional knowledge, genetic resources, their derivatives and/or associated traditional knowledge and traditional cultural expressions and certainty and clarity for prior informed consent and fair and equitable benefit-sharing.</p> <p>Protect creativity, reward investments and ensure prior informed consent and fair and equitable benefit-sharing with the knowledge holders. Promoting transparency and dissemination of information by disclosing country of origin and publishing and disclosing</p>	<p>knowledge and in the protection of traditional knowledge, genetic resources, their derivatives and/or associated traditional knowledge and traditional cultural expressions and fair and equitable sharing of benefits arising from their use.</p> <p>Promote certainty and clarity of intellectual property rights, noting the relationship with genetic resources, their derivatives and/or associated traditional knowledge and obligations with respect to the protection of traditional knowledge, genetic resources, their derivatives and/or associated traditional knowledge and traditional cultural expressions and certainty and clarity for prior informed consent and fair and equitable benefit-sharing.</p> <p>Protect creativity, reward investments and ensure prior informed consent and fair and equitable benefit-sharing with the knowledge holders. Promoting transparency and dissemination of information by disclosing country of origin and publishing and disclosing</p>	<p>with complex ABS procedures and delays in administrative response. Also, delays in the granting of IP titles have been mentioned as a common problem. For indigenous and local communities, the lack of legal certainty is highly important as they have been historically marginalized and many agreements have not been fulfilled. Also, their legal status as nations, their human rights, land rights and recognition of customary law have never been fully understood or respected.</p> <p>As mentioned above, references to legal certainty are made in several parts of the draft principles and objectives in relation to users and providers, the relationship between IP rights and GRs, derivatives and ATK, with a mandatory disclosure of origin and source. While there is merit in including all these calls for legal certainty, no specific measure to improve legal certainty has been incorporated.</p> <p>The level of legal certainty that a new instrument(s) can provide will depend on the drafting by IGC members and if there are specific measures to address the lack of certainty. Specific mechanisms that could be incorporated to improve legal certainty include the following:</p>



Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<b>PRINCIPLES OF OBJECTIVE 5</b>		
<p>equitable benefit-sharing.</p> <p>Protect creativity, reward investments and ensure prior informed consent and fair and equitable benefit-sharing with the knowledge holders.</p> <p>Promoting transparency and dissemination of information by disclosing country of origin and publishing and disclosing technical information related to new inventions, where appropriate and where publicly available, so as to enrich the total body of technical knowledge accessible to the public.</p> <p><i>Principles of Objective 5 - Option 5</i></p> <p>Increase legal certainty and trust between users and providers of genetic resources and traditional knowledge through a mandatory disclosure of origin or source.</p> <p><i>Principles of Objective 5 - Option 12</i></p> <p>Promote transparency and dissemination of information where not in contrast with public morality and/or public order.</p>	<p>technical information related to new inventions, where appropriate and where publicly available, so as to enrich the total body of technical knowledge accessible to the public.</p> <p><i>Principles of Objective 5 - Option 3</i></p> <p>Increase legal certainty and trust between users and providers of genetic resources and traditional knowledge through a mandatory disclosure of origin or source.</p> <p><i>Principles of Objective 5 - Option 4</i></p> <p>Promote transparency and dissemination of information where not in contrast with public morality and/or public order.</p>	<ul style="list-style-type: none"> <li>• Notification of implementing legislation;</li> <li>• Regulatory reviews;</li> <li>• Exchange of best practices;</li> <li>• Development of implementing regulations;</li> <li>• The availability of an interpretation mechanism; and</li> <li>• Mutual consultations and goods offices.</li> </ul> <p>These mechanisms could be built into the future IGC instrument(s) under different modalities without much difficulty.</p>

Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<b>OTHER PROPOSED ARTICLES</b>		
	<p data-bbox="451 353 576 383">ARTICLE 8</p> <p data-bbox="451 412 911 479">SANCTIONS, REMEDIES AND EXERCISE OF RIGHTS</p> <ol style="list-style-type: none"> <li data-bbox="451 510 916 949">1. Contracting Parties shall ensure, in accordance with their legal systems, adequate criminal, civil and administrative enforcement procedures and dispute resolution mechanisms are available under their laws against the wilful infringement of the protection provided genetic resources, their derivatives and associated traditional knowledge under this instrument.</li> <li data-bbox="451 981 916 1771">2. Contracting Parties shall provide that administrative and/or judicial authorities have the right to:               <ol style="list-style-type: none"> <li data-bbox="451 1151 874 1256">(a) prevent the further processing of the intellectual property applications;</li> <li data-bbox="451 1288 839 1355">(b) prevent the granting of intellectual property rights;</li> <li data-bbox="451 1386 842 1453">(c) revoke intellectual property rights; and</li> <li data-bbox="451 1485 916 1771">(d) render unenforceable intellectual property rights when the applicant has either failed to comply with the obligations of mandatory disclosure requirements as provided in this instrument or provided false or fraudulent information.</li> </ol> </li> <li data-bbox="451 1803 916 1908">3. Where a dispute arises in relation to mutually agreed terms between users, beneficiaries and</li> </ol>	<p data-bbox="940 353 1353 1317">Specific provisions on enforcement and the incorporation of sanctions are not found in the current draft on principles and objectives. The GLMC proposal included for the first time a new operational provision on the matter. While the text builds on Nagoya, it goes even further by including references to dispute resolution mechanisms. The article also requires members to give competence to judicial and administrative authorities to impose measures in cases of wilful infringement of the protection to be provided by the new instrument. Such provisions will be highly important to ensure that the future instrument is more than a declaration of intent and incorporates effective enforcement measures and dispute settlement mechanisms.</p> <p data-bbox="940 1348 1353 1928">This study contains several proposals on monitoring and dispute settlement that could be of use in the IGC negotiations. They include good offices, an interpretative mechanism, a CBD/WIPO arbitration service, mutual recognition agreements and setting national monitoring and enforcing institutions. Different modalities could be agreed to include state-to-state, state-to-other-stakeholder disputes and stakeholder-to-stakeholder disputes.</p>

Selected objectives and principles	Relevant section of the GLMC proposal	Comments
<b>OTHER PROPOSED ARTICLES</b>		
	<p>providers of genetic resources, their derivatives and associated traditional knowledge each Party may be entitled to refer the issue to an alternative dispute resolution mechanism recognized by domestic legislation.</p>	
	<p><b>ARTICLE 9</b></p> <p><b>TECHNICAL ASSISTANCE, COOPERATION AND CAPACITY BUILDING</b></p> <p>Relevant WIPO bodies shall develop modalities for the creation, funding and implementation of the provisions under this instrument. WIPO shall provide technical assistance, cooperation, capacity building and financial support for developing countries in particular the least developed countries to implement the obligations under this instrument.</p>	<p>Current draft text on objectives and principles does not yet include provisions on technical assistance. These provisions will be important if new specific mechanisms are agreed with the new international instrument(s). In that sense, many countries would need assistance in exploring best implementation options in light of future obligations and specific national needs. Due to the strong linkages with ABS regulations, it is highly recommended to undertake the provision of such assistance jointly with the CBD and UNEP secretariats. A particular emphasis should be placed on technical assistance needs by LDCs. However, this Group has not been particularly active in the IGC as such but through regional groups. As the negotiations advance these latter groups of countries would need to be more precise in expressing their particular concerns and technical assistance needs.</p>

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