

ICTSD Project on Genetic Resources



# The Political Economy of the International ABS Regime Negotiations



Options and Synergies with Relevant IPR Instruments and Processes

By **Jorge Cabrera Medaglia**, Costa Rica's National Biodiversity Institute and  
Centre for International Sustainable Development Law



International Centre for Trade  
and Sustainable Development

Issue Paper No. 2

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## LIST OF ABBREVIATIONS AND ACRONYMS

ABS	Access to genetic resources and benefit sharing
CBD	Convention on Biological Diversity
COP	Conference of the Parties to the CBD
CTE	Committee on Trade and Environment
EG	Expert group
GR	Genetic resources
IGC	Intergovernmental Committee on Genetic Resources and Intellectual Property Rights, Traditional Knowledge and Folklore
IT	International Treaty on Plant Genetic Resources for Food and Agriculture of the FAO
IP	Intellectual property
IPR	Intellectual property rights
IR	International Regime on Access to Genetic Resources and Benefit Sharing
MAT	Mutually agreed terms
PCT	Patent Cooperation Treaty
PIC	Prior informed consent
PBR	Plant breeders rights
TEG	Technical Expert Group of the CBD
TT	Technology transfer
TK	Traditional knowledge
TRIPS	WTO Agreement on Trade-Related Aspects of Intellectual Property Rights
UNCTAD	United Nations Committee on Trade and Development
UPOV	International Union for the Protection of New Varieties of Plants
WG ABS	Working Group on Access to Genetic Resources and Benefit Sharing
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

## FOREWORD

Loss of biological diversity - understood as our biosphere's total endowment of living organisms, their genetic variation and functions and the ecosystems of which they are a part of - stands, alongside climate change, as one of the most pressing and daunting global challenges of our times. The increasingly rapid and massive rates of deterioration and loss of environmental resources and functions have brought an acute awareness of the urgent need for effective policies and mechanisms to ensure these valuable resources are used sustainably; this is an imperative beyond moral and ethical concerns that cannot be further postponed as societies become clearer about biodiversity's critical role in human well-being, global economic development and poverty reduction.

Diversity in nature is the key to the natural regulation of global climate and the equilibrium in the gaseous composition of our atmosphere. This diversity is the essence of healthy soils; it allows for natural regeneration and recycling of nutrients, and the maintenance of a biological balance between destructive and useful plants and organisms. It enables the existence of waterways, watersheds and aquifers and allows marine life and environments to thrive. Furthermore, diversity in natural resources forms the cornerstone of strategic and pivotal industries in critical areas of economic activity for the provision of food, health, energy and fuels, clothing, and shelter. In addition, biodiversity has proven to be critical in advancements on waste treatment, environmental services and the venturing into the new frontiers of nanotechnology, and geoen지니어ing.

Diversity of living organisms is dwindling at a much faster pace than generally realized. Not only species are disappearing, we now know for certain that their genetic richness and functions are also dramatically affected by changes in ecosystems. Even though alterations to our natural stock through either innate biophysical causes (such as natural processes and disasters) or human activity has been a characteristic of the world throughout its existence, destruction and change now occurs on a much greater magnitude and scale, and in exceptional ways. Propelled by an explosion in economic activity, ever-increasing demand and global integration of economies, impacts on diversity of living organisms are also more rapid and of major reach across ecosystems and regions.

In order to better grasp the enormity of the problem and our passion for it at ICTSD, allow me to quote one of the pioneers of our understanding of the diversity of life, Professor E.O. Wilson from Harvard University, when he states: "Almost all current biodiversity analysts agree that the extinction of species is proceeding at one hundred to 10,000 times the pre-human rate, while the rate of origin of new species is decreasing. [...] Each species is the repository of an immense amount of genetic information. The number of genes range from about 1,000 in bacteria and 10,000 in some fungi to 400,000 or more in many flowering plants and a few animals. A typical mammal such as the house mouse (*Mus musculus*) has about 100,000 genes. This full complement is found in each of its myriad cells, organized from four strings of DNA, each of which comprises about a billion nucleotide pairs..."

Concluded at the Global Earth Summit (1992), the United Nations Convention on Biological Diversity (CBD) acknowledges this important reality when underlining the "intrinsic ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic value" of biodiversity. Unlike former and other multilateral environmental agreements, it addresses global biodiversity as a whole rather than limiting itself to certain ecosystems, species, or forms of biological diversity.

Premised on a global strategy for sustainable development, the CBD recognizes the sovereign rights of States over their natural resources and pursues three objectives: 1) the conservation of biological diversity, 2) the sustainable use of its components and 3) the fair and equitable sharing of the benefits arising out of the utilization of genetic resources and associated traditional knowledge.

The realization of these objectives has faced immense challenges. The third objective in particular - fair and equitable sharing of benefits arising out of the use of genetic resources - has proven difficult to implement in an effective manner, as the use of genetic resources is increasingly linked with international

trade. Users of genetic resources, such as individuals and firms that develop innovative applications based on such resources, often are located outside the country of origin of these resources.

In addition, only relatively recently have countries, mostly developing ones, started to implement domestic rules that provide for access and benefit sharing. In contrast, many developed countries - where pharmaceutical, biotechnological and agricultural companies, have their headquarters - have not put in place corresponding regulations in order to ensure benefit sharing.

In this context, well known cases of misappropriation of genetic resources and associated traditional knowledge during the past two decades have crystallized the tensions between CBD objectives of promoting the fair and equitable sharing of benefits and the types of incentives established by trade and intellectual property rules, in particular those of the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). While measures such as the disclosure of origin requirement, certificates of compliance and geographical indications related to trade in genetic resources and associated traditional knowledge have been introduced in domestic legislations in recent years to prevent such misappropriation, they still raise critical questions for all the actors involved.

Against this backdrop, following protracted negotiations and a critical political underwriting of all UN members at the 2002 Johannesburg Summit on Sustainable Development, the CBD Conference of the Parties (COP) mandated, in 2004, the Working Group on access and benefit sharing (ABS) to negotiate an international regime (IR) on ABS. The aim of the IR is focussed on adopting an instrument(s) to effectively implement the objectives of the convention and its relevant provisions (Article 15 on access to genetic resources and Article 8(j) on traditional knowledge). In 2008, the COP instructed the Working Group to finalize the negotiation of the IR before its tenth meeting, in 2010, in Japan.

The negotiations of the IR took place amid an extraordinarily complex global landscape where a profusion of fora - such as the WTO, the World Intellectual Property Organization (WIPO), the Food and Agricultural Organization (FAO) and the Union for International Protection of New Varieties of Plants (UPOV) - address issues relating to the sustainable use of genetic resources according to their respective mandates. While countries reaffirm the need to ensure consistency between deliberations and outcomes in these different fora, they tend to disagree on how such consistency is to be achieved.

At the WTO, an increasingly large number of countries are arguing that in order to ensure there is consistency between the specific provisions of the CBD and the patent provisions under the TRIPS agreement, an amendment to TRIPS should be introduced. This proposed adjustment would require the disclosure of origin of genetic resources in patent applications as evidence of 'prior informed consent' and 'equitable benefit sharing'.

Countries that oppose such measure at the WTO favour discussions at the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) of WIPO, which was established in 2001. After several years of deliberations with little progress in terms of norm-setting, the IGC was finally provided in 2009 with an explicit mandate to 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 genetic resources, traditional knowledge and the protection of traditional cultural expressions."

Countries which oppose discussions on intellectual property aspects in the context of the negotiations of the IR often invoke this new IGC mandate arguing that WIPO is the appropriate forum to address these aspects.

Despite these 'forum-shifting' strategies and the fact that few tangible advances have ultimately been made in several of these fora, the terms of the debate have significantly evolved in recent years. Many developing countries, now better aware of the multifaceted relevance of their biodiversity, are factoring its valuation into their economic strategies. Furthermore, all stakeholders have also come to recognize the complexity of the issues at hand and that there is no single 'magic' solution that would

ensure effective ‘equitable benefit sharing’; but rather a variety of complementary measures to be pursued at the national, regional and international levels. Drawing lessons from national and regional experiences on ABS implementation can benefit international discussions. Virtually all countries agree on the need to diffuse potential tensions between the biodiversity, trade and intellectual property regimes, though disagreements persist on the most appropriate means to do so.

Since its establishment in 1996, the International Centre for Trade and Sustainable Development (ICTSD) has been working on these issues from various angles and perspectives, following and participating in the process that brought upon the system in place today: from Rio to Johannesburg, from Bonn to Geneva. As a non-partisan actor, it has generated sound and novel analysis on viable and sustainable policy options and convened exchange between a wide range of stakeholders from developing and developed countries alike.

In 2009, the German Development Agency (GTZ) and ICTSD undertook a collaborative initiative to create regional platforms for interactive and generative dialogue among key actors. The collaboration focused on problem-solving and consensus-building in regards to biodiversity issues with a high priority in development and environmental policies in Central and South America. As part of this project, in coordination with local partners, ICTSD and GTZ jointly organised two regional dialogues in Costa Rica and Peru bringing together international experts to explore concerns, knowledge gaps and priority areas for action at the political and technical level on the interface between intellectual property rights and the sustainable use of biological resources.

Almost two decades after the conclusion of the CBD a number of countries have made critical advances in design and implementation of domestic mechanisms that address these concerns. To bring their view to the international level and to analyse their experiences will be critical for the successful conclusion of multilateral processes. As we now move towards the Tenth Conference of the Parties (COP 10) to the CBD in Nagoya in October 2010, there is indeed an urgent need for deepening efforts to provide sound analysis on pressing systemic challenges and flaws, domestic and regional experiences, needs and abilities, and potential political and technical solutions.

This issue paper - published by ICTSD’s project on Genetic Resources -is one of several outcomes generated during the 2009-2010 dialogue series; it builds on, and is complemented by, ICTSD work through its various related projects. The paper aims to contribute to this discussion by providing an in depth overview on the relationship between the emerging international regime on access and benefit sharing and the World Trade Organization, the International Union for the Protection of New Varieties of Plants and the World Intellectual Property Organization. The paper provides research on existing relations, possible conflicts and possibilities for cooperation and mutual supportiveness at a stage where negotiations gain momentum. As a result, stakeholders using this information will hopefully be better positioned to consider options and approaches, which will support the adoption of an efficient system. In that regard, the paper highlights options and scenarios for a synergistic implementation of the intellectual property rights instruments, processes and the possible outcomes of the international regime. The paper also raises some questions that require further scrutiny.

We hope that you will find this paper a stimulating and useful contribution to the ongoing debate and negotiations on an international regime for access and benefit sharing of genetic resources.



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## EXECUTIVE SUMMARY

This paper examines the history, evolution and current status of the negotiations of an international regime (IR) on access to genetic resources and benefit sharing (ABS) in the context of the Convention on Biological Diversity (CBD). It addresses the relationship between the IR and the World Trade Organization (WTO), the International Union for the Protection of New Varieties of Plants (UPOV) and the World Intellectual Property Organization (WIPO). The article highlights options and scenarios for a synergistic implementation of the intellectual property rights (IPR) instruments, processes and the possible outcomes of the IR and raises some questions that require further scrutiny.

This document covers the following:

- The general dynamics of the negotiations under the international ABS regime.
- The different options in the current negotiations in relation to trade, intellectual property and biodiversity issues and in particular disclosure of origin in IPR applications.
- The possible outcomes for the negotiations on these issues.
- The relationship of the ABS negotiations with other relevant fora and negotiations at the multilateral (WTO-WIPO-UPOV), bilateral and regional level.

The IR negotiations have addressed a wide range of issues of interest for developing countries. However, this paper is limited to describing and analyzing the most relevant elements related to IPR and biodiversity under discussion in the IR.<sup>1</sup>

# 1. BACKGROUND ON THE PROCESS OF ELABORATING AND NEGOTIATING THE INTERNATIONAL REGIME<sup>2</sup>

## 1.1 Preliminary Considerations

It is generally recognized - particularly by developing countries - that it has not yet been possible to achieve fully the third objective (access and benefit sharing) of the CBD, or at least that the degree of attainment has been disappointing.<sup>3</sup>

Although the perception of limited benefit sharing may explain the motivation behind the initiative to create an IR, it is striking that there are no systematic studies describing the fundamental factors hindering the effective achievement of the third objective of the CBD. These factors should be addressed by the IR.<sup>4</sup>

In this regard, the current negotiations on the IR, taking account of the partial failure of existing mechanisms are mainly the result of the following factors:

First, there is frustration due to the limited economic and non-economic benefits (monetary and non-monetary) perceived to be derived from the different bioprospecting projects and, in general, from the application of ABS frameworks.<sup>5</sup>

Second, there have been, cases of illegal access, misappropriation or “biopiracy” that have occurred in countries and communities, especially in Latin America, Asia, and Africa, and there are difficulties in finding cost-effective legal solutions within the framework of national ABS legislation or in the context of industrial property law.<sup>6</sup> Emblematic cases such as *Maca* in Peru or the *Neem* in India, among many others, have frequently been mentioned as a rationale for undertaking modifications to the text or operation of IPR systems, particularly patents, which so far have proven to be one of the main causes of complaints being filed for misappropriation or biopiracy.<sup>7</sup>

Third, although the CBD requires the Parties to take measures to ensure fair and equitable

benefit sharing (see particularly the provisions of article 15.7), it has mostly been developing countries that have issued regulations on ABS<sup>8</sup>. Thus, the nations where pharmaceutical, biotechnological and agricultural companies have their headquarters (mostly developed countries) have not put in place corresponding regulations in order to ensure benefit sharing and thus compliance with their legally binding international obligations. The absence or limited presence of so-called “user country measures” (which will be explained further) has been criticized as one of the causes of high transaction costs and the highly controlling nature of current access laws. The need for “user country measures”<sup>9</sup> has been stressed by those who have noted the transboundary nature of ABS in trade relations<sup>10</sup> as well as the inadequacy of local regulations after the samples or information on the genetic resources (GR) leave the country that provided them. In this context, it can be stated that the ABS provisions in the countries of origin are markedly inadequate for creating an ABS system that is functional and consistent.

## 1.2 Current Status and Perspectives of the IR Negotiations<sup>11</sup>

The World Summit on Sustainable Development in Johannesburg in 2002 agreed to the establishment of an IR to promote and safeguard fair and equitable benefit sharing. On 20 December 2002, Resolution 57-260 of the United Nations General Assembly invited the Conference of the Parties to take the necessary measures regarding the commitment established at the Summit to negotiate this regime.<sup>12</sup> Taken together with the Convention’s decision this represents a commitment to create an IR.

However, paragraph 42(n) of the Johannesburg Plan of Action provided a related commitment to:

“ Promote the wide implementation of and continued work on the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising out of their Utilization of the Convention, as an input to assist Parties to the Convention when developing and drafting legislative, administrative or policy measures on access and benefit-sharing, and contracts and other arrangements under mutually agreed terms for access and benefit-sharing.”<sup>13</sup>

Decision VII/19 of the Conference of the Parties of the CBD is potentially one of the most comprehensive and detailed of all decisions relating to the issue of access to genetic resources. This decision calls for the Working Group on ABS to meet again:

“ . . . with the collaboration of the Ad Hoc Open-ended Inter-Sessional Working Group on Article 8 (j) and Related Provisions, ensuring the participation of indigenous and local communities, non-governmental organisations, industry and scientific and academic institutions, as well as intergovernmental organisations, to elaborate and negotiate an International Regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement the provisions in Article 15 and Article 8 (J) of the Convention and the three objectives of the Convention.”<sup>14</sup>

The group has operated in accordance with the terms of reference contained in the Annex to Decision VII/19. The Conference of the Parties also decided on the terms of reference for such a negotiation, including the process, nature, scope and elements for consideration in the elaboration of the regime. The terms of reference are contained in the annex to Decision VII/19 D. As set out in the terms of reference of the Working Group on ABS, the IR could be composed of one or more instruments within a set of principles, norms, rules and decision-making procedures, legally binding and/or non-binding.

According to these same terms of reference, the scope of the IR is to include:

- Access to genetic resources and promotion and safeguarding of fair and equitable sharing of the benefits arising out of the utilization of genetic resources in accordance with relevant provisions of the CBD;
- Traditional knowledge (TK), innovations and practices in accordance with Article 8(j).

At the eighth meeting of the Conference of the Parties (COP) in Curitiba, Brazil, the Working Group was asked to complete its work as soon as possible and no later than 2010.<sup>15</sup> In addition to COP 8, two meetings of the Working Group on ABS, as the negotiating body of the IR, were held prior to the ninth meeting of the COP. The Working Group held its fifth meeting in Montreal, Canada, during 8-12 October 2007,<sup>16</sup> and its sixth meeting in Geneva, Switzerland, on 21-25 January 2008.<sup>17</sup> At its ninth meeting in Bonn, in May 2008, the COP extended the mandate of the Working Group on ABS, and instructed it to finalize the negotiation of the IR before its tenth meeting, in 2010.<sup>18</sup> The COP adopted a detailed calendar of meetings to achieve this objective and decided that the Ad Hoc Open-ended Working Group on Access and Benefit Sharing (WG-ABS) should meet three times prior to the tenth meeting of the COP. In addition, the COP decided to establish three distinct groups of technical and legal experts to address key substantive issues at the core of the negotiation process.

The seventh meeting of the Working Group, held in Paris, France, in April 2009, focused on the objective and scope of the IR, as well as the components of the IR related to compliance, benefit sharing and access.

At its eighth meeting (9-15 November 2009, in Montreal, Canada), the Working Group addressed operative text on all components of the regime, and discussed its legal nature. The meeting adopted the Montreal Annex,<sup>19</sup>

consisting of a single, consolidated draft of the IR and a second annex on proposals for operational texts left in abeyance for consideration at its ninth meeting, referred to as ABS 9. The Working Group also established an intersessional process leading up to ABS 9, including: a Friends of the Co-Chairs group; a Co-Chairs' Inter-Regional Informal Consultation; and a series of regional consultations. Yet, given the fundamental disagreements, only a heavily bracketed structure exists as a basis for the negotiations on the regime.<sup>20</sup> The document has four sections, covering the objective, scope, main components and nature of the regime. The content of each section, however, identifies various options or is heavily bracketed. The text regarding the main components includes: benefit sharing, access, compliance, capacity building and TK, thus reflecting the wide divergence of positions among countries.

On 16-18 March 2010 in Cali, Colombia, inter-regional consultations were held in order to identify concrete solutions to facilitate and accelerate ABS 9 negotiations. As a result, the co-chairs prepared a draft protocol, and a draft COP decision was circulated prior to ABS 9. At the ninth meeting of the Working Group in Cali, Colombia, from 22-28 March

2010, a draft protocol was tabled by the co-chairs and accepted by Parties as a basis for further negotiations. However, since it was not possible to finalize the text at this session, the Working Group decided to suspend the meeting at the end of the seven days and to resume the ninth meeting of the Working Group in order for it to complete its mandate.<sup>21</sup> The text of the Protocol (still subject to negotiation) became Annex I of the Report.<sup>22</sup> Subsequently the CBD Secretary notified<sup>23</sup> formally to the Parties and other stakeholders the text of the Protocol pursuant to article 28 of the CBD.<sup>24</sup> A roadmap to Nagoya, including the reassumed session of the WG-ABS to be held in Montreal on 10-16 July 2010 was also agreed. Out of the Cali meeting came a draft protocol text upon which negotiations can move forward on creating the IR. It should be pointed out that the current text of the Draft Protocol is entirely open to further negotiations, and nothing of its content can be considered agreed.

As a result of the ninth meeting, the Draft Protocol on ABS<sup>25</sup> addresses the following issues of interest for this article: disclosure requirements in IPR applications; the certificate of compliance, technology transfer (TT) and the protection of TK associated with genetic resources.

## 2. POSSIBLE OPTIONS, SCENARIOS AND SYNERGIES BETWEEN THE IR AND OTHER IPR-RELATED INSTRUMENTS OR PROCESSES<sup>26</sup>

This section focuses on the possible results and outcomes of the IR on matters related to IPR and biodiversity; the disclosure of origin, the certificate of compliance, the transfer of technology as a mechanism for sharing benefits, and the protection of TK.<sup>27</sup>

### 2.1 The IR and the WTO

Since the entry into force of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), there have been calls, mainly by developing countries, to explore the relationship between the CBD and IPRs. In parallel, CBD COP decisions<sup>28</sup> have stressed the need to gather information on the impact of IPRs on achieving the objectives of the CBD and to explore the relationship between the Convention and the TRIPS.<sup>29</sup>

As early as COP 3,<sup>30</sup> the CBD Secretariat was asked to cooperate with the WTO through the Committee on Trade and Environment (CTE) to explore the extent to which there may be linkages between CBD Article 15 on ABS and relevant provisions of the TRIPS. In the WTO context, the TRIPS Council has included the relationship between TRIPS and the CBD on numerous occasions in its discussions.<sup>31</sup> Some of the debates about the links between the CBD and WTO took place in the context of the TRIPS review of Article 27.3(b), which was initiated by the TRIPS Council during 1999, four years after the entry into force of the Agreement.

There have also been similar discussions regarding the TRIPS under the CTE, including protection of TK; the transfer of environmentally sound technology, ethical concerns associated with the patenting of living organisms and compatibility between TRIPS and the CBD.<sup>32</sup>

The TRIPS Council has also discussed what the implications of IPRs are for access to and transfers of technology. One view has been that IPRs in respect of genetic resources could

impede access to and raise the cost of technology in this area, by virtue of the exclusive rights given to rights holders to prevent others from using the protected technology. In response, it has been argued that full implementation of the TRIPS in developing countries would stimulate investment in those countries and, therefore, facilitated TT forms part or the basis of benefit sharing as envisaged under the CBD.<sup>33</sup> Technology transfer is also a relevant issue addressed by the CBD. Article 16 of the CBD on access to and transfer of technology contains numerous references to IPRs. The CBD COP 7 adopted a program of work on TT and technological and scientific cooperation that required the CBD Secretariat to prepare, in collaboration with the United Nations Conference on Trade and Development (UNCTAD), the World Intellectual Property Organization (WIPO) and other relevant international organizations, technical studies<sup>34</sup> to explore and analyze the role of IPRs in TT, in the context of the CBD, and identify potential options to increase synergy and overcome barriers to TT and cooperation.<sup>35</sup>

Later, in 2001, the Doha Declaration, which launched the current round of trade negotiations, specifically instructed the TRIPS Council to examine the relationship between the TRIPS and, the protection of TK and folklore and other new and relevant developments pointed out by the Members. In particular, the TRIPS Council shall take this into account in conducting the examination provided for in paragraph 3(b) of article 27; the examination of the application of the TRIPS provided for in paragraph 1 of article 71; and in its work in compliance with paragraph 12 of the Declaration. In carrying out this work, the TRIPS Council shall be governed by the objectives and principles stated in articles 7 and 8 of the TRIPS and shall fully consider the dimension of development.

Though this debate was originally wide ranging,<sup>36</sup> it now focuses on how the TRIPS relates to the CBD and particularly whether the agreement

should be amended to require disclosure in IPR applications, which has been discussed in the WTO based on the mandate established in Doha, or whether alternative approaches, including contractual based systems or databases of genetic resources and TK, could be more effective in ensuring mutual supportiveness between the TRIPS and the CBD.

One of the first measures suggested to achieve mutual supportiveness between the CBD and intellectual property systems (in particular, the TRIPS) was the disclosure of the origin of genetic resources or associated TK in IPRs applications, particularly in patents. It has been suggested, mostly by developing countries that the TRIPS should be amended to require that patent applicants disclose, as a condition to patentability one or more of the following: the source and origin of any genetic material used in a claimed invention; and/or any related TK used in the invention; evidence of prior informed consent from the competent authority in the country of origin of the genetic material and evidence of fair and equitable benefit sharing. Proponents of disclosure requirements argue that this stipulation would help to support compliance with the CBD provisions on access to genetic resources and benefit sharing.<sup>37</sup> In response, it has been expressed that such a modification is not necessary to implement the CBD requirements as they should be implemented through corresponding contracts at the national level, and that the TRIPS is not the appropriate instrument to regulate ABS.

The Declaration adopted at the Ministerial Summit in 2005 in Hong Kong provides (in paragraph 44) that note be taken of the work carried out by the TRIPS Council, in accordance with paragraph 19 of the Doha Declaration, and agrees that work will continue based on this paragraph and on the progress made to date. In addition, in accordance with paragraph 39 concerning implementation, it was decided to address the relationship between the TRIPS and the CBD through a consultation process on different aspects of implementation. This

consultation is being carried out with the intervention of the Deputy Director General of the WTO.

In May 2006, six countries, including Brazil, India and Peru, submitted a proposal to the TRIPS Council suggesting concrete changes to the TRIPS in order to support disclosure of origin. The Communication<sup>38</sup> aims to incorporate a new article 29 bis into the TRIPS. It proposes an amendment to the TRIPS to incorporate requirements for disclosure of the origin of genetic resources<sup>39</sup> and associated TK in patent applications along with evidence of prior informed consent and benefit sharing.<sup>40</sup>

At the Mini-Ministerial Conference held in July 2008,<sup>41</sup> not much changed. A Draft Modality text on IP was presented including negotiations on disclosure.<sup>42</sup> The Draft called<sup>43</sup> for text based negotiations on the IP issues, including disclosure. This Draft Modalities proposal for negotiating the IP issues at the ministerial level has gathered the support of the majority of developing country Members and some developed countries as well. A large coalition of more than hundred developing and developed countries led by Brazil, the EU, India and Switzerland, were pushing for the three TRIPS issues to be moved forward as a single undertaking in the round, but the proposal was strongly rebuffed by some country Members who contended that the IP issues should not be discussed in tandem with the Doha negotiations on liberalizing trade in agricultural and industrial goods.

The issue of disclosure was also raised at the several TRIPS Council Meetings after the July Mini-Ministerial<sup>44</sup> in 2009 and 2010, with similar results. In essence, countries largely reiterated known positions on the relationship between the TRIPS and the CBD. Meanwhile, informal consultations on how to move the issue forward are ongoing. However, like all matters discussed at the July Mini-Ministerial Conference, the future of the TRIPS issues depend on the future of the negotiations.

## 2.2 Relationship Between Provisions of the IR and WTO Rules

As presented in the previous section, discussions on the relationship between the CBD and the WTO provisions have addressed a range of issues and several proposals have been presented. However, the current debate has focused on the disclosure of origin in patent applications or whether alternative approaches including contractual based systems or databases of genetic resources and TK could be more effective in ensuring mutual supportiveness between TRIPS and the CBD. In addition, TT is a relevant issue connecting the IR and the WTO. The following paragraphs explore the different scenarios and options regarding these subjects.

There are other issues connecting the WTO and the potential IR, which, however, can be mentioned only briefly here, including: the applicability of the WTO investment provisions to the ABS activities; the relationships between the principle of non-discrimination (the most favoured nation and national treatment principles) and ABS legislation and practices, among others.<sup>45</sup>

### Disclosure of origin

The Annex of Decision IX/12 has identified five components for the IR. These include access; fair and equitable benefit sharing, compliance measures, traditional knowledge and capacity building. Under the compliance component one of the measures for “further consideration”<sup>46</sup> is the disclosure requirements. Decision VIII/4/D is clearer about disclosure in the context of the CBD IR negotiations.<sup>47</sup> The Draft Protocol<sup>48</sup> provides:

“In implementing Article 12, paragraph 1, Parties shall take measures, as appropriate, to monitor the utilization of genetic resources, including from derivatives produced through expression, replication and characterization, having regard to the list of typical uses of genetic resources provided in Annex II of the present Protocol. Such

measures include: (a) The identification and establishment of check points and disclosure requirements including at”:

(iv) Intellectual property examination offices<sup>49</sup>

### Certificate of origin, source, legal provenance, compliance<sup>50</sup>

One element ABS negotiations have focused on in order to respond to the call for user country measures, and to contribute to solving problems related to the monitoring and traceability of genetic resources, is the development of some form of certificate of origin/source/legal provenance—more recently called a “certificate of compliance.” The idea of the certificate is to prevent or minimize problems generated by the existence of two different jurisdictions for ABS arrangements—that of the place where the material is collected and that of the place where research and development activities are carried out. The existence of an internationally recognized document would make it possible to check the legality of access at the place where the activity (patent, product approval, etc.) generates value, and to discover the subsequent use of the resources and corresponding benefit sharing. At the same time, this supposedly<sup>51</sup> would favour the creation of simpler access systems in provider countries, because existing control mechanisms would be applied, via the certificate, in the later stages of research and development, thus helping to make the regulation of access to genetic resources more flexible. In this way, monitoring and regulation would be less strict during the access phase and stricter during the research and development phase, where control or check points would be established. This implies that the documentation would need to pass through the various buyers, but the monitoring points would be reserved only for certain milestones in the research and development process, such as those related to product approval, IPR applications, publications and the presentation of funding proposals, etc.

CBD COP Decision VIII/4C established an Expert Group (EG) on an internationally recognized certificate of origin/source/legal provenance.<sup>52</sup> The Group agreed that the basic role of any certificate system would be to provide evidence of compliance with national ABS legislation. This could be achieved by a system of national certificates with standard features to allow for their international recognition.

The Group<sup>53</sup> identified a number of points common for all proposals of a certificate, including that it could be required for presentation at specific checkpoints in the user countries, *inter alia* patent and in general IP applications.<sup>54</sup> Indeed, the certificate of origin could perhaps be integrated into the existing system of requirements for disclosure of information in the patent system. A majority of certificate proposals envisages a system of checkpoints at which disclosure of the certificate of origin would be required for the purposes of processing IP applications, among other things. Compliance with disclosure requirements would be facilitated where an internationally recognized certificate could act as evidence of conformity with national and international law.<sup>55</sup>

Depending on the certificate's final design, some rules of the trade system, especially those related to technical barriers to trade, might apply.<sup>56</sup> For instance, if the certificate is going to be checked at customs the legal consequence of not producing a certificate is the prohibition of the entry of the genetic resources - for which the certificate should have been issued - into a country. However, the potential implications of such rules on the certificate need to be better understood.

Moreover, the certificate, depending on its design, may raise other international trade issues. In this regard, considering that the certificate could be a document attached to the transfer/export (international trade) of genetic resources it also should be analyzed in the context of the relevant rules of the WTO regarding non-discrimination (the most favoured nation principle and the national treatment

principle) as well as the appropriate measures contained in the Agreement on Technical Barriers to Trade (TBT), which governs the elaboration and use of technical regulations, standards and conformity assessment procedures in ways that do not create unnecessary obstacles to international trade. The certificate could be considered a technical regulation, and it must take into account the relevant provisions of the TBT, especially article 2.2: technical regulations shall be no more restrictive than necessary to fulfill a legitimate objective and the requirement that technical measures shall be the less trade restrictive in light of applicable risks.<sup>57</sup>

With respect to the compliance component of the IR, the Annex of Decision IX/12 identified as an area for "further elaboration" the "Development of tools to monitor compliance: ... b) (an) internationally recognized certificate issued by a domestic competent authority."<sup>58</sup> The Draft Protocol provides that the:

"disclosure requirement shall be met by providing *bona fide* evidence that a permit or certificate was granted at the time of access in accordance with Article 5, paragraph 1 (d);

The permit or certificate issued at the time of access in accordance with Article 5, paragraph 1 (d) and registered with the ABS Clearing House Mechanism; in accordance with Article 5 paragraph 2 shall constitute an internationally recognized certificate of compliance.

The internationally recognized certificate of compliance shall serve as evidence that the genetic resource in question has been obtained, accessed and used in accordance with prior informed consent and that mutually agreed terms have been entered into, in accordance with national legislation on access and benefit-sharing of the country providing the genetic resource. Disclosure requirements shall be met by providing an internationally recognized certificate or permit. The internationally recognized

certificate of compliance shall contain the following minimum information:

- a) Issuing national authority;
- b) Details of the provider;
- c) A codified unique alpha numeric identifier where feasible;
- d) Details of the rights holders of associated traditional knowledge, as appropriate;
- e) Details of the user;
- f) Subject-matter covered by the certificate;
- g) Geographic location of the access activity;
- h) Link to mutually agreed terms;
- i) Uses permitted and restrictions of use;
- j) Conditions of transfer to third parties if any;
- k) Date of issuance.

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider additional modalities of the internationally recognized certificate of compliance system, taking into account the need to minimize transaction costs and to ensure feasibility, practicality and flexibility.”<sup>59</sup>

The certificate can contribute to the monitoring and traceability of genetic resources. It could be required in patent applications to provide evidence of compliance with national legislation on ABS, including prior informed consent and benefit sharing, thus fulfilling a role in supporting the disclosure of origin requirement.

#### **Technology transfer as an element of the benefit-sharing component of the IR**

Annex I to Decision IX/12, under section III B on “Fair and equitable benefit sharing”

also includes as a component to be further elaborated, the access and transfer of technology. A TT measure could be developed in the context of the benefit-sharing component of the IR.<sup>60</sup>

The Draft Protocol provides (article 18 bis) that:

“In accordance with Articles 15, 16 and 19, Parties shall collaborate, cooperate and contribute in scientific research and development programmes, particularly biotechnological research activities, as a means to generate and share benefits in accordance with Article 4 of this Protocol. This shall include measures by developed country Parties that provide incentives, to companies and institutions within their jurisdiction, to promote and encourage access to technology by, and transfer of technology to, developing countries, including the least developed among them, in order to enable them to create a sound and viable technological base. Where possible, such collaborative activities shall take place in the country providing genetic resources.”<sup>61</sup>

It is outside the scope of this paper to analyze the relationship between TT and IPRs in general and TRIPS in particular in the context of the CBD. However, it is clear that TT is a key element of the ABS CBD provisions<sup>62</sup> and of the IR. As one study has pointed out “The provisions of the Convention on technology transfer reflect the consensus of the international community laid down in key international policy documents, that the development, transfer, adaptation and diffusion of technology and the building of capacity is crucial for achieving sustainable development.” For instance, TT could be one element of structuring mutually agreed terms and benefit-sharing arrangements.

At the same time, TT (e.g. protected by IPRs) may create some links between the IR and TRIPS provisions on this matter.<sup>64</sup>

### **Disclosure requirements, certificate of compliance as developed in the CBD IR negotiations and its relationship to WTO provisions**

The inclusion and discussion of disclosure requirements and the use of the certificate in patent applications have both been contentious issues during the IR negotiations.<sup>65</sup> However, one potential scenario would be the inclusion of some form of disclosure requirement in the IR negotiations. In this regard, it has been suggested that the inclusion of mechanisms such as the disclosure of origin of genetic resources and TK, or the certificate in patent or other IPR filing procedures as proposed, would strengthen mutual supportiveness between the WTO's IPR system and the CBD ABS IR. Due to the nature of a legally binding instrument of the ABS Protocol, the countries should develop – in their national legislation – disclosure of origin requirements to comply with the international obligations. While there may be some variances with regard to the scope, consequences and practical operations of these requirements, some experts agree that<sup>66</sup> in general the requirements of disclosure do not run counter to the international IP agreements (with regard to the UPOV Convention, see paragraph 78) and the TRIPS in particular.<sup>67</sup> In addition, there are ongoing negotiations regarding disclosure at the WTO, and no final decision has been made yet on whether or not to accept the disclosure requirements in the TRIPS.

Alternatively, a “soft version” of the disclosure requirement could also be developed at the CBD to encourage the adherence of some countries that are already opposed to disclosure requirements (both in the WTO and the CBD).<sup>68</sup> However, some delegations and stakeholders do not support any disclosure requirements in IP applications and support alternative mechanisms to address concerns regarding misappropriation. In their view, new patent disclosure requirements will be ineffective in promoting the objectives sought and will introduce uncertainties into the patent system.

Under this scenario (the development of disclosure requirements in the IR), the IR

negotiations could promote more clarity on relevant issues, such as the meaning and implications of prior informed consent (PIC) and benefit-sharing requirements. Some of the objections to the disclosure provisions are related to the lack of clarity about the exact scope and the legal implications of the terms used. A number of terms and concepts that are central to the ABS regime, such as “fair and equitable benefit sharing”, “traditional knowledge”, and “access to genetic resources” are not defined in the CBD. The definition of terms is an ongoing process in the CBD that was included in the mandate of prior ABS Working Group meetings.<sup>69</sup> The IR could clarify issues of PIC, benefit sharing and certificate of origin, etc. It also could offer guidance on key topics, such as the scope of the term “genetic resource”.

This scenario would present two main disadvantages: the condition of non-CBD Party United States, a relevant IP country, and difficulties for the integration of the disclosure requirements into the IP system if the provisions would be integrated in the CBD.<sup>70</sup>

In relation to the certificate, the IR could provide the necessary practical and operational details for its use in IPR applications. The certificate as such has not been discussed at the WTO, but the development of appropriate provisions on the certificate under the IR could facilitate the use of the certificate for disclosure of origin purposes. It is clear that the certificate has a broader scope and objectives than merely serving as an instrument to promote disclosure.<sup>71</sup> However, a certificate system that serves merely to demonstrate compliance with the requirements of the laws of the providing country a legal title to use of the resources and the identification of the rights and limitations attached to the access and use would not appear to run counter the WTO rules. It would depend on how the certificate, if agreed, is finally designed. The certificate, if it is designed in a non-discriminatory fashion, could be in harmony with the trade system, and both instruments could be developed in a mutually supportive manner.

### Disclosure of origin at the WTO

A different scenario is the incorporation of disclosure provisions at the WTO (in this case through a legally binding amendment to the TRIPS Agreement). The exact scope and precise content of a potential amendment of the WTO is still uncertain (whether or not sanctions for non-compliance will be outside the patent law or not; the necessity of proving compliance with PIC and benefit-sharing; etc) as well as the amendment per se. This scenario would also create mutual supportiveness between the IPR system of the WTO and the CBD ABS IR.

In addition, under this scenario the disclosure could contribute to the “defensive protection”<sup>72</sup> of traditional knowledge (“TK”), therefore supporting the TK component as well as the compliance component under the IR. Requirements for disclosure of the origin of traditional knowledge associated with genetic resources may assist in ensuring prior informed consent and equitable benefit-sharing with regard to both traditional knowledge and the associated genetic resources.

Considering the large membership of the WTO and its economic relevance for the Contracting Parties, this amendment would promote a better and wider integration of the disclosure of origin in the IP system (and in the national laws) and would promote broad implementation of the instrument. In this case, the CBD may provide assistance and coordination in developing and implementing disclosure requirements by clarifying terms and instruments, including the certificate role in the disclosure. A reference and description of the disclosure mechanism in the context Protocol could also be established, but the substantive provisions would be integrated into the TRIPS agreement.

### No disclosure requirements in either instrument

Another scenario would be the absence of disclosure requirement provisions in both the CBD IR and in the WTO. In this case there will be no conflict between the IR and WTO, but,

in the view of some countries and experts, an opportunity to promote mutual supportiveness between the WTO IPR system and the CBD ABS IR could be lost. However, some countries and stakeholders support this approach because it would avoid the alleged negative consequences of new patent disclosure requirements mentioned before. These delegations and stakeholders support other mechanisms to address concerns regarding misappropriation.

### Technology transfer provisions developed in the IR

Technology transfer provisions could be specifically developed in the context of the IR benefit sharing component in line with the current provisions and language of the CBD itself. This actually has been included in the current Draft Protocol (article 18 bis).

However, considering that the current text is open for negotiations, TT provisions could end up in different forms in the final version of the Protocol. The IR could set minimum requirements for benefit-sharing to be included in the mutually agreed terms, including TT. Technology transfer measures could also be developed as a direct obligation for CBD Members. These provisions could be similar to the ones already included in the CBD (articles 15, 16 and 19).

Both types of provisions could be drafted to be in harmony and provide mutual supportiveness between the IR and the WTO/TRIPS IPR provisions.<sup>73</sup> These measures would be compatible and mutually supportive of the WTO efforts and text regarding technology transfer, including the Doha Mandate (par. 19).

### 2.3 International Union for The Protection of New Varieties of Plants (UPOV)<sup>74</sup>

The International Convention for the Protection of New Varieties of Plants was signed in Paris in 1961 and entered into force in 1968. It was revised in 1972, 1978 and 1991. The 1991 Act of the Convention entered into force in 1998.

The purpose of the International Union for the Protection of New Varieties of Plants (UPOV) Convention is “to ensure that the members of the Union acknowledge the achievement of breeders of new varieties of plants, by granting to them an intellectual property right, on the basis of a set of clearly defined principles.”<sup>75</sup> Thus, the Convention provides a *sui generis* form of intellectual protection specifically adapted to the process of plant breeding and developed with the aim of encouraging breeders to develop new varieties of plants. To be eligible for protection, varieties have to be: (i) distinct from existing, commonly known varieties; (ii) sufficiently uniform, (iii) stable and, (iv) new in the sense that they must not have been commercialized prior to certain dates established by reference to the date of the application for protection.<sup>76</sup> The Convention offers protection to the breeder, in the form of a “breeder’s right,” if his plant variety satisfies the above conditions. The scope of the breeder’s right is, however, limited by two important exceptions in Article 15. The first exception, known as the “breeder’s exemption,” allows the use of the propagating material of the protected variety, without prior authorization, for the purpose of breeding other varieties. The breeder’s exemption optimizes variety improvement by ensuring that germplasm sources remain accessible to all breeders. The second exception concerns the right of farmers to use farm-saved seed for replanting. This is known as the “farmers’ privilege” and seeks to safeguard the common practice of farmers saving their own seed for the purpose of re-sowing. However, the Convention requires that the farmers’ privilege be regulated “within reasonable limits and subject to safeguarding of the legitimate interests of the breeder.” The mission of UPOV is “to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society”.

In response to notifications by the Executive Secretary inviting relevant international organizations to contribute to the work on access

and benefit sharing, the Vice Secretary-General of UPOV provided detailed replies highlighting the access and benefit-sharing aspects of the UPOV Convention. The UPOV submission is included in the compilation of submissions by Parties, international organizations and other relevant stakeholders.<sup>77</sup>

In these communications, UPOV highlighted the importance of access to genetic resources to ensure progress in plant breeding. It also pointed to the concept of the breeder’s exemption in the UPOV Convention, which reflects the view of UPOV that the worldwide community of breeders needs access to all forms of breeding material to sustain progress in plant breeding and hence maximize the use of genetic resources for the benefit of society. The communications also include reference to the inherent benefit-sharing principles of the UPOV Convention, in the form of breeder’s exemption and other exceptions to the breeder’s right. Concern is expressed with respect to any other measures for benefit sharing that could introduce unnecessary barriers to progress in breeding and the utilization of genetic resources. Finally, UPOV urges the Working Group on ABS to recognize these principles in its work and to ensure that any measures it develops are supportive of these principles and of the UPOV Convention.

The International Union for the Protection of New Varieties of Plants is of the opinion that the CBD and the UPOV Convention should be mutually supportive and the IR on ABS should be designed so that the mutual supportiveness of the UPOV Convention and the CBD will not be affected. The views of UPOV with respect to the work of the Working Group on ABS, adopted by the Council of UPOV at its thirty-seventh ordinary session on 23 October 2003, were provided to the Secretariat prior to the second meeting of the Working Group. These views provide a useful overview of issues related to the IR from the perspective of UPOV.<sup>78</sup>

A further contribution was provided by UPOV in preparation for the fourth meeting of the Working Group on ABS and was made

available in a document that highlights that the UPOV Convention is not an instrument relating to ABS.<sup>79</sup> As further detailed in the UPOV contribution, it was requested that “consideration is made that any measures pursued in the international regime do not undermine plant variety protection according to the UPOV Convention. For its part UPOV supports the view that the Convention on Biological Diversity and relevant international instruments dealing with intellectual property rights, including the UPOV Convention, should be mutually supportive.”<sup>80</sup>

UPOV has also prepared a study<sup>81</sup> on the impact of plant variety protection and its report is now available on UPOV’s website. The study indicates that “the UPOV system of plant variety protection provides an effective incentive for plant breeding in many different situations and in various sectors, and results in the development of new, improved varieties of benefit for farmers, growers and consumers” and that “farmers, growers and breeders have access to best varieties produced by the breeders throughout UPOV member territories.”

The position of the UPOV Council on access to genetic resources and benefit sharing related to plant breeders’ rights (PBR) (adopted by the UPOV Council in its thirty-seventh session, on 23 October 23 2003), mentioned above, needs to be briefly presented here to fully understand the options and scenarios.<sup>82</sup>

#### **Access to genetic resources**

“UPOV considers that plant breeding is a fundamental aspect of sustainable use and development of genetic resources. It is of the opinion that access to genetic resources is a key requirement for sustainable and substantial progress in plant breeding. The concept of the ‘breeders exemption’ in the UPOV Convention, whereby acts done for the purpose of breeding other varieties are not subject to any restriction, reflects the view of UPOV that the worldwide community of breeders needs access to all forms of breeding material to sustain greatest

progress in plant breeding, and thereby, to maximize the use of genetic resources for the benefit of society.”

#### **Disclosure of origin**

“UPOV encourages information on the origin of the plant material, used in breeding of the variety, to be provided where this facilitates the examination [for compliance with the conditions of protection], but could not accept this as an additional condition of protection since the UPOV Convention provides that protection should be granted to plant varieties fulfilling the conditions of novelty, distinctness, uniformity, stability and a suitable denomination and does not allow any further or different conditions for protection ... Thus, if a country decides, in the frame of its overall policy, to introduce a mechanism for the disclosure of countries of origin or geographical origin of genetic resources, such a mechanism should not be introduced in a narrow sense, as a condition for plant variety protection. A separate mechanism from the plant variety legislation, such as that used for phytosanitary requirements, could be applied uniformly to all activities concerning the commercialization of varieties, including, for example, seed quality or other marketing related regulations.”

#### **Prior informed consent**

“UPOV encourages the principles of transparency and ethical behaviour in the course of conducting breeding activities and, in this regard, the access to the genetic material used for the development of a new variety should be done respecting the legal framework of the country of origin of the genetic material. However, the UPOV Convention requires that the breeder rights should not be subject to any further or different conditions than those required to obtain protection. UPOV notes that this is consistent with article 15 of the CBD, which provides that the determination of access to genetic resources rests with the national governments and is subject to national legislation.”

### Benefit-sharing

“UPOV would be concerned if any mechanisms to claim the sharing of revenues were to impose an additional administrative burden on the authority entrusted with the grant of breeder’s rights and an additional financial obligation on the breeder when varieties are used for further breeding. Indeed, such an obligation for benefit sharing would be incompatible with the principle of the breeder’s exemption established in the UPOV Convention whereby acts done for the purpose of breeding other varieties are not, under the UPOV Convention, subject to any restriction and the breeders of protected varieties (initial varieties) are not entitled to financial benefit sharing of varieties developed from the initial varieties, except in the case of essentially derived varieties.”

### Access and PBR

The legislation on access to genetic material and the legislation dealing with the grant of PBR pursue different objectives, have different scopes of application and require a different administrative structure to monitor their implementation. Therefore, it was considered appropriate to include them in different legislation, although such legislation should be compatible and mutually supportive.

Later, the UPOV Council, at its twenty-fifth extraordinary session held in Geneva on 11 April 2008, decided to request the COP IX to include in the IR decisions the following paragraphs: “Recognizing that UPOV supports the view that the Convention on Biological Resources and the UPOV Convention should be mutually supportive” and “Further Instructs the Ad-hoc Open Ended Working Group on Access and Benefit Sharing that any provisions which it develops for an international regime on access and benefit sharing should ensure mutual supportiveness with the UPOV Convention.”<sup>83</sup>

Despite the UPOV Council position on the IR and the UPOV Convention, some authors are of the opinion that a disclosure of origin

requirement does not necessarily conflict with UPOV basic rules.<sup>84</sup> At the same time, there are no known initiatives within UPOV to modify the UPOV Convention for the inclusion of disclosure requirements. With regard to the WTO discussions on disclosure, these take place in the context of the patent system and would not affect PBR protection.<sup>85</sup>

- **Disclosure and certificate requirements for PBR established in the IR<sup>86</sup>**

For these reasons, a potential option to include the disclosure of origin in PBR as a result of the CBD IR negotiations could conflict with the UPOV interpretation of the compatibility between the disclosure requirements and UPOV conditions for protection,<sup>87</sup> if the disclosure requirements were drafted as an additional condition for protection.

Because the IR negotiations outcome on disclosure is to be contained in a legally binding instrument, a potential inconsistency between the two agreements would exist. Such an approach could be a disincentive for the UPOV Members to become Parties to the legally binding IR.

Another option is to amend the UPOV Convention to include a disclosure of origin condition for the protection of PBR. However, there is no information that such a process has been suggested by UPOV members.

- **Exclusion of PBR from the disclosure and/or certificate requirement**

One option is to exclude PBR applications from the disclosure provisions or to create a different and special system, taking into account both the legal and technical implications of such system for the case of plant varieties. A special disclosure requirement could be designed taking into account the legal requirements and conditions established in the UPOV Convention and the process of the access and use of plant genetic material for the breeding of new varieties.

- **Technology transfer provisions and UPOV**

There are no specific TT provisions as such in the UPOV Convention. However, similar arguments and conclusions to the ones presented in the WTO section could be made with regard to TT provisions developed in the IR and UPOV.<sup>88</sup> The IR could establish TT provisions related to plant variety protection, which could co-exist in harmony and be mutually supportive with the UPOV Convention.

- **IR statement on mutual supportiveness with the UPOV Convention**

UPOV Council statements have called repeatedly for mutual supportiveness between both instruments. In addition, references to UPOV in the current IR negotiating text are found under some of the options for the IR scope. One possible option is to expressly include a reference to the mutual supportiveness between the UPOV Convention and the IR. However, it could be objected to on the grounds that similar statements could also be made for many other international instruments and processes.

#### **2.4 The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)<sup>89</sup>**

The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) was established by the WIPO General Assembly in October 2000 as a forum for debate and dialogue on the relationship between IP, TK, genetic resources and traditional cultural expressions. It was considered that these topics did not fall within the scope of other WIPO bodies.<sup>90</sup> The IGC's mandate encompasses analyzing aspects of IP related to genetic resources, TK and the protection of expressions of folklore. At a session of the WIPO General Assembly in 2005, it was decided to extend the mandate for another two years, allowing for the possible drafting of legally binding instruments. One of the topics the Committee had considered - and

continues to do so under its new mandate - is precisely the disclosure of origin in patent applications and the protection of TK. The Committee has met on 16 occasions.

To date, the main work of the WIPO on the IR can be summarized as follows:

##### **Access to genetic resources**

With respect to access to genetic resources, the WIPO has prepared several analyses of the clauses on IPR in the agreements on ABS, including materials transfer agreements and model clauses. A database with public examples has also been created, with an emphasis on IPR clauses. Draft guidelines have also been prepared on IPR clauses in access and benefit-sharing agreements.

In addition, following through on COP Decision VI/24, the WIPO was invited to prepare an article on disclosure of origin in patent applications, to include the following aspects, among others: a) genetic resources utilised in inventions, b) the country of origin of the genetic resources utilised in the inventions, c) the associated TK, innovations and practices utilised in the inventions, d) the source of the associated TK, e) evidence of prior informed consent. This study, called the Technical Study on Disclosure of Origin Requirements in Patent Applications, was presented at the COP 7 in Malaysia and was well received by the COP (Decision VII/19/E). In addition, the COP 7 requested that WIPO prepare a new technical study including the examination and discussion, as appropriate, of aspects related to the relationship between access to genetic resources and disclosure of origin in patent applications, including the following aspects, among others:

- Options for model provisions on proposed disclosure requirements
- Practical options for IPR application procedures with regard to the triggers of disclosure requirements
- Options for incentive measures for applicants

- d) Identification of the implications for the functioning of disclosure requirements in various WIPO-administered treaties
- e) Intellectual property-related issues raised by a proposed international certificate of origin/source/legal provenance.

The WIPO has responded<sup>91</sup> to the COP invitation by preparing a new technical document (WO/GA/32/8) entitled “Examination of Issues Regarding the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Right Applications”.

The WIPO has also jointly prepared a study with UNCTAD and the CBD Secretariat on the role of IPR in TT in the context of the CBD (in February 2006).

Despite the abundant information generated by the WIPO, to a certain degree in response to requests from the CBD, and the exchange of opinions and positions that has taken place in the Committee’s sessions, these debates have not resulted in initiatives to take disclosure of origin in IPR applications into account in initiatives to reform national and international legal systems.<sup>92</sup> For this reason, fearing that the discussions will not generate actual regulatory progress, some countries have questioned why WIPO instead of the WTO is the entity charged with discussing issues of disclosure of origin.<sup>93</sup>

The issue of disclosure of origin has also been discussed in the framework of revisions to the Substantive Treaty on Patent Law. In accordance with the mandate of the 2005 General Assembly, a process of two sessions of the Permanent Committee on Patent Law, one formal and another informal, was established to analyze this proposed instrument. Likewise, due to Swiss proposals, this issue is being discussed by the Patent Cooperation Treaty. In conclusion, in order to harmonize patents, developing countries have presented proposals in the WIPO that include disclosure of origin, proof of PIC and of benefit sharing, as well as effective mechanisms for questioning the validity of patents.

### Traditional knowledge

The WIPO has prepared an extensive number of documents on positive and defensive measures for the protection of TK.<sup>94</sup> In addition, a range of activities of interest have been carried out on this subject, such as:

- The systematic study and clarification of legal options for the protection of TK
- The analysis of cases of the use of IPR for the protection of TK, as well as of the establishment of *sui generis* protection systems
- Case studies and analyses of practical experiences
- A draft of a “tool kit” to document TK associated with genetic resources
- The progressive recognition of TK in patent systems, through the development of guidelines for patent examiners; mechanisms involving links to databases to ensure a better understanding of TK as prior art, the incorporation of TK in minimum standards for searches for novel forms by the Patent Cooperation Treaty (PCT).
- The development of a draft of policy objectives and basic principles on TK. These provisions are considered compatible with the CBD although their scope is broader than TK related to biodiversity, and they have taken into account the contributions and progress of the Working Group on Article 8 (j). These guidelines are more relevant for establishing national norms than international ones.<sup>95</sup>

The current mandate of the Committee (2009-2011) includes:

- “ (a) The Committee will, during the next budgetary biennium (2010/2011), and without prejudice to the work pursued in other fora,<sup>96</sup> 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.

- (b) The Committee will follow, as set out in the Annex, a clearly defined work program for the 2010/2011 biennium. This work program will make provision for; in addition to the 15th session of the Committee scheduled for December 2009, four sessions of the IGC and three intersessional working groups, in the 2010-2011 bienniums.
- (c) The focus of the Committee's work in the 2010/2011 biennium will build on the existing work carried out by the Committee and use all WIPO working documents, including WIPO/GRTKF/IC/9/4, WIPO/GRTKF/IC/9/5 and WIPO/GRTKF/IC/11/8A (Traditional Cultural Expressions, Traditional Knowledge and Genetic Resources), which are to constitute the basis of the Committee's work on text-based negotiations.
- (d) The Committee is requested to submit to the 2011 General Assembly the text (or texts) of an international legal instrument (or instruments) which will ensure the effective protection of GRs, TK and TCEs. The General Assembly in 2011 will decide on convening a Diplomatic Conference."

Thus far, this represents the Committee's strongest mandate. The scope of work of the IGC includes the possible development of an

international instrument or instruments on IPR and genetic resources as well as TK.

Over the last several years, the IGC had stalled on negotiations related to future work, and in particular on negotiations over "intersessional" working groups to take place between biannual meetings of the full IGC. At the last meeting of the IGC (May 2010) after intensive negotiations, an agreement was reached on how to conduct intersessional working groups, and a date was found for the next one: 19-23 July 2010. These intersessionals are intended to help speed the committee's work towards an "international legal instrument" for the protection of TK, traditional cultural expressions and genetic resources. The intersessional working groups will provide "legal and technical advice and analysis" and will "report to the IGC on the outcomes of their work and submit recommendations and texts relating to the discussion" at the IGC. With this matter resolved, it is possible to accelerate the committee's substantive work, which aims to produce a draft legal instrument by September 2011. It was also decided that "all three subjects of the IGC shall be treated on an equal footing" and that each subject should be allocated an equal amount of time for discussion. Over the course of the session, IGC delegates also engaged in text-based negotiations on substantive issues.

The following chart summarizes the most relevant TK related provisions included in the Draft Protocol.

#### Summary of Relevant TK Aspects Included in the Draft Protocol

##### Scope

This Protocol shall also apply to traditional knowledge associated with genetic resources and to the benefits arising from the utilization of such knowledge.

##### Fair and equitable benefit sharing

4. Parties shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources with indigenous and local communities holding such knowledge pursuant to mutually agreed terms, taking into consideration the provisions of Article 9.

**Access to genetic resources**

In the exercise of their sovereign rights over their natural resources, in accordance with Article 15 (1) of the Convention, Parties shall take the necessary legislative, administrative or policy measures, as appropriate, to provide for legal certainty, clarity and transparency of their national access and benefit-sharing requirements. Such measures shall inter alia:

- e) Where applicable national law recognizes and affirms existing rights of indigenous and local communities to genetic resources, set out criteria for prior informed consent of such indigenous and local communities for access to their genetic resources;

**Access to traditional knowledge associated with genetic resources**

Parties shall take legislative, administrative, or policy measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources held by indigenous and local communities is accessed with the prior and informed consent/approval and involvement of indigenous and local communities, and is based on mutually agreed terms.

**Transboundary cooperation**

- 2. Where the same traditional knowledge associated with genetic resources is shared by different indigenous and local communities in several Parties, those Parties shall cooperate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol.

**Traditional knowledge associates with genetic resources.**

- 1. In implementing their obligations under this Protocol, Parties shall give due consideration to indigenous and local community laws, customary laws, community protocols and procedures, of indigenous and local communities, as applicable, in accordance to national law with respect to traditional knowledge associated with genetic resources.
- 2. Parties, with the effective participation of the indigenous and local communities concerned, shall establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations for access to and fair and equitable sharing of benefits arising from the utilization of such knowledge.
- 3. Parties shall support, as appropriate, the development by indigenous and local communities of:
  - (a) Community protocols in relation to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of its utilization;
  - (b) Minimum requirements for mutually agreed terms to secure the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources; and
  - (c) Model contractual clauses for benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources.
- 4. Parties, in their implementation of this Protocol, shall not restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities.
- 5. Parties shall encourage the users of publicly available traditional knowledge associated with genetic resources to take all reasonable measures, including due diligence, to enter into fair and equitable benefit sharing arrangements with the rightful holders of that knowledge.

**Capacity**

3bis.

Parties shall support capacity-building for indigenous and local communities, based on needs and priorities identified by them.

**The IR and the IGC**

There are different scenarios depending on the final outcome of the IGC and the IR.

- **IR and IGC continue their work in parallel without specific coordination**

It could be argued, that the Draft Provisions<sup>97</sup> for the protection of TK could provide the normative substance and content of the international outcome on the protection of TK.

In essence, the Draft Provisions on TK protection, which embody policy objectives and core principles, could be the basis for a proposed international instrument, in line with the current mandate of the IGC, which is to focus on the international dimension and contemplates the development of an international instrument for TK protection.<sup>98</sup> The Draft is thus in full harmony with the CBD, even if the scope of the TK covered by the Draft Provisions is not limited to biodiversity-related TK.<sup>99</sup> The Draft Provisions cover all TK falling within the scope of the definition contained in the principle B.3 of the Draft Provisions.

If the result of the IGC were to be a legally binding instrument - based on the current content of the Draft Provisions for TK protection - there would not be conflict with the IR process.<sup>100</sup> Any binding outcome of the IR would, in principle, support and be complementary to the IGC efforts. This outcome, of course, would likely finally depend on how these instruments are drafted. Close cooperation between the IGC and the CBD is more than ever necessary to ensure mutual support and avoid overlap.

- **IR focuses on specific TK issues taking into account the WIPO developments**

However, a different scenario may also be considered. Despite the fact that there is no potential conflict between the IR content on TK and the IGC outcomes, there is a likely overlap of some of the provisions under negotiation in both fora. If the final outcomes of the IGC and the IR are binding instruments, this potential overlap could create some duplication of legal obligations. Having this in mind, one possible option, taking into account the detailed developments found in the Draft Provisions, is that the IR could establish provisions for TK protection, focusing on specific issues to be agreed sometime during the IR negotiating process.

It could be an option that the IR would include, for instance, umbrella or general provisions. Among the elements to be considered for inclusion in the IR are the following: the role of customary law in the protection of TK; the development of obligations and procedures for obtaining PIC and providing BS from local communities and indigenous peoples.<sup>101</sup> Measures to support the PIC and MAT of indigenous peoples and local communities could constitute another element of the IR relating to the protection of TK. Specifically, the regime could consider the acquisition of TK without having obtained PIC as an act of misappropriation. The WIPO IGC could continue its work on more detailed provisions for TK protection, e.g. those found in the current Draft Provisions.

However, this option presents several disadvantages, such as the following: the uncertainty

about the potential outcome to be expected (both the content and the nature) at WIPO; the different Membership in both fora; and finally, the risk of losing control by CBD Members of the results to be achieved if some content of the negotiation is left under the WIPO process.

- **IR recognition of some IGC tools and instruments**

The IR could also benefit from the extensive information and resources developed at the IGC both in the area of TK and genetic resources. The technical input of the IGC could help in the implementation of the IR outcome. In this regard, the IR could *recognize* the relevance of these instruments to the IR content (e.g. for disclosure of origin purposes; for TK protection and for capacity building, etc.) and decide to use these technical inputs and tools, as appropriate. It does not imply that the IR could not develop specific tools and instruments to address particular concerns and needs. With regard to disclosure requirements, the IGC

work so far has focused more on technical studies and other related activities to improve the understanding of these requirements. Whether an outcome of the IR is a legally binding disclosure requirement, the IGC work could also facilitate the implementation of the disclosure provisions or alternative measures to address issues related to the relationships between IP and genetic resources if included in the IR negotiations. Some delegations and stakeholders also expressed the notion that WIPO has the appropriate expertise to address IP issues related to the IR negotiations.

- **The IR and other WIPO treaties**

Finally, even if some commentators and States are of the opinion that a disclosure requirement, when agreed internationally, would entail changes in two IPRs treaties administered by the WIPO, namely, the Patent Law Treaty (PLT) and the PCT, there is no final legal conclusion on the consequences of disclosure on these treaties administered by the WIPO.<sup>102</sup>

### 3. CONCLUSIONS

There is plenty of space to strengthen mutual supportiveness between the IR outcome and the WTO, WIPO and UPOV processes and instruments. In principle, the IR Protocol could co-exist in harmony with the other treaties or processes, taking into account the arguments and options presented in this article.

The calls for mutual supportiveness between the CBD, WTO, WIPO and UPOV regimes can be read as implying the need to make compatible multiple regimes with very different objectives, approaches and values demanding and claiming legal protection.<sup>103</sup>

The effective implementation of the IR will demand input and collaboration from a range of organizations and fora to ensure that all cross-sectoral issues are given due consideration and effect.<sup>104</sup>

Therefore, it is important to foster closer cooperation and coordination between the processes of the WTO, WIPO and UPOV and the Convention IR negotiations in order to better capitalize on potential synergies between the prospective international regime on ABS and the IP system.

## ENDNOTES

- 1 The paper does not address the relationship between the IR and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture. The relationship with IT has been raised in the context of the scope of the IR and not in the discussions on IPR issues. See regarding the IT Bulmer, Jane, *Study on the relationship between an international regimen on access and benefit sharing and other international instruments and forums that governs the use of genetic resources: the International Treaty for Plant Genetic Resources and the Commission on Genetic Resources for Food and Agriculture*; UNEP/CBD/WG-ABS/7/INF3/Part 1; prepared for the SCBD, March 2009.
- 2 Some parts of this section are based on a prior article Cabrera Medaglia, Jorge, *El Régimen Internacional de Acceso a Recursos Genéticos y Distribución de Beneficios: elementos, progresos y recomendaciones*; UICN Oficina Regional Sur, Quito, 2006
- 3 See, among others, Young, Tomme, *Gaps and Obstacles in Developing/Implementing National ABS Legislation*, document presented at the Expert Workshop on Access to Genetic Resources and Benefit-sharing, Cape Town, September, 2005.
- 4 Studies or analyses can basically be found on specific aspects, such as the challenges of regulating the utilization of GR in user countries once they have left the provider country, etc.
- 5 The implementation of ABS regulation, and the existence of concrete initiatives on bioprospecting, has not generated the huge benefits some had expected for the provider countries and the communities or indigenous peoples. Cfr. Cabrera Medaglia, Jorge, *A Comparative Analysis of the Legislation and Practices on Access to Genetic Resources and Benefit Sharing: Critical Aspects for Implementation and Interpretation*, IUCN, ABS Project, Bonn, 2004 and Cabrera Medaglia, Jorge, *Biodiversity Prospecting In Practice, IP Strategy Today*, No 11, Biodevelopments, New York, 2004.
- 6 It is difficult to quantify the level of these activities due to the lack of legal certainty on the definition of biopiracy. For some, it consists of the acquisition of genetic resources and traditional knowledge without the consent of the country or holder of the resource or knowledge; when rules for fair and equitable benefit-sharing are not established; when IPR protects innovations that are copies or cosmetic modifications of the genetic resources; or when IPR protects biotechnological innovations based on the genetic resources, whether or not prior informed consent exists, etc. On the topic of biopiracy and the difficulties of judging whether certain activities constitute misappropriation, Cfr. Dutfield, Graham, *What is Biopiracy?*, document presented at the Expert Workshop on Access and Benefit-sharing, Cuernavaca, Mexico, October, 2004; and, Young, Tomme, *Analysis of Claims of Unauthorized Access and Misappropriation of Genetic Resources and Associated Traditional Knowledge*, a report prepared for IUCN-Canada and distributed at the Fourth Meeting of the Working Group on ABS, Granada, Document UNEP/CBD/WG-ABS/4/INF/6, January, 2006.
- 7 The idea of disclosure of origin, which will be explained further on, is partly in response to this.
- 8 Cfr. the study by Gatforth et al., who describes current ABS measures and legislation. According to this study, approximately 25 countries have some kind of specific legislation on ABS. In many cases, they are laws of a general nature whose effective application requires additional regulations or laws to further develop the general precepts.

- 9 Cfr. Barber, Charles, et al, *User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit Sharing Provisions of the Convention on Biological Diversity*, UNU/IAS, Japan, 2003.
- 10 Young, Tomme, *Gaps and Obstacles*, op. cit. Cfr. Young, Tomme, *Genetic Resources and Utilisation of Genetic Resources: a Legislative View*, document presented to the International Expert Workshop on Access to Genetic Resources and Benefit Sharing, Cuernavaca, Mexico, October, 2004.
- 11 A significant amount of literature is now being written about the IR. I particularly recommend Kathryn Garforth & Jorge Cabrera Medaglia, *Sustainable Biodiversity Law: Global Access, Local Benefits*, ICFAI J. INT'L L., Oct. 2005, Vol. IV, No. 4; MIRIAM DROSS & FRANCISCA WOLFF, *BFN-SKRIPTE, NEW ELEMENTS OF THE INTERNATIONAL REGIME ON ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING- THE ROLE OF CERTIFICATES OF ORIGIN* (2005); Miriam Dross & Francisca Wolff, *Do we need a new access and benefit-sharing instrument?*, Y.B. OF INT'L ENV'T L., 2004, Vol. 15; Jorge Cabrera Medaglia, *Las negociaciones sobre el Régimen Internacional de acceso a recursos genéticos y distribución de beneficios: opciones para un país en desarrollo*, PUENTES, May-June 2004, Vol V, No. 3; Tim Hodges & Anne Daniel, *Promises and Pitfalls: a First Step on the Road to the ABS International Regime*, RECIEL, 2005, Vol. 14, No. 2; Tomme Young, *Opciones y Procesos de desarrollo de un Régimen Internacional sobre Acceso y Distribución de Beneficios: Manual de Resumen para las delegaciones de la CBD* (on file with author).
- 12 G.A. Res. 57/260, U.N. Doc. A/RES/57/260 (Dec. 20, 2002). Although the language of the Summit refers only to benefit-sharing, the meeting on the Convention's Program of Work (Montreal, Mar. 2003) recommended that the Working Group on ABS consider, at its second meeting, the process, nature, scope, elements and modalities for an international regime on access to genetic resources and benefit-sharing.
- 13 World Summit on Sustainable Development, Johannesburg, S. Afr., Aug. 26-Sep. 4, *Plan of Implementation of the World Summit on Sustainable Development*, 42, U.N. Doc. A/CONF.199/20.
- 14 Seventh Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Kuala Lumpur, Malay., Feb. 9-20, 2004, *Access and benefit-sharing as related to genetic resources*, D, U.N. Doc. UNEP/CBD/COP/DEC/VII/19 (Feb. 20, 2004).
- 15 Eighth Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Curitiba, Braz., Mar. 20-31, 2006, *Access and benefit-sharing*, U.N. Doc. UNEP/CBD/COP/DEC/VIII/4 (Jun. 15, 2006).
- 16 See Fifth Meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, <http://www.cbd.int/wgabs5/> (last visited May 4, 2010).
- 17 See Sixth Meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, <http://www.cbd.int/wgabs6/> (last visited May 4, 2010).
- 18 Ninth Meeting of the Conference of the Parties to the Convention on Biological Diversity, Bonn, Ger., May 19-30, 2008, *Access and benefit-sharing*, U.N. Doc. UNEP/CDB/COP/DEC/IX/12 (Oct. 9, 2008).
- 19 Eighth Meeting of The Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, Montreal, Canada, Nov. 9-15, 2009, Annex 1, U.N. Doc. UNEP/CBD/WG-ABS/8/8 (Nov. 20, 2009).

- 20 The so-called “Montreal text” was considered unusable due to both its length and the number of bracketed areas of texts, 3400 pairs of them.
- 21 See Earth Negotiations Bulletin, Ninth Meeting of the Ad-Hoc Open-ended Working Group on Access to Genetic Resources and Benefit Sharing of the Convention on Biological Diversity, <http://www.iisd.ca/biodiv/abs9/> (last visited May 4, 2010).
- 22 See Ad Hoc Open-Ended Working Group On Access And Benefit-Sharing, *Report of the Ninth Meeting of the ABS/WG*, Annex I, UN Doc. UNEP/CBD/WG-ABS/9/3 (Apr. 26, 2010), available at <http://www.cbd.int/doc/meetings/abs/abswg-09/official/abswg-09-03-en.pdf> [hereinafter Report of the Ninth Meeting of the ABS/WG].
- 23 See Secretariat of the Convention on Biological Diversity, *Access and Benefit-Sharing: Communication of a Proposed Protocol Pursuant to Article 28, Paragraph 3 of the Convention on Biological Diversity*, SCBD/SEL/LG/71198 (Apr. 15, 2010), available at <http://www.cbd.int/doc/notifications/2010/ntf-2010-071-abs-en.pdf>.
- 24 Article 28 (Adoption of Protocols) provides that any if this instruments shall be adopted at a meeting of the Conference of the Parties and that “The text of any proposed Protocol shall be communicated to the Contracting Parties by the Secretariat at least six months before such meeting.” See Convention on Biological Diversity art. 28, June 5, 1992, 1760 U.N.T.S. 79.
- 25 A note in the Protocol is written with the following statement: “This document, which was not negotiated, reflects the efforts by the Co-Chairs to elaborate the elements of a draft Protocol, and is without prejudice to the rights of the Parties to make further amendments and additions to the text. This document should be read in conjunction with the main body of the report, which reflects the views of the Parties during the ninth meeting of the Working Group on Access and Benefit-sharing, which took place in Cali, Colombia.” See *Report of the Ninth Meeting of the ABS/WG*.
- 26 One of the most contentious issues of the negotiations in Cali, was the relationship between the Protocol and other international instruments. These discussions and disagreements are not reflected in the current text. For many delegations it is important that the ABS Protocol includes a self-standing article on its relationship with other international agreements and processes.
- 27 Part of this section has been taken from, Jorge, *The Relationship op cit*.
- 28 See Third Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Buenos Aires, Argentina, Nov. 4-15, 1996, *Access to Genetic Resources*, 8, U.N. Doc. UNEP/CBD/COP/DEC/III/15; Fifth Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Nairobi, Kenya, May 15-26, 2000, *Access to Genetic Resources*, 1-4, U.N. Doc. UNEP/CBD/COP/DEC/V/26 B (May 26, 2000); Sixth Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, the Hague, Neth., Apr. 7-19, 2002, *Access And Benefit-Sharing As Related To Genetic Resources* 10, U.N. Doc. UNEP/CBD/COP/DEC/VI/24(D); Id. UNEP/CBD/COP/DEC/VI/24/24(C)(1); Eighth Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Curitiba, Braz., Mar. 20-31, 2006, *Access and Benefit-Sharing*, U.N. Doc. UNEP/CBD/COP/DEC/VIII/4(D).
- 29 Kent Nnadozie *et al.*, *Synergetic Implementation: Coordinated National Implementation Of Access And Benefit Sharing Issues - CBD, Biosafety Protocol, ITPGRA and Relevant IPR Instruments* (unpublished manuscript, on the file with the author).

- 30 See Convention on Biological Diversity Conference of Parties, *Access to Genetic Resources*, 8, U.N. Doc. UNEP/CBD/COP/DEC/III/15.
- 31 See e.g., Council for Trade-Related Aspects of Intellectual Property Rights, *Summary Of Issues Raised And Points Made With Regard The Relationship Between The Trips Agreement And The CBD*, IP/C/W/368/rev 1 (Feb. 8, 2006), available at [http://www.wto.org/english/tratop\\_e/TRIPs\\_e/ipcw368\\_e.pdf](http://www.wto.org/english/tratop_e/TRIPs_e/ipcw368_e.pdf).
- 32 See World Trade Organization, Ministerial Declaration of 20 November 2001, 32(i), WT/MIN(01)/DEC/1 [hereinafter Doha Declaration].
- 33 Nnadozie *et al.*
- 34 Ninth Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Bonn, Ger., May 19-30, 2008, *The Role of Intellectual Property Rights and Technology Transfer in the Context of the Convention on Biological Diversity*, U.N. Doc. UNEP/CBD/COP/9/INF/7 (May 3, 2008), available at <https://www.cbd.int/doc/meetings/cop/cop-09/information/cop-09-inf-07-en.pdf>.
- 35 Seventh Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Kuala Lumpur, Malay., Feb. 9-20, 2004, *Transfer of Technology and Technology Cooperation Annex*, U.N. Doc. UNEP/CBD/COP/DEC/VII/29 (Apr. 13, 2004).
- 36 There are several issues that were discussed by the delegations at the TRIPS Council, which are relevant to the CBD, such as the “patentability of life,” removal of references to patenting of microorganisms from article 27, inclusion of the Traditional Knowledge protection on the concept of sui generis systems found in article 27.3(b), the scope and extension of the exemptions of article 27.3 (b), among others. See Eighth Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Curitiba, Braz., Mar. 20-31, 2006, *The Relationship between the TRIPS Agreement and the Convention on Biological Diversity - Summary of Issues Raised and Points Made - Submission by the WTO Secretariat*, U.N. Doc. UNEP/CBD/COP//8/Inf/37.
- 37 For a detailed analysis of the different legal ways in which some countries have included disclosure of origin in patent applications at the national level, see Thomas Henninger, *Disclosure requirements in patent law and related measures. An overview of existing national and regional legislation on IP and biodiversity*, ICTSD, Mar., 2010.
- 38 Communication from Brazil, China, Colombia, Cuba, India, Pakistan, Peru, Thailand and Tanzania, *Doha Work Programme - The Outstanding Implementation Issue on the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity*, WT/GC/W/564 (May, 31 2006), available at [http://www.wto.org/english/tratop\\_e/trips\\_e/art27\\_3b\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm). Norway has also submitted an alternative proposal for disclosure of origin. Communication from Norway, *The Relationship Between the TRIPS Agreement, the Convention on Biological Diversity and the Protection of Traditional Knowledge*, IP/C/W/473 (June 14, 2006).
- 39 The language of the proposal is broader and makes reference to “biological resources.”
- 40 For further details see documents WT/GC/W/564/Rev.2, TN/C/W/41/Rev.2, IP/C/W/474 and WT/GC/W/564/Rev.2/Add.2, TN/C/W/41/Rev.2/Add.2, IP/C/W/474/Add.2.
- 41 See WT/GC/W/591TN/C/W/50 (June, 9 2008) (“Issues related to the extension of the protection of geographical indications provided for in article 23 of the TRIPS Agreement to products other than wines and spirits and those related to the relationship between

the TRIPS Agreement and the Convention on Biological Diversity,” which summarized the different positions on this issue before the Mini-Ministerial.).

- 42 The three current intellectual property issues: the relationship between the TRIPS Agreement and the CBD; the extension of the protection of geographical indications provided for under Article 23 to products other than wines and spirits; and the establishment of a multilateral system of notification and registration of geographical indications for wines and spirits.
- 43 Communication from Albania, Brazil, China, Colombia, Ecuador, the European Communities, Iceland, India, Indonesia, the Kyrgyz Republic, Liechtenstein, the Former Yugoslav Republic of Macedonia, Pakistan, Peru, Sri Lanka, Switzerland, Thailand, Turkey, the ACP Group and the African Group, *Draft Modalities for TRIPS Related Issues*, TN/C/W/52 (July 19, 2008). Draft Modality text as contained in document TN/C/W/52 have been cosponsored by 110 Members that request the inclusion of the TRIPS related issues as part of the horizontal process for the negotiations. The Draft speaks of country providing/source of genetic resources not of origin. This proposal of Draft Modalities attempts to link the amendments to the TRIPs agreement on three issues, creation of a registry for geographical indications, establishment a disclosure of origin obligation and the extension of the geographical indications protection. The proposal suggest the inclusion of these issues as part of the horizontal process in order to elaborate a final draft legal texts with respect to each of the issues as part of the “single undertaking of the Doha Round.” See Carlos Correa, *The TRIPs draft modalities: analysis and implications*, paper prepared for ICTSD, November 2010.
- 44 The minutes of the meetings of the TRIPs Council can be found on the WTO website.
- 45 See generally Jorge Cabrera Medaglia, *Trade (in particular free trade agreements) and access to genetic resources and benefit sharing: exploring some the linkages*, ASIAN BIOTECHNOLOGY AND DEV. R., July 2008, Vol. 10, No. 3.
- 46 Ninth Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Bonn, Ger., May 19-30, 2008, *Access and Benefit Sharing Annex*, U.N. Doc. UNEP/CBD/COP/IX/12.1 (Oct. 9, 2008). The Annex in accordance to Decision IX/12.1 shall be the basis for the negotiations. The Components have been divided in two different categories: “Components to be further elaborated with the aim of incorporating them in the IR” and “Components for Further Consideration.” The distinction was later on abandoned at the Seventh Meeting of the ABS-WG.
- 47 Eighth Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Curitiba, Braz., Mar. 20-31, 2006, *Access and Benefit-Sharing*, U.N. Doc. UNEP/CBD/COP/DEC/VIII/4(D).
- 48 This issue has not been agreed yet, important disagreements about this language remain. See Ninth meeting of the Conference of the Parties to the Convention on Biological Diversity, Bonn, Ger., May 19-30, 2008, *Access and benefit-sharing*, U.N. Doc. UNEP/CDB/COP/DEC/IX/12 (Oct. 9, 2008).
- 49 *Id.*
- 50 It is not the intention of this article to develop the idea of the certificate in depth. For further detail, see the following documents; Miriam Dross & Franziska Wolff, *New Elements of the International Regime on Access and Benefit Sharing of Genetic Resources: the Role of Certificates of Origin*, BFN, 2005; Jose Carlos Fernandez, *The*

- Feasibility, Practicality And Cost Of A Certificate Of Origin System For Genetic Resources: Economic Considerations, in Yokohama Round Table: Toward Fair and Equitable Benefit Sharing: Instruments for the Effective Implementation of the Bonn Guidelines under the Convention On Biological Diversity; Yokohama, Japan, Mar. 11, 2005; Brendan Tobin, David Cunningham, and Kazuo Watanabe, *The Feasibility, Practicality and Cost of a Certificate of Origin System for Genetic Resources*, United Nations University Institute of Advanced Studies Yokohama, Japan, Dec. 2004, available at [http://www.ias.unu.edu/binaries2/abswg-03-inf-05-en\\_revised%202.pdf](http://www.ias.unu.edu/binaries2/abswg-03-inf-05-en_revised%202.pdf).
- 51 An analysis of the causes behind processes to reform the implementation of ABS laws can be found in, Kathryn Garforth And Jorge Cabrera Medaglia, *Legal Reform For The Development And Implementation Of Measures On Access To Genetic Resources And Benefit-Sharing* (T.W. McInerney, ed., International Development Law Organization 2006).
- 52 Eighth Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Curitiba, Braz., Mar. 20-31, 2006, *Access and Benefit-Sharing*, U.N. Doc. UNEP/CBD/COP/DEC/VIII/4(C).
- 53 Fifth Meeting of the Ad Hoc Open Ended Working Group On Access and Benefit-Sharing, *Report of the meeting of the Group of Technical Experts on an international recognized certificate of origin/source/legal provenance* U.N. Doc. UNEP/CBD/WG-ABS/5/7 (Feb. 20, 2007), available at <http://www.cbd.int/doc/meetings/abs/abswg-05/official/abswg-05-07-en.pdf>.
- 54 Brendan Tobin, Geoff Burton, & Jose Carlos Fernandez-Ugalde, *Certificates Of Clarity And Confusion: The Search For A Practical, Feasible And Cost Effective System For Certifying Compliance With Pic And Mat Unu-Ias (2008)* available at [http://www.ias.unu.edu/resource\\_centre/Certificates%20of%20Clarity%20or%20Confusion\\_The%20search%20for%20a%20practical\\_%20feasible%20and%20cost%20effective%20system%20for%20certifying%20compliance%20with%20%20PIC%20and%20MAT.pdf](http://www.ias.unu.edu/resource_centre/Certificates%20of%20Clarity%20or%20Confusion_The%20search%20for%20a%20practical_%20feasible%20and%20cost%20effective%20system%20for%20certifying%20compliance%20with%20%20PIC%20and%20MAT.pdf).
- 55 *Id.*
- 56 On this last aspect, see Sélim Louafi & Jean-Frédéric Morin, *Certificates of Origin for Genetic Resources and International Trade Law* (IDRRI 2004).
- 57 See Sélim Louafi & Jean-Frédéric Morin, *Certificates of Origin for Genetic Resources and International Trade Law* (IDRRI 2004), (suggesting that in order to ensure consistency with WTO rules, any certification system should be designed on a product basis- not on that of a country or an individual company).
- 58 Ninth meeting of the Conference of the Parties to the Convention on Biological Diversity, Bonn, Ger., May 19-30, 2008, *Access and benefit-sharing*, U.N. Doc. UNEP/CDB/COP/DEC/IX/12 (Oct. 9, 2008).
- 59 Ninth Meeting of the Ad Hoc Open Ended Working Group On Access and Benefit-Sharing, *Revised Draft Protocol on access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity* art. 13(1)-(5), U.N. Doc. UNEP/CBD/WG-ABS/9/3 Annex I, available at <https://www.cbd.int/doc/meetings/abs/abswg-09/official/abswg-09-03-en.pdf>.
- 60 Transfer of Technology has also been identified as a benefit sharing option in the Bonn Guidelines.

- 61 Ninth Meeting of the Ad Hoc Open Ended Working Group On Access and Benefit-Sharing, *Revised Draft Protocol on access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity* art. 18, U.N. Doc. UNEP/CBD/WG-ABS/9/3 Annex I, available at <https://www.cbd.int/doc/meetings/abs/abswg-09/official/abswg-09-03-en.pdf>.
- 62 In this regard article 1 of the CBD has been pointed out, “It is noteworthy that this fundamental provision of the Convention already includes an explicit reference to technology transfer as a means to implement its third objective.” See Ninth Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Bonn, Ger., May 19-30, 2008, *The Role of Intellectual Property Rights and Technology Transfer in the Context of the Convention on Biological Diversity*, U.N. Doc. UNEP/CBD/COP/9/INF/7 (May 3, 2008), available at <https://www.cbd.int/doc/meetings/cop/cop-09/information/cop-09-inf-07-en.pdf>. Decision VII/19 makes an explicit reference to the elaboration and negotiation of the IR to effectively implement the provisions in article 15, 8 (J) and three objectives of the CBD. Seventh Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Kuala Lumpur, Malay., Feb. 9-20, 2004, *Access and benefit-sharing as related to genetic resources*, D, U.N. Doc. UNEP/CBD/COP/DEC/VII/19 (Feb. 20, 2004).
- 63 Ninth Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Bonn, Ger., May 19-30, 2008, *The Role of Intellectual Property Rights and Technology Transfer in the Context of the Convention on Biological Diversity*, U.N. Doc. UNEP/CBD/COP/9/INF/7 (May 3, 2008), available at <https://www.cbd.int/doc/meetings/cop/cop-09/information/cop-09-inf-07-en.pdf>.
- 64 Part 2 of article 16 provides that technology subject to patents or other IPRs access and transfer must be provided “on terms which recognize and are consistent with the adequate and effective protection of IPR.” The inclusion of the phrase “adequate and effective” makes a direct link to the TRIPs. See Susan Bragdon et al., *Safeguarding Biodiversity: The Convention on Biological Diversity (CBD)*, in *The Future Control of Food* (Geoff Tansey & Tasmin Rajotteeds., 2008).
- 65 COP Decision VII/19 reaffirms the fact that disclosure of origin in IPR applications is part of the terms of reference of the Annex to Decision VII/19 D for the development of the IR. It recognizes that this issue has been discussed in the WIPO and the WTO, and invites the relevant fora to begin (or continue) discussing the topic of disclosure of origin in IPR applications, bearing in mind the need to ensure that their work is supportive of and does run counter to CBD objectives. Seventh Ordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Kuala Lumpur, Malay., Feb. 9-20, 2004, *Access and benefit-sharing as related to genetic resources*, U.N. Doc. UNEP/CBD/COP/DEC/VII/19 (Feb. 20, 2004). See also Ninth Meeting of the Ad Hoc Open Ended Working Group On Access and Benefit-Sharing, *Revised Draft Protocol on access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity* art. 18, U.N. Doc. UNEP/CBD/WG-ABS/9/3 Annex I, available at <https://www.cbd.int/doc/meetings/abs/abswg-09/official/abswg-09-03-en.pdf>.
- 66 See Nnadozie et al. ; Joshua Sarnoff & Carlos Correa, *Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications - A contribution to UNCTAD’s response to the invitation of the Seventh Conference of the Parties of the Convention on Biological Diversity*, UN Doc. UNCTAD/DITC/TED/2004/14 (2006); IUCN Et Al., *Disclosure Requirements: Ensuring Mutual Supportiveness Between The WTO Trips*

- agreement and the CBD (2005), *available at* [http://www.iprsonline.org/resources/docs/Disclosure\\_req\\_book.pdf](http://www.iprsonline.org/resources/docs/Disclosure_req_book.pdf); Tobin et al., *supra* note 59; Jorge Cabrera Medaglia, IUCN, *The International Regimen For Access And Benefit Sharing* (2006).
- 67 Interpretation of the TRIPS agreement is undertaken under the procedures of the WTO (Article IX.2 of the WTO Agreement). For the intellectual property point of view existing standard on patentability scope and use of patents, such as those set out in articles 27, 29, 32, and 62 of the TRIPS agreement may afford some guidance to how WIPO and WTO Member States may address this concept. See World Intell. Prop. Org. [WIPO], *Technical Study on Patent Disclosure Requirements Related to Genetic Resources and Traditional Knowledge*, WIPO Publication No.786(E) (2003), *available at* [http://www.wipo.int/tk/en/publications/technical\\_study.pdf](http://www.wipo.int/tk/en/publications/technical_study.pdf).
- 68 The current drafting of the disclosure requirements in article 13 of the Draft Protocol, could respond to this approach. The text does not address what could happen in the case of non compliance with the disclosure requirements, e.g. if the patent could be revoked or otherwise limited in its effect if obtained in a breach of a disclosure obligation. The lack of clarity on the legal consequences of the lack of disclosure or insufficient or false disclosure is one of the critics of the current provisions. See *Earth Negotiations Bulletin*, *op cit*.
- 69 Decision IX/12 created an Expert Group on concepts, terms, working definitions and sectoral approaches.
- 70 “Locating such provisions within the CBD regime would not incorporate disclosure requirements directly into the intellectual property law system, and thus would complicate efforts to assure that disclosure obligations are adopted within the intellectual property treaty regimes. Further disclosure requirements mandated within the CBD would not directly apply to the intellectual property systems of countries that are not Parties of the CBD.” See Sarnoff & Correa. This is the case for the United States, which is a signatory but has not yet ratified the CBD.
- 71 See Report of the Technical Expert Group, *op cit*, par. 4 (regarding the objectives of the certificates).
- 72 World Intell. Prop. Org. [WIPO], *Intellectual Property and Traditional Knowledge*, Booklet No. 2, WIPO Publication No. 920(E), (2009).
- 73 See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Art. 7, 8, 66.2, 1869 U.N.T.S. 299 (1994), *available at* [http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm2_e.htm) (declaring objectives: “the protection and enforcement of IPR should contribute to the promotion of technological innovation and to the transfer and dissemination of technology. . . .”); *id.* art. 8 (stating principles: “Members may, in formulating or amending other laws and regulations, adopt measures necessary to. . . promote the public interest in sector of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement”); *id.* art. 66.2 (addressing Least Developed Country Members: “Developed Countries shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least developed country Members. . . .” The TRIPs Council adopted a Decision on February 2003 which lays down an obligation to developed countries to submit reports on actions taken or envisaged to provide such incentives.

- 74 A general description of the International Union for the Protection of New Varieties of Plants was provided in document UNEP/CBD/WG-ABS/3/2, which highlights its relationship to access and benefit-sharing. Third Meeting of the Ad Hoc Open Ended Working Group On Access and Benefit-Sharing, *Analysis of Existing National, Regional, and International Legal Instruments Relating to Access and Benefit Sharing and Experience Gained in their Implementation, Including Identification of Gaps*, U.N. Doc. UNEP/CBD/WG-ABS/3/2 (Nov. 10, 2004).
- 75 *Id.*
- 76 International Union For The Protection Of New Varieties Of Plants, What It Is, What It Does, Upov Publication No. 437 (E)(2003), available at <http://upov.int/export/sites/upov/en/about/pdf/pub437.pdf> [hereinafter UPOV].
- 77 Third Meeting of the Ad Hoc Open Ended Working Group On Access and Benefit-Sharing, *Compilation of submissions provided by parties, governments, indigenous and local communities and relevant stakeholders in preparation for the third meeting of the ad hoc open-ended working group on access and benefit-sharing*, U.N. Doc. UNEP/CBD/WG-ABS/3/INF/1.
- 78 International Union for the Protection of New Varieties of Plants, *Reply of UPOV to the Notification of June 26, 2003, from the Executive Secretary of the Convention on Biological Diversity (CBD)*, [http://www.upov.int/export/sites/upov/en/news/2003/pdf/cbd\\_response\\_oct232003.pdf](http://www.upov.int/export/sites/upov/en/news/2003/pdf/cbd_response_oct232003.pdf) (last visited May 5, 2010).
- 79 Third Meeting of the Ad Hoc Open Ended Working Group On Access and Benefit-Sharing, *Compilation of Submissions Provided by Parties, Governments, International Organizations, Indigenous and Local Communities and Relevant Stakeholders Related to the International Regime on Access and Benefit-Sharing*, U.N. Doc. UNEP/CBD/WG-ABS/4/INF/3 (Dec. 14, 2005), available at <http://www.cbd.int/doc/meetings/abs/abswg-04/information/abswg-04-inf-03-en.pdf>.
- 80 Fifth Meeting of the Ad Hoc Open Ended Working Group On Access and Benefit-Sharing, *Overview of recent developments at the international level relating to access and benefit-sharing, Convention on Biological Diversity*, U.N. Doc. UNEP/CBD/WG-ABS/5/4/Add.1
- 81 Upov, Report On The Impact Of Plant Variety Protection (2005), available at <http://www.upov.int/en/publications/impact.html>.
- 82 Int'l Union for the Protection of New Varieties of Plants, *Access to Genetic Resources and Benefit Sharing*; 6, available at [http://www.upov.int/en/news/2003/pdf/cbd\\_response\\_oct232003.pdf](http://www.upov.int/en/news/2003/pdf/cbd_response_oct232003.pdf).
- 83 Letter from Kamil Idris, Secretary-General, UPOV, to Ahmed Djoghlaif, Executive Secretary, CBD (Apr. 17, 2008), available at [http://www.upov.int/export/sites/upov/en/about/pdf/upov\\_cbd\\_17\\_04\\_2008.pdf](http://www.upov.int/export/sites/upov/en/about/pdf/upov_cbd_17_04_2008.pdf).
- 84 Sarnoff & Correa (“Although UPOV has suggested that disclosure obligations that would deny or invalidate plant rights conflict with the UPOV Convention, UPOV did not directly address the issue of entitlement to apply for such rights, but rather treated such requirements as an additional condition for protection”).
- 85 Sarnoff & Correa (“Applying such disclosure requirements only in the context of patents, however, would not affect other intellectual property applications whose subject matter implicates CBD access and benefit sharing requirements. Of particular relevance such

a limitation would not apply mandatory disclosure obligations to the subject matter of plant breeders' rights”).

- 86 The current text of the Protocol (Article 13) refers broadly to disclosure requirements and check points, including IPR Offices. It may also include PBR offices. However, the formulation of the obligation is unclear in terms of legal sanctions, to what extent is a condition for protection or not, etc.
- 87 The same argument applies to the certificate as an instrument to facilitate the disclosure requirements.
- 88 See *The Role of Intellectual Property... op cit*, paragraph 48, note 14.
- 89 Other aspects related to the topic of disclosure of origin are also being discussed by other WIPO Committees, such as the Standing Committee on Patent Law, in its work on the elaboration of a Substantive Patent Law Treaty, and the Working Group on Reform of the Patent Cooperation Treaty (PCT).
- 90 See further details at [www.wipo.int/tk/en/igc/](http://www.wipo.int/tk/en/igc/).
- 91 A procedure for consultation and information exchange was specially established in order to prepare the document.
- 92 However, note should be taken of the proposal prepared by the European Union and presented to the Committee (16th November 2004) on the subject of disclosure of the origin or source of genetic resources and associated traditional knowledge in patent applications. In synthesis, it proposes the following: a mandatory requirement should be introduced to disclose the country of origin or source in patent applications; the requirement would apply to national, regional and international applications; the applicant shall declare the country of origin or, if it is unknown, the specific source to which the inventor had physical access; the invention shall be based directly on genetic resources; the requirement would apply in the case of traditional knowledge - a concept requiring further study; if the patent applicant does not present the information, despite having been granted the possibility of rectifying the omission, the application will not be processed; if the information is incorrect or incomplete, effective, proportional and dissuasive sanctions shall be taken outside patent law; a notification procedure must be introduced, such as the Clearing-House Mechanism (CHM) of the Convention on Biological Diversity, to be implemented by the Patent Office for the purpose of bringing the respective application to the attention of the country of origin.
- 93 In accordance to IP Watch, the IGC's discussions on GR could be move forward by a joint submission Australia, Canada, New Zealand, Norway and the US that was made last week. The countries presented a proposal that lays out five “objectives and principles” for the GR discussions. Countries are expected to discuss the proposal at the next session of the IGC, which will be held from 6 to 10 December.
- 94 Cfr. WIPO, *Intellectual Property and Traditional Knowledge*, Booklet No 2.
- 95 The Committee has also elaborated a draft document on the fundamental objectives and principles of traditional cultural expressions or folklore, which may become one of the mechanisms for the protection of traditional knowledge in a broad sense. The Committee has already been distinguishing between protection in a strict sense (TK) and a broad sense (traditional cultural expressions).

- 96 World Intell. Prop. Org. [WIPO], *Matters Concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, 1-2, Agenda Item 28, WIPO G.A. 38th Sess. (Sept. 22- Oct. 1, 2009), available at [http://www.wipo.int/edocs/mdocs/tk/en/wipo\\_grtkf\\_ic\\_15/wipo\\_grtkf\\_ic\\_15\\_ref\\_decision\\_28.pdf](http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_15/wipo_grtkf_ic_15_ref_decision_28.pdf).
- 97 Draft set of Revised Objectives and Principles for the Protection of Traditional Knowledge (the Draft Provisions). The Draft Provisions contained 16 policy objectives; 10 General Guiding Principles; and 14 substantive principles (protection against misappropriation; legal form of protection, etc).
- 98 See WIPO, *Information Resources on IP and Genetic Resources, TK and TCE: Information source*, 2006.
- 99 The Draft Provisions include a core principle 7 (g) “Respect for and cooperation with other international and regional instruments and processes”.
- 100 See the African Group proposal document WIPO/GRTKF/IC/13/9 (September 2008), which expressed the opinion that the ultimate objective of the process should be the development and adoption of a legally binding instrument for the protection of TK, Folklore and Genetic Resources.
- 101 See Decision VIII/5 and Decision IX/13 H adopted at COP IX.
- 102 See Sarnoff and Correa *op cit.* consider unnecessary of such modification. It has been also indicated that the PCT does not have a mechanism for a distinct declaration concerning source of GR/TK as a separate element of form or content of an international application, or as an additional national requirement relating to the form or content of an international application. The PCT stipulates that it is “ not intended to be construed as prescribing anything that would limit the freedom of each Contracting Party to prescribe such substantive conditions of patentability as it desires” See WIPO Technical Study on patent disclosure requirements related to genetic resources and traditional knowledge. Study No. 3. For an analysis of the reasons behind this proposal, see Girberger, Martin, Transparency Measures under Patent Law regarding Genetic Resources and Traditional Knowledge. Disclosure of Source and Evidence of Prior Informed Consent and Benefit-Sharing, *Journal of World Intellectual Property*, Vol. 7, No.4, July 2004, Geneva.
- 103 See Nnadozie et al.
- 104 Center for International Sustainable Development Law Biodiversity and Biosafety Law Programme, *The Interface Between Sustainable Forest Management and Access and Benefit Sharing: Outlining Potential Areas of Synergy*, Jorge Cabrera, Oliver Rukundo, & Frederic Perron-Welch, Montreal, Can., 2010.

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