Disclosure Requirements: Ensuring mutual supportiveness between the WTO TRIPS Agreement and the CBD

IUCN The World Conservation Union
CIEL The Center for International Environmental Law
ICTSD INTERNATIONAL CENTRE FOR TRADE AND SUSTAINABLE DEVELOPMENT
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Preface

The misappropriation of genetic resources and traditional knowledge – and the forgone benefits derived from their use – continues to elicit serious misgivings among the biodiversity community and indigenous peoples. High-profile cases – such as the neem tree, basmati rice and maca – fuelled calls for a more effective system to prevent such illegal access and ensure fair and equitable benefit-sharing. The Convention on Biological Diversity (CBD) marked an attempt by the international community to address this issue at the multilateral level. To this end, it aims to strike a balance between interests of those countries that are seeking facilitated access to genetic resources (commonly referred to as the "user" countries) and those holding the genetic resources and associated traditional knowledge (the "provider" countries). Negotiations are also underway to design an international regime specifically dedicated to governing access and benefit-sharing under the auspices of the CBD.

However, the CBD and other international legal systems to regulate access and benefitsharing, including the International Treaty on Plant Genetic Resources for Food and Agriculture, are weak in scope and enforceability vis-à-vis the global intellectual property systems. The WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), the International Convention for the Protection of New Varieties of Plants (UPOV) and the treaties and processes under the World Intellectual Property Organization (WIPO) – all components of this global Intellectual Property (IP) regime – have thus far neglected to properly reflect communities' and national ownership of traditional knowledge and genetic resources.
It is imperative to redress this imbalance by ensuring that biodiversity conservation and sustainable use objectives are upheld in global IP governance. Requiring patent applicants to disclose the source of the genetic resource and traditional knowledge used in their inventions

– as well as evidence of prior informed consent and benefit-sharing – has been raised as a possible mechanism for using the intellectual property system to ensure legal access and benefit-sharing. Multilateral obligations to implement such requirements – proposed to be incorporated, for instance, in the TRIPS Agreements – are expected to ensure a level playing field among those using and providing the resources. Critics, however, point out that the intellectual property regime is not suitable for this task, not least because genetic resourcebased inventions might never be patented, and that alternative avenues should be explored.

This collection of essays, written by leading experts in this field, aims to shed some light onto the utility of disclosure requirements as a means for integrating biodiversity concerns into intellectual property systems. We hope that the thinking provided here will stimulate debate and help strengthen international governance on access and benefit-sharing in accordance with the CBD objectives.

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Introduction

There is an urgent need for concrete steps to foster the mutual supportiveness of the objectives embodied in the Convention on Biological Diversity (CBD) and multilateral trade rules under the World Trade Organization (WTO). Intellectual property has crystallised as an area of debate where such efforts could be undertaken. Specifically, attention has focused on the question of including requirements to disclose the origin / legal provenance of genetic resources and traditional knowledge – along with evidence of prior informed consent and benefit-sharing – in intellectual property rights applications, particularly in patent applications. Some see this as a suitable option to establish positive synergies between the CBD, intellectual property and trade regimes to ensure that trade contributes to sustainable development.

Initial conceptual debates on this issue began in the early 1990s with the development of the Andean regime on access to genetic resources *(Andean Community Decision 391 on a Common Regime on Access to Genetic Resources,* adopted in July, 1996). First viewed with considerable scepticism, the idea of disclosure gradually began to attract more attention, generating interest among experts and policy makers. Representatives of indigenous peoples organisations have expressed support for the concept, particularly where traditional knowledge is concerned, highlighting its potential for preventing the misappropriation of the knowledge and practices used by their communities to conserve and sustainably use biodiversity and its components.

Ten years later, the issue of disclosure of origin has found its way into national, regional and international discussions and negotiations related to a variety of instruments and fora. Research papers, seminars, workshops, side events at meetings of the Conference of the Parties (COP) to the CBD, and books have been produced analysing the legal, policy, economic, cultural and social implications of the disclosure of origin requirements.

A number of countries – including both providers and users of genetic resources – have already moved to apply these ideas in practice by incorporating disclosure of origin requirements (in different forms and conditions) in their domestic legislation, including in the Andean Community (Bolivia, Colombia, Ecuador, Peru and Venezuela), Brazil, Costa Rica, Denmark, India, Nepal, Norway and the African Union (53 African countries). Many others are also considering similar measures. In some cases, disclosure has been incorporated as part of laws governing biodiversity or access to genetic resources; in others, requirements are part of intellectual property legislation.

At the international level, policy declarations supporting disclosure requirements abound,, including from the Group of Like Minded Megadiverse Countries[1] (see for example, Cancun Declaration 2002, Cusco Declaration 2002). The Group has repeatedly pointed to the link between biodiversity conservation and intellectual property protection during discussions under the CBD, including the ongoing negotiations on an international access and benefit-sharing regime mandated by the World Summit on Sustainable Development Plan of Implementation.[2]

Related discussions are also taking place in the WTO Council on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under paragraph 19 of the Doha mandate, which calls on WTO Members to consider the relationship between the TRIPS Agreement and the CBD, the protection of traditional knowledge and folklore in their review of Article 27.3(b) of the TRIPS Agreement (patentability of life forms) and other issues raised by Article 71.1.[3] This mandate is further strengthened and broadened by Paragraphs 12 and 31 of the Doha Declaration, respectively, which call for mutual support between the trade and environment regimes, and Paragraph 51 intended to ensure an outcome of negotiations supportive of the objective of sustainable development.

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[1] The Group brings together seventeen countries rich in biological diversity and associated traditional knowledge – including Bolivia, Brazil, China, Colombia, Costa Rica, Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, South Africa and Venezuela – which have formed a negotiating bloc in the CBD negotiations.

[2] Paragraph 42(o) calls for negotiations of «an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilisation of genetic resources» within the framework of the CBD.

[3] "We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension." WT/MIN(01)/DEC/1, 20 November 2001, Ministerial Declaration, adopted on 14 November 2001, Paragraph 19.

At the initiative of a number of developing countries led by Brazil and India[4], discussions on the TRIPS-CBD relationship in the WTO have focused on the question of whether and how patent applicants should be obliged to disclose the origin or source of genetic resources and traditional knowledge used in inventions and provide evidence of prior informed consent and benefit-sharing. These countries are promoting amendments to the TRIPS Agreement to ensure that the necessary requirements are incorporated into patent application procedures.

Some countries, notably Switzerland and some developing countries, have also raised the issue in the World Intellectual Property Organization (WIPO), including during discussions on Patent Law Treaty, Patent Cooperation Treaty and Substantive Patent Law Treaty, although most developing countries clearly favour a multilateral solution in the WTO. WIPO members have also set up the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore in 2001 to discuss this issue. At the regional level, disclosure of origin is the subject of negotiations on trade and economic integration, most recently in the context of the US-Andean Countries Free Trade Agreement.

Clearly, disclosure of origin discussions and the processes they have generated at different levels are an example of how an issue can trigger international and national public policy development and legislative action. However, the recent developments, proposals and reforms to incorporate disclosure requirements in patent filing processes continue to be controversial. Various countries and industry groups are sceptical about such a move as the best solution. These sceptics have suggested that solutions such as access contracts are more appropriate to deal with access and benefit-sharing issues and that intellectual property has no link with conservation and sustainable use concerns. Moreover, in light of the myriad of parallel developments, efforts must be made to ensure coherence at the national and regional level as well as with related globalising regimes such as the WTO (especially TRIPS), the CBD, WIPO treaties and process, and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, all of which address certain aspects of traditional knowledge, benefit sharing and intellectual property rights.

Stimulating debate, identifying options

In an effort to help assess the potential of disclosure requirements to support conservation and sustainable development objectives, this publication includes a compilation of short essays and articles addressing disclosure from different perspectives. The papers were presented by and discussed among some of the leading experts on intellectual property during the ICTSD/CIEL/IDDRI/IUCN/QUNO *Dialogue on Disclosure Requirements: Incorporating the CBD Principles in the TRIPS Agreement on the Road to Hong Kong.* In light of ongoing negotiations on these issues at the WTO, this publication aims to provide useful insights with a particular focus on the mandate of the WTO TRIPS Council and its interaction with other global biodiversity and intellectual property regimes and fora. In addition, the papers evaluate mechanisms and give practical examples on how to implement disclosure requirements at the national level in a manner that is supportive of the TRIPS Agreement and the CBD.

The publication brings together a wide variety of leading thinkers in this field, including Felix Addor (from the Swiss Federal Institute of Intellectual Property); Graham Dutfield (from the Queen Mary Intellectual Property Institute in London); Michael Gollin (from Venable LLP in Washington DC and founder of Public Interest Intellectual Property Advisors (PIIPA)); Begoña Venero (from the National Institute for Intellectual Property and Competition in Peru); Selim Louafi (from the Institut du Développement Durable et des Relations Internationales in France) and Brendan Tobin (from the Institute for Advanced Studies of the United Nations University in Japan); Anne Perrault and Maria Julia Oliva (from the Center for International Environmental Law in Washington DC); David Vivas (from the International Centre for Trade and Sustainable Development in Switzerland); and Manuel Ruiz Muller (from the Sociedad Peruana de Derecho Ambiental in Peru). The workshop also benefited from a presentation and contributions by N.S. Gopalakrishnan (from the Centre for IPR Studies, of the University of Science and Technology, India).

The papers provide technical input and proposals which should serve to build an analytical foundation to promote and stimulate legislative, regulatory and policy processes on disclosure at the national and international levels. Although with different emphases, legal approaches and expectations, the authors recognise that disclosure requirements could contribute to the process of finding mechanisms and tools for achieving the CBD objectives, and constitute the most visible linkage yet proposed between the CBD and the international intellectual property regime. Thus, while disclosure requirements should not be re-

[4] I.e. Bolivia, Brazil, Colombia, Cuba, Dominican Republic, Ecuador, India, Peru and Thailand, see for example: Document IP/C/W/447 (June 2005), Submission to TRIPS Council by Peru regarding the relationship between TRIPS and the CDB; Document IP/C/W/429 (2004), Submission to TRIPS Council by Brazil, India, Pakistan, Peru, Thailand, and Venezuela supported by Cuba and Ecuador.

garded as *the* solution to the problem of misappropriation (or "biopiracy" as it is more commonly known) of genetic resources and traditional knowledge, they should be seen as part of a package of measures and actions which need to be taken.

User measures to resolve potential conflicts between the WTO and the CBD

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I. Overview

The development and implementation of regulations to govern access to genetic resources and benefit sharing (ABS) in various countries has been well documented. Much less attention has been given to the possibility of using a wider range of policy instruments which aim to ensure that commercial and scientific users carry out their activities in a manner which supports the realisation of the objectives of the Convention on Biological Diversity (CBD), assist in compliance with ABS agreements and facilitate access to technologies developed through the use of genetic resources.

"User measures" could constitute such instruments. When compared with existing legislative solutions, "user measures" are a much better match for the diversity of actors, values and interests involved in the field of genetic resources. The legal development and incorporation of user measures could promote the emergence of a more cooperative vision of the interface between biotechnology and biodiversity, thus recasting the relationship between TRIPS and the CBD as one of interdependence rather than fundamental conflict. This essay will give some insights on innovative policy and institutional tools that could promote greater cooperation between the CBD and TRIPs.

II. CBD and benefit sharing – 10 years on

Ten years after the CBD was signed, the objective of fair and equitable sharing of the benefits arising from the utilisation of genetic resources—one of the three objectives of this convention—is far from being achieved and continues to stir up heated discussions. The current international system is based on an arrangement of bilateral transactions with the CBD providing that benefit sharing shall be upon "mutually agreed terms" between the provider and the user of genetic resources (CBD, Article 15.7). In other words, private contracts set the specific conditions governing access to genetic resources and the advantages granted to the provider. To date about 50 countries have adopted legislative, administrative and/or policy measures to help establish the parameters under which such private transactions may take place. These measures are based on the CBD and in some cases have been inspired by the Bonn Guidelines on ABS adopted in 2002. However, only about 25 countries have established specific ABS regulations to govern negotiation of contracts and establish conditions for access and benefit sharing.

This lack of legislative control reflects a number of differing challenges faced in the development of ABS law and policy. Developing countries have complained of the high costs of developing and implementing regulations while the spin-offs are still low, whether in financial or technology-transfer terms. Agreement on where responsibility lies for securing effective governance of ABS is hard to obtain due to the varying perspectives of stakeholders, including provider and user countries, local and indigenous communities, commercial and scientific users, and civil society organisations. Uncertainty regarding the value of genetic resources is a further factor leading to reluctance to take on the costs of developing national or international measures.

III. Failure of the status quo

It is now clear that the *status quo* is no longer tenable. Both in terms of economic efficiency (investment in genetic resources) and social legitimacy (legal certainty of genetic resources transactions) current mechanisms regulating bioprospection activities have proven to be insufficient. Although provider countries, local and indigenous communities and the large corporations, who would like to make use of their genetic resources and associated traditional knowledge, are theoretically natural allies, the current ABS mechanism has failed to bring them together in an effective form.

Many scholars have analysed the reasons for this "market" failure: evolutionary nature of genetic resources, collective character of the innovation process, high degree of uncertainty surrounding the value of genetic resources, high transaction costs, lack of trust, divergence of cultural values, etc. These issues make it clear that when addressing the difficulties posed by intellectual property rights to the issue of ABS, simple legal solutions cannot be made. When consideration is given to the need to promote other social values (self-determination, distribution of wealth, equity or cultural identity) in the development of ABS law and policy, the existing legal resources for the protection of property rights and promotion of innovation (essentially intellectual property rights or even human rights) are clearly insufficient.

IV. User measures

However, it is possible to envisage a more cooperative interface between biotechnology and biodiversity, one that redefines the relationship between TRIPS and the CBD as one of interdependence rather than conflict. This could be achieved through the use of a broad set of mechanisms aimed at the users of genetic resources. Such user measures may include: self-regulation by users, involving the development and enforcement of codes of conduct; the development of monitoring mechanisms such as certificates of origin and controls such as disclosure requirements for patent and product approval processes; the development of institutional capacity to monitor resource transfers and enforce compliance with ABS agreements; and improved access to dispute resolution mechanisms. Putting in place effective user measures will require more than mere legislative changes.

The development and implementation of an efficient system of ABS governance requires looking beyond the law, to the network of actors and institutions on which its implementation will depend. The different expectations of the plethora of actors concerned by the use of genetic resources (companies, local communities, botanical gardens, researchers, and private brokers) have major implications for the design of any regulatory framework. From this perspective user measures represent an innovation insofar as emphasis is on the users who intervene in the exchange of genetic resources. The diversity of different actors and interests is matched by the variety and flexibility of different user measures, which can help to fill the legislative gap between the stage of acquisition of a right (access contract) and the exercise of a right (i.e. development, marketing, and/or patenting of a product). This provides incentives for adding value throughout the whole production process and not only at the final stage of the innovation process as is currently the case with intellectual property rights regimes. User measures could also help to reduce the legislative, economic and administrative burden of developing and maintaining ABS regulations and monitoring and enforcement systems from developing countries, in particular less developed countries (LDC's) and small island developing states (SIDS).

V. Certificates of origin

Certificates of origin provide a good illustration of how user measures could achieve this. The rationale for a certificate of origin is to build bridges between national and international jurisdictions as well as between providers and users of resources. As an instrument to facilitate traceability, certificates of origin can help monitor trade and movement of resources and discourage their unapproved and illegal use. Certificates could provide evidence of rights to transfer resources, thereby helping to reduce the complexities involved with cumbersome systems involving the multiple permits and licenses associated with access, collection and export and import of resources.

By increasing legal certainty regarding the rights to use resources and thereby enhancing their value, a certificate scheme could create incentives for the provision and protection of genetic resources, create a known link to benefit sharing provisions, and support conservation. It has also been suggested that a certificate of origin can convert simple commodities into differentiated products by providing information to users. A certificate system could also help to simplify the processing of intellectual property rights applications in regimes with disclosure of origin requirements.

Given that the majority of genetic and biological resource use is not for commercial industrial purposes, it has been proposed that a certificate could accompany genetic resources like a passport through their entire history from collection to use. However, the obligation to produce a certificate would arise only at specific trigger points such as in the event of transboundary movements, when required by patent and product approval authorities, as well as by the international depository system within WIPO's Budapest Treaty.

Certificates of origin present the advantage of reflecting the diversity of use and the changing nature of genetic resources along the processing chain (change of purpose, from research to commercial, over a

period of time; mutant nature of genetic resources from biological material to information contained in genes). However, in order to determine the viability of any system it will be important to consider, where possible, the use of existing infrastructure, human resources and existing checkpoints. Indeed, certificates of origin might perhaps be integrated into the existing system of requirements for disclosure of information in the patent system.

VI. Conclusion

In recent years, given the dramatic evolution in the biological sciences characterised by changing institutional relationships (particularly involving the public sector), new corporate structures, and evolving laws and policies, political tensions over the ownership and exchange of genetic resources have intensified. User measures might help to overcome these tensions by proposing a new way of governing the exchange and use of genetic resources, and facilitating convergence between CBD objectives and innovation strategy. A certificate of origin system is just one of a number of potential measures which could be considered, but it is one which cannot be easily overlooked.

Prior informed consent and access to genetic resources

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I. Overview

Paragraph 19 of the Doha Ministerial Declaration calls on the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS), in its review of Article 27.3(b) and Article 71.1 of the TRIPS Agreement, to consider the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD). Recent work within the TRIPS Council has focused particularly on whether and how disclosure requirements could contribute to building a more coherent and supportive relationship between the two instruments. Submissions by several developing countries involved in the discussions include proposals for amending the TRIPS Agreement in order to require parties applying for patents to disclose the source and country of origin of any genetic resources and associated traditional knowledge used in an invention; as well as to provide evidence of prior informed consent (PIC) and details of arrangements for fair and equitable benefit sharing according to national legislation.[5]

The issue of the disclosure of the origin and source of genetic resources and traditional knowledge used in inventions and the question of PIC are closely related. Article 15 of the CBD, in recognition of the sovereign rights of states over their genetic resources, requires that access to genetic resources be subject to PIC. As a result, PIC must feature prominently in any outcome emerging from negotiations on Paragraph 19. The close relationship between disclosure of origin and PIC therefore will require the intellectual property system to consider the implementation of PIC as a fundamental part of the negotiations relating to Paragraph 19.

The objective of this essay is to contribute to these and other ongoing negotiations. Section I of this chapter will start by analysing briefly the PIC principle and some of the issues surrounding its implementation. Section II will address the evolution of the concept of PIC. Section III will then identify the scope and characteristics of PIC in the context of genetic resources—both in terms of rights of states and rights of indigenous peoples and other local communities. Section IV will examine the relationship between intellectual property and the recognition and implementation of PIC. Finally, Section V will offer some concluding thoughts on ways to support the implementation of PIC at the Sixth World Trade Organization (WTO) Ministerial Conference in Hong Kong.

II. Background: evolution of the concept of PIC

PIC has become an essential principle in international relations as a necessary corollary to the permanent sovereignty of states over their natural resources.[6] It has also become increasingly important in the debate on sustainable development as global interdependencies, both economic and environmental, increase. This recognition was first acknowledged in 1989 by the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, and since that time, multilateral environmental agreements have consistently acknowledged the importance of PIC as a tool to control the movement of potentially harmful materials. The right of states to some form of prior informed consent is thus recognised in a variety of contexts, including the transboundary movement of hazardous and toxic materials, genetically engineered organisms, and persistent organic pollutants.[7]

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[5] In this chapter, the three principal elements of the proposal by Brazil, India, and other developing countries are jointly referred to as "disclosure requirements".

[6] Article 3 of the CBD recognises that "States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies…".

[7] See, e.g. Rotterdam Convention on Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in: International Trade, Sept. 10, 1998, U.N. Doc. UNEP/CHEMICALS/98/17, available at http://www.pic.int/en/ViewPage.asp?id=104; Stockholm Convention on Persistent Organic Pollutants, May 23, 2001, 40 I.L.M. 532, available at http://www.pops.int/; Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, Mar. 22, 1989, 28 I.L.M. 657, available at http://www.basel.int/; Cartagena Protocol on Biosafety, Jan. 29, 2000, 39 I.L.M. 1027, available at http://www.biodiv.org/biosafety/background.asp.

The application of the PIC principle to the rights of indigenous peoples and other local communities is also finding increasing favour. Official interpretations of several international instruments, including the Convention on the Elimination of Racial Discrimination (CERD), the American Convention on Human Rights, and the International Covenant on Civil and Political Rights (ICCPR), among others, seem to indicate that PIC of indigenous peoples is central to respect for their basic human rights as expressed within these conventions, including the right to non-discrimination, the right to property, and the right to culture.[8] PIC is indeed viewed by indigenous and other local communities as a means of securing their rights in relation to access to genetic resources, and logging, mining, resettlement, and dam building activities. As a result, over the last few decades, PIC has also been promoted through voluntary guidelines, social and environmental codes, contractual agreements and political referendums.[9]

III. PIC in the context of access to genetic resources

PIC is particularly significant in the context of access to genetic resources because of concerns about companies, research institutions, other entities, and individuals acquiring and using genetic resources and traditional knowledge from biodiversity-rich countries without the knowledge and permission of the rightful owners. Several instances of misappropriation, including cases where patents have been obtained in "user" countries, have been documented.[10] Where access to genetic resources is concerned, PIC does not focus on preventing adverse impacts of the movement of materials into a country, as it does with hazardous wastes or genetically engineered organisms. Rather, the emphasis is on preventing the exploitation and movement out of a country of potentially beneficial materials, as well as on ensuring that the benefits derived from the use of these materials accrue to the holders (providers) of these materials.

(a) Rights of states to PIC

Article 15 of the CBD recognises the right of national governments to PIC as a pre-requisite to ensuring environmentally sound access to genetic resources. Moreover, the lack of PIC actually impedes the fulfilment the objectives of the CBD, as set out in its Article 1, including, for example, the "fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including by appropriate access to genetic resources". Although PIC in the context of access to genetic resources presents certain particularities, activities for implementing PIC requirements in other fields can be used to inform its development in relation to genetic resources. Information about the implementation of PIC, including what it means, when information should be provided, how responsibilities for developing and providing information are allocated, and how concerns about due process are addressed may be extremely valuable for addressing these issues in the CBD. The Sixth Conference of the Parties of the CBD developed the Bonn Guidelines, which provide direction on procedures for obtaining PIC. For instance, the Bonn Guidelines provide mechanisms for involving stakeholders; they suggest reasonable timeframes and deadlines; they specify types of use, and links under mutually agreed terms; and provide detailed procedures for obtaining consent as well as a description of general procedures that should be followed to obtain access.[11]

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[8] See, The International Convention on the Elimination of All Forms of Racial Discrimination, Dec. 21, 1965, 660 U.N.T.S. 195, available at http://www.ohchr.org/english/law/cerd.htm [hereinafter CERD]; American Convention on Human Rights, Nov. 22, 1969, 1144 U.N.T.S. 123, available at http://www.oas.org/juridico/english/Treaties/b-32.htm; The International Covenant on Civil and Political Rights . For example, within the last several years, the Committee interpreting CERD issued Recommendation XXIII, which calls for all parties to the Convention to obtain informed consent of indigenous peoples in all decisions that may concern their rights or interests. In March 2003, the Committee censured Ecuador for "falling short" of meeting PIC requirements for indigenous communities, finding that in the context of resource exploitation on traditional lands, mere consultation was insufficient. Botswana was censured the previous year for failing to ensure that prior informed consent was secured prior to resettlement of indigenous communities. Additionally, in several recent cases in the Inter-American System of Human Rights, including Mayagna (Sumo) Awas Tingni Community v. Nicaragua, Maya Indigenous Communities v. Belize, and the Moiwana Village v. Suriname, it was determined that the rights of indigenous peoples and tribal communities were violated by a failure to ensure that prior informed consent was obtained prior to activities that deprived the peoples and communities of their land and other natural resources. Finally, the Human Rights Committee, interpreting the ICCPR, found that enjoyment of the right to culture "may require positive legal measures of protection and measures to ensure the effective participation of members of minority communities in decisions which affect them...".

[9] For example, in 2000, the World Commission on Dams issued a set of voluntary PIC guidelines recognising the need for "all people whose rights are involved and who bear the risks" to have a role in negotiations. In 2004, the Extractive Industries Review, commissioned by the World Bank, recommended implementation of the rights of local communities to PIC as a precondition to World Bank funding of extractive industry projects.

[10] In March 2005, for instance, the European Patent Office upheld a decision to revoke in its entirety a patent on a fungicidal product derived from seeds of the neem, a tree indigenous to the Indian subcontinent. The challenge to the patent, which began over ten years ago, was based on the fact the fungicidal properties of the neem tree have been public knowledge in India for many centuries. In addition, challengers (Indian environmentalist Vandana Shiva, Magda Aelvoet, former MEP and President of the Greens in the European Parliament, and the International Federation of Organic Agriculture Movements (IFOAM)) claimed the case exemplified how international law was being misused to transfer biological wealth from the South into the hands of a few corporations, scientists, and countries of the North.

(b) Rights of indigenous people and other local communities to PIC under the CBD

The CBD does not refer expressly to PIC of indigenous and other local communities. However, PIC is a necessary corollary of the rights of indigenous and other local communities to enable them to participate in the management of the resources found on the lands they occupy, and of all associated traditional knowledge. Article 8 of the CBD requires that "each contracting party shall respect, preserve and maintain knowledge, innovation and practices of indigenous and local communities and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from their utilisation". This provision supports the rights of communities to PIC. Recent discussions at the CBD have, therefore, focused on the rights of indigenous peoples and other local communities to PIC.

Though PIC procedures necessarily have culturally specific variations, a number of common features or "best practices" can be identified and many communities have indeed already articulated PIC procedures.[12] Some of these include: (a) the person seeking access must obtain consent from every affected community in the traditionally recognised manner; (b) before seeking consent, the person seeking access should organise discussions within the community and share and impart all information of relevance to the community in a culturally appropriate manner; (c) consent should be part of an ongoing process in which the community may choose to give or not to give consent; and (d) community leaders may revoke consent for legitimate reasons.

(c) The FAO International Treaty on Plant Genetic Resources

The International Treaty on Plant Genetic Resources (ITPGR) was adopted on 3 November 2001 and entered into force on 29 June 2004. The treaty, negotiated under the auspices of the FAO, was designed to respond to concerns about the increasing privatisation and monopolisation of plant genetic resources for food and agriculture and the potentially negative impacts that this trend may have on agricultural biodiversity. The ITPGR, which dovetails with the Convention on Biological Diversity, recognises that food and agriculture have particular requirements when it comes to plant genetic resources and makes special provisions for this. In particular, it establishes a multilateral system of facilitated access and benefit sharing for selected plant genetic resources. Because the plant breeding process requires a broad range of plant genetic resources in order to produce any one product, this creates difficulties for applying the notion of country of origin and the bilateral system of access established in the CBD. The Contracting Parties to the ITPGR, therefore, in the exercise of their sovereign rights over their plant genetic resources, provide their PIC through a multilateral system that establishes the terms and conditions that will determine access and benefit sharing. With regard to PIC of local and indigenous communities, Article 9 of the ITPGR, which focuses on farmers' rights, establishes the need for Parties to protect traditional knowledge and the right of farmers to an equitable share of the benefits arising from the use of plant genetic resources for food and agriculture.

IV. Intellectual property and the recognition and implementation of PIC

Despite growing recognition and development of the PIC principle, its implementation in the context of genetic resources still presents several difficulties. Implementation by bioprospectors often is impeded, for example, by the absence of adequate laws, regulations and procedures that provide a clear understanding of from whom and how consent should be obtained. Unrealistic expectations and a desire for PIC processes to be governed by "Western" approaches may also impede efforts of bioprospectors. Governments may be hindered in their efforts by uncertainties about how best to structure mechanisms and procedures to facilitate access given the complexities of the intellectual property system. Moreover, they may be hesitant to address issues about which vocal segments of the population have differing views. Some indigenous peoples and other local communities simply do not want to facilitate access, while others are concerned that their rights and values will not be respected during PIC processes. Additionally, questions remain about what mechanisms are available for enforcement of PIC requirements and their effectiveness. The Bonn Guidelines, for instance, provide little guidance on how enforcement mechanisms and measures might be structured, and, by virtue of being voluntary, do not provide any mechanism by which PIC requirements could be enforced.

[11] Several parties are currently working to develop national legislation in response to these guidelines. The Seventh Conference of the Parties of the CBD recognised "that the Guidelines are making a useful contribution to the development of national regimes and contractual arrangements for access and benefit-sharing and to the implementation of the objectives of the Convention". Parties, governments, indigenous and local communities and all relevant stakeholders were invited to continue to promote the wide implementation of the Bonn Guidelines. They were also encouraged to submit further information on relevant experience and lessons learned, including successes and constraints, in the implementation of the Guidelines. The information is available, for instance, through the Clearing House Mechanism of the CBD.

[12] Laird, Sarah, ed., (2001), Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice, ed. Sarah A. Laird, and World Commission on Dams Guidelines.

Many parties to the CBD, as well as some local communities, believe that a fundamental enforcement mechanism should be built into the intellectual property system. In this regard, coherence with the objectives of the CBD and, in particular, its requirements for PIC, is perceived as compelling international intellectual property norms to require evidence of PIC in the rights acquisition process. Mechanisms to implement PIC in patent filing and patent granting procedures, for instance, have been developed at national and regional levels. These mechanisms include voluntary and mandatory PIC requirements, and incorporate various approaches to enforcement. The view of several of these and other countries, however, is that action at the international level is necessary to secure compliance with PIC requirements, particularly in user countries. Proposals have been tabled which describe how this might be accomplished, either through a new international instrument developed through, and perhaps as a protocol to, the CBD, or by amending the TRIPS Agreement.

V. Conclusions

As the TRIPS Council hastens its work on ensuring mutual supportiveness between the TRIPS Agreement and the CBD, it is vital that the question of PIC not be overlooked. PIC is an essential principle in international relations and, in the context of genetic resources, is fundamental to the fulfilment of the objectives of the CBD. Moreover, even though PIC is currently required in patent applications at national and regional levels, it is only through a mandatory international requirement that effective recognition and implementation can be achieved.

The recognition of PIC is also essential for the legitimacy of the intellectual property system. In intellectual property law, equitable principles require that applications for intellectual property rights, or their enforcement, be refused if these rights have been procured by fraud or deception. The contrary would allow the intellectual property system to assist and reward inequitable conduct. In this regard, the requirement to disclose evidence of PIC in patent applications is critical to advancing a more equitable and balanced international intellectual property system.

Feasibility of national requirements for disclosure of origin

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I. Overview

Is it feasible for countries to adopt national disclosure of origin (DOO) requirements, compelling applicants for patents to (1) disclose the source of genetic resources used in an invention; (2) disclose the source of traditional knowledge used in the invention; and/or (3) to provide evidence that the provider gave prior informed consent and received a share of benefits? DOO requirements could be direct (mandatory and enforceable through a loss of patent rights), indirect (mandatory but enforceable only through means other than the patent system), or voluntary/permissive. The feasibility of DOO requirements may be assessed in terms of compatibility with existing international treaties, compatibility with national legislation, political viability domestically and internationally, consistency with rules and customs of patent practice, and ease of implementation. Measured this way, direct DOO requirements that encompass (1), (2), or (3) above may prove more problematic than indirect or voluntary approaches. All approaches may impose implementation costs and concerns.

II. Disclosure in the Convention on Biological Diversity (CBD)

DOO requirements can be traced to two provisions in the Convention on Biological Diversity: Article 15 established the basis for access and benefit sharing (ABS) agreements.[13] Article 8(j) required Parties to protect traditional knowledge.[14] The informed consent and benefit sharing provisions have led to much discourse at the international level, and many countries have promulgated laws or regulations that specify requirements that must be fulfilled by people seeking access to genetic resources before they will be permitted to do so. The Bonn Guidelines provided voluntary guidelines for improving ABS agreements, and recommended that Parties encourage disclosure of origin as a mechanism to track compliance with ABS requirements.[15] Such mechanisms are currently being considered by committees of the World Trade Organization (WTO)[16] and the World Intellectual Property Organization (WIPO).[17]

III. Implementing disclosure requirements at the national level

As a general matter, to implement DOO requirements, a country would need to pass national legislation amending patent laws, and promulgate regulations to be followed by the national patent office. Further, countries would have to avoid entering into multilateral or bilateral agreements that preclude DOO requirements. To satisfy principles of jurisprudence, DOO laws would need to be clear, comprehensible, and fair. Such laws would have to specify many details, including: the circumstances leading to a requirement for disclosure; the timing, content, format and level of detail required from the applicant; and the consequences of a failure to disclose. An optional system might include incentives such as a discount in official fees.

DOO requirements directly tied to patent rights, for example, could add as a requirement for patentability that for every patent application based on genetic resources or traditional knowledge obtained anywhere in the world, the applicant must identify where the material was obtained, the person or organisation providing it, and any traditional or indigenous knowledge that was employed; and the applicant must have

[13] «Access to genetic resources shall be subject to the prior informed consent of the Contracting Party providing such resources….» Article 15.5. Access «shall be on mutually agreed terms.» Article 15.4.

[14] Parties shall «respect, preserve and maintain» traditional knowledge of traditional and indigenous communities, and «encourage the equitable sharing of benefits arising from the utilisation of such knowledge, innovations, and practices".

[15] See CBD COP 6, Decision VI-24, at p. 268, Access and Benefit Sharing as Related to Genetic Resources, A. Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising Out of their Utilisation (Bonn Guidelines), available at http://www.biodiv.org/doc/decisions/COP-06-dec-en.pdf

[16] These include the Committee on Trade and Environment and the TRIPS Council.

[17] The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

entered into an ABS agreement with the appropriate rights-holder, and must provide a copy of the agreement. Failure to satisfy any of these requirements would result in the rejection of a patent application, or the invalidity of a patent that was erroneously issued.

Factors that would limit the stringency of a DOO law include: (a) permitting retroactive cure for any provision that was not satisfied initially; (b) accepting the applicant's certification that all applicable ABS requirements were satisfied (instead of requiring copies of ABS agreements); and (c) requiring disclosure only for genetic resources and traditional knowledge obtained from within the country that has a DOO law. On the last point, for example, an applicant (Peruvian or not) seeking a Peruvian patent might only need to provide disclosure of origin information for genetic resources or traditional knowledge whose source was within Peru. Alternatively, a regional framework such as the Andean Community could provide that an applicant seeking a patent from any country in the Community would need to disclose information about the resources or knowledge obtained from any of them.

IV. Arguments against DOO requirements

Four main arguments have been made against DOO requirements: (1) inconsistency with international treaties as a matter of law; (2) inconsistency with domestic laws; (3) opposition by particular countries; and (4) impracticality and other negative domestic public policy consequences. The first argument was addressed in a paper prepared for Public Interest Intellectual Property Advisors (PIIPA), which concluded that most forms of DOO requirements would be consistent with international treaties.[18] However, DOO requirements in a particular country would need to apply to applicants from all countries, and could not preclude the filing of national PCT applications. As to the second argument, in principle DOO rules are not necessarily incompatible with domestic laws in most countries, although this issue does depend on the specific laws in existence in individual countries. The third argument is a political issue not addressed here.

The fourth argument, impracticality and domestic consequences, remains a crucial issue for countries to address when reaching decisions about DOO requirements. For example, for countries that lack practical ABS regimes, a strict DOO requirement might be impossible to satisfy, thereby precluding genetic resources patents.[19] National patent offices are generally under-funded and are already required to examine extremely complex technical and bibliographic information, so they may lack capacity to handle additional DOO requirements. DOO requirements would place greater burden on patent applicants in the life sciences than applicants in other technologies. Finally, other measures outside patent law, like civil or criminal sanctions, might be a better way and represent a better use of resources to improve compliance with ABS regimes. All these policy and procedural concerns need to be addressed if a DOO regime is to succeed.

V. Conclusions

As international consideration of DOO requirements moves through discussions involving the CBD, WIPO, and WTO, countries may wish to commission intellectual property professionals to draft model legislation for a range of specific DOO requirements. This would help focus attention on the key issue—whether DOO requirements are an effective way to achieve the ultimate goals of promoting conservation of biological and cultural diversity, in balance with innovation and technology transfer. The specifics of draft model legislation could also help build a consensus about consistency with international treaties and domestic laws, and the policy merits of particular options.

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[18] Joshua D. Sarnoff, Consistency with Patent Law Treaties of Application Disclosure Requirements Regarding Origins of Genetic Resources and Traditional Knowledge, Discussion draft of June 23, 2004 available at http://www.piipa.org/DOO_Memo.doc. This memorandum includes a comprehensive study of the relevant treaties.

[19] IP/C/M/46 Council for Trade Related Aspects of Intellectual Property Rights – Minutes of the Meeting – Held in the Centre William Rappard on 1–2 December, 2004.

Toward an effective disclosure mechanism: justification, scope and legal effects

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I. Introduction

During the last 10 years, discussions on the relationship between the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) and the Convention on Biological Diversity (CBD)[20] have taken place in the World Trade Organization (WTO). At the center of these discussions has been a question of how to develop an in-built mechanism as part of the patent filing system to reduce or avoid further "misappropriation" of genetic resources and associated traditional knowledge. While many WTO Members recognise the need to reconcile both international instruments, the role of the patent system in dealing with the implementation of CBD objectives and misappropriation issues is still very controversial, especially regarding the incorporation of a requirement to disclose the origin of genetic resources and traditional knowledge used in an invention and evidence of prior informed consent and benefit-sharing in patent application ("disclosure requirement").

The Doha Ministerial Declaration has three mandates to address the TRIPS-CBD relationship:

- Paragraph 19 which instruct the TRIPS Council "in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Articla 71.1".

- Paragraph 32 (ii) which instructs the Committee on Trade and Environment to give particular attention to (among others) the relevant provisions of the TRIPS Agreement.

- Ongoing work on implementation issues in light of paragraph 12 of the Doha Ministerial Declaration,[21] paragraph 13 of the Decision on Implementation related issues and concerns[22] and tirets 88 and 91 on the Compilation on Outstanding Implementation Issues prepared by WTO Members in the preliminary discussions to the WTO Doha Ministerial.[23]

Under these mandates there should have been a solution on outstanding implementation issues, a set of recommendations under Paragraph 19 in the TRIPS Council and particular attention given to the issue in the CTE. Due to a lack of political will to seriously address the concerns of biodiversity rich countries, little substantive progress has been made in these discussions throughout the Doha round. Some of the requirement's strongest advocates including Brazil, India and Peru, have been pushing for a specific outcome in the lead-up to the Hong Kong Ministerial Conference in December 2005, strongly opposed by the US and Japan.

This document provides an analytical overview of the different aspects of a potential disclosure requirement and their feasibility, and addresses the justification for a mechanism, objectives, scope, legal nature and effects.

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[20] The CBD has been ratified by more than 183 countries and it has been implemented through limited number of national biodiversity legislations or biodiversity action plans.

[21] WT/MIN/(01)/DEC/1 of the 14 of December 2001

[22] WT/MIN(01)/17 of the 14 of December 2001

[23] JOB(01)/152/Rev.1 del 27 de Octubre 2001

II. What type of mechanism and why?

Discussions to create synergies between the TRIPS Agreement and the CBD have been ongoing for more than a decade. This debate has also been undertaken in the fora of the international intellectual property system more broadly, including some of the Conventions under the World Intellectual Property Organization (WIPO) and more specifically the Patent Cooperation Treaty, the Patent Law Treaty and the potential Substantive Patent Law Treaty. The three main positions regarding the TRIPS-CBD relationship are as follows:

- There is no relationship between the access and benefit-sharing regimes and patent filing processes, each system has a purpose and they do not match;

- The relation is incompatible: there are incompatibilities in objectives and mechanisms of implementation;

- There is a certain level of overlap in the subject matter of both agreements: this position considers that there is an overlap over the material subject to access under the CBD and the material used or incorporated in a particular invention subject to a potential patent. Therefore there is a need to make some adjustments in the patent system so as to avoid cases where the genetic resources being used or incorporated in inventions without respecting national access laws and to promote the creation of synergies.

The disclosure requirement has been pushed by proponents of the third approach as a solution, among others, to foster the above-mentioned synergies. Specifically the submissions made by these parties so far have sought to incorporate disclosure requirements in the TRIPS Agreement as a mechanism that allows the verification that any genetic resource or associated traditional knowledge have been obtained in a legitimate manner and that the legal requirements of the country of origin have been fulfilled as an integral part of the patent filing process. This type of requirement has already been incorporated through different modalities and legal systems in a number of national jurisdictions, including Brazil, the Andean Community countries, Costa Rica, India, Nepal, Norway, Belgium, Denmark and the European Union. It is also under legislative evaluation in some other countries including Switzerland, Thailand and the Dominican Republic .

A number of recent proposals have been presented by various countries[24] to address the biodiversity-related the mandates in the Doha Declaration. These proposals indicate that the TRIPS Council needs to reform the TRIPS Agreement, specifically Article 29, with the purpose of incorporating an obligation for patent applicants to disclose all biological resources and associated traditional knowledge that have been directly or indirectly incorporated in an invention. In these submissions it has been stated by the proponent countries that the disclosure requirement would be a condition to the granting of a patent and would have to specifically include the following aspects:

(i) Disclosure of the country of origin and legal source of the biological recourses and traditional knowledge used or incorporated in the invention;

(ii) Evidence of prior informed consent and approval by national biodiversity authorities when relevant;

(iii) Evidence of prior informed consent and approval by national authorities in relation to traditional knowledge;

(iv) Evidence of fair and equitable benefit-sharing in accordance with national laws.

The disclosure mechanism has been designed to address concerns of a transnational nature. Most national laws and actions currently in place to regulate access and use of genetic resources and associated traditional knowledge are arguably insufficient due to the following difficulties:

- Cross border nature of R&D activities, and continuous transfer and movement of genetic resources and associated traditional knowledge;

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[24] See for example, the following submissions: Peru, 8 June 2005 (IP/C/W/447); Bolivia, Brazil, Colombia, Cuba, Dominican Republic Ecuador, India, Peru and Thailand, 18 March 2005 (IP/C/W/442); Bolivia, Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand and Venezuela, 10 Dec, 2004 (IP/C/W/438); Brazil, Bolivia, Cuba, Dominican Republic, Ecuador, India, Thailand, Perú and Venezuela, 24 June, 2003 (IP/C/W/403).

- Ineffectiveness or inconsistency of enforcement mechanisms for biodiversity laws in both provider and users countries, including the lack of extraterritorial enforcement mechanisms;

- Most cases of "misappropriation" have occurred outside the territory of the provider country;

- Difficulties in cooperation among environmental authorities and private companies in identifying potential cases of illegal access or misappropriation;

- Lack of patent examination quality on biotechnological patents due generally to an overwhelming supply of patent applications with advancements in the technology;

- Overly broad claims in biotechnological inventions presented in patent procedures in other countries;

As a consequence, it is necessary to achieve an international solution in various fora to generate positive synergies among international agreements and create complementary mechanisms designed to tackle misappropriation of genetic resources and associated traditional knowledge. This international solution should include the disclosure mechanism but also the adoption of a uniform set of international principles and access conditions that could ultimately take the form of an international regime on access and benefit-sharing as mandated by the World Summit on Sustainable Development Plan of Implementation.

Given that the TRIPS Agreement is broadly recognised as the most important international instrument on intellectual property – establishing a set of minimum principles which all WTO Members are required to implement – it is natural to identify it as the primary instrument to be modified in order to include the disclosure mechanism and therefore facilitate coherence with the CBD. The TRIPS Agreement is currently under a specific and complete review under articles 27.3(b) (on the patentability of life forms) and 71.1. However, this does not necessarily mean that substantial reforms will also be needed in the Patent Cooperation Treaty or other WIPO treaties. Also, the current negotiations on an international regime on access and benefit-sharing in the CBD will need to establish the adequate links between the mechanism and the future regime so as to facilitate the generation of relevant evidence of prior informed consent and fair and equitable benefit-sharing.

III. Objectives of the mechanism

A disclosure mechanism at the international level should seek to:

- Fulfil the objectives of the CBD and create synergies among various international agreements including the TRIPS Agreement, WIPO agreements, the FAO Treaty on Plant Genetic Resources for Food and Agriculture, etc.

- Address the issue of misappropriation of genetic resources and associated traditional knowledge;

- Increase transparency and credibility of the patent system;

- Increase quality of patent examinations (such a mechanism could assist in the determination of the state of the art, the examination of the patentability criteria and more especially novelty and inventive step);

- Generate more precision in the determination of the scope of the claims of the applicant;

- Complement property and competition policies by tackling problems of inventorship, fraud, and abuse of rights;

- Create a favourable environment among providers and users;

- Facilitate the flow of genetic resources at all levels.

IV. Scope of a disclosure mechanism

A particular biotechnological invention derives directly or indirectly from *biological resources and associated traditional knowledge* if those resources or knowledge were used in any phase of the research and develop-

ment process leading to an invention or in a patentable invention itself. While in many cases the invention will be an isolated chemical component or a simple blend of isolated components of the original material, such material needs to be disclosed so as to identify any biological resources used. Definitions of biological / genetic resources or associated traditional knowledge could be taken from the CBD or left for national access legislations to be defined. In any case broader definitions will be the most appropriate option.

The disclosure requirement is mainly applicable to inventions and discoveries in the field of biotechnology where specific requirements in patent filing procedure, such as the deposit of a sample of the genetic material, already exist.[25] Arguably, applicants should not consider this particular requirement as burdensome or discriminatory.[26] On the contrary it contributes to complementing the description of the invention. The costs associated with a disclosure requirement could be even lower than the deposit of the genetic materials where cooling facilities are needed to preserve it.

The *geographical origin* (country, region, community) of biological resources and associated traditional knowledge should be part of an international disclosure obligation to be incorporated in the TRIPS Agreement. Information of the geographical origin is fundamental for bioprospecting activities and relevant in research and development processes due to the interaction and interdependency of living organisms with the environment, the climate as well as reproduction factors among others.

The obligations of disclosure must also apply to the *legal source* of the biological materials and traditional knowledge. In this case it will be necessary to present evidence of such legal precedence in the form of permits, authorisations, contracts of transfer and certificates that legitimate access and use as established in national biodiversity laws.

Additionally a requirement of *evidence of prior informed consent and existence of benefit-sharing arrangements* has been sought. The consent of the country and communities is a fundamental part of the chain of legitimacy over access and use of a genetic resource in light of the CBD and national laws. This evidence can take many forms according to national laws, including permits, authorisations, contracts, customary law protocols but also minutes of consultations and any pre-contractual arrangements. In determining the evidence and its value the Bonn Guidelines of the CBD are of assistance. It should not be a requirement of the national intellectual property agencies to enter into considerations and evaluations of whether the benefit-sharing agreements are *fair and equitable.* It should be sufficient for them to consider that there is evidence of prior informed consent and existence of a benefit-sharing arrangement such that there no undue burden is placed on the operation of the patent system. It is for the parties to define the concept of fairness in their agreement. Nevertheless, this does not restrict the intellectual property office from seeking assistance from biodiversity authorities, whether national or in other countries, to assess if the evidence is sufficient.

While the TRIPS Agreement is the most suitable treaty to incorporate a more general international obligation of disclosure, harmonising processes to clarify prior informed consent, benefits sharing arrangements and possible means of gathering and evaluating evidence should be left to current negotiations of an international regime on access and benefit-sharing or to national laws.

Arguably, the disclosure of origin of all the aspects mentioned above must be mandatory to be effective and for all cases where the biological resources or traditional knowledge has been used or incorporated in:

- The invention itself,
- During the research and development process leading to an invention;
- As a prerequisite or complementary information for replication or further development of the invention.

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[25] Similar procedures can be found in the "Budapest Treaty on the International Recognition of the Deposit of Microorganisms" to deposit genetic material for the purposes of the patent procedures. See article 3. of the Budapest Treaty on the International Recognition of the Deposit of Micro organisms. Subscribed under the auspices of WIPO of 1980.

[26] In relation to the argument of discrimination on the field of technology the WTO (panel decision) on Patents of Canada vs. EU (Report of the Special Group on Patent Protection to certain pharmaceuticals, Canada vs. the European Communities. Document WT/DS114/R del 17 March , 2000) has affirmed that Article 27.1 does not prohibit authenticated exceptions destined to solve problems that only exist in certain product sectors, and as it could be the case of the requirement of the origin of the Genetic resources or the traditional knowledge. The panel made clear that the conduct prohibited by Article 27.1 is "discrimination", and that "discrimination" is not the same as "differentiation". For more information on the legal debate about the compatibility of the disclosure requirement see David Vivas-Eugui, Requiring the disclosure of the origin of genetic resources and traditional knowledge: The current debate and possible legal alternatives. Trading in Knowledge, ICTSD/Earthscan, 2002.

V. Legal nature and procedural aspects

There are various legal and procedural aspects of an international disclosure mechanism that could assist WTO Members in assessing its usefulness and effectiveness. These aspects include the following:

The mechanism is based on the *good faith of the applicant.* A patent applicant must present the best information known to him related to:

- The requirements already mentioned above (biological resources, associated traditional knowledge, geographical origin, legal source, evidence of prior informed consent and benefit-sharing;
- Information relevant to the examination of the patentability criteria (whether the invention is new, novel, and industrially applicable);
- Information relevant to determination of inventorship.

Presentation of all these information will be conditional to the granting of the patent.

- The request of information must be included in patent application forms that will be presented to the intellectual property authority;
- The information requested must be presented in the evaluation of the state of the art and in the description of the invention;
- The disclosure should include the best mode to replicate the invention;
- The mechanism must be effective. Lacking or incomplete disclosure, fraudulent behavior, problems related to the inventorship or misrepresentation needs to be prevented;
- There is a need to complement the disclosure mechanism with international cooperation and consultations among intellectual property offices and/or biodiversity offices. Improved databases of the state of the art, whether open or confidential in the case of traditional knowledge, and further expansion of the basic and minimum literature[27] could be of assistance;
- There must be an option for interested parties to present additional information in the patent filing procedure with the objective of providing additional clarifying information to be disclosed or related to the patentability criteria or inventorship.

VI. Legal effects

Depending on the particular case there could be various legal effects for lack of fulfilment of the disclosure requirement. Some possible causes and legal effects include the following:

Lack of disclosure will result in a presumption of abandonment of the procedure by the applicant. If there is no full disclosure of country of origin, legal source or presentation of evidence of prior informed consent and benefit-sharing arrangement, the process of patent/intellectual property rights application will be considered deserted and no right granted.

In the case of *incomplete disclosure,* there will be suspension of the patent filing procedure while priority rights of the applicant are safeguarded. The administrative process will be temporarily suspended (not generating legal effects) until requirement is fulfilled. The applicant will have an opportunity to complete the application with the provision of the actual and complete information or by presenting complementary information.

Granting of a patent under fraudulent behaviour or omitting known information. In this case there are two possible options:

- Invalidation of some of the claims;

[27] Some expansion of the minimum literature has already occurred under the Patent Cooperation Treaty in WIPO discussions.

- Suspension of patent effects until the irregular situation is repaired;

- Revocation of the patent.

In this particular case, there should not be limits to the complaining party to also initiate civil or administrative actions for violation of access and benefit-sharing laws or damages caused in both the country of origin and the country where the patent was filed.

VII. Conclusions

Encouragement of mechanisms such as the disclosure of origin of genetic resources and traditional knowledge or any other reasonable mechanism[28] in patent or other intellectual property rights filing procedures as proposed by developing countries would create mutual supportiveness between the intellectual property systems and the access and benefit-sharing regimes. Mutual supportiveness of the TRIPS and CBD objectives would generate less complex or burdensome access regimes and increase confidence among private enterprises, research centres, biodiversity rich countries, and indigenous and local communities. Countries should be allowed to explore the options that could be supportive to intellectual property protection and CBD objectives including a detailed disclosure mechanism.

The Hong Kong Ministerial Conference in December 2005 is a good opportunity to obtain a more precise negotiating mandate to amend the TRIPS Agreement in order to incorporate a disclosure requirement. There is already a substantial body of documentation of elements and justifications for the design of an effective disclosure mechanism, which can both address concerns over misappropriation and potential excessive burdens on the patent system. While significant resistance by some Members to finding a solution in the WTO can be expected, some countries are already deploying political efforts for moving the issues forward. In the end, the political will of the parties will be the key determinant. Support from civil society will also play an important role by pushing for negotiating parties to address the concerns of biodiversity rich countries and take action as required under the mandate of the Doha Development Agenda.

[28] Brendan Tobin has proposed the use a certificate of origin as an alternative to the disclosure. See Tobin Brendan. "Certificates of origin: a role for IPRs regimens in securing prior informed consent", 1997. Graham Dutfield considers this alternative more restrictive that the disclosure. See Dutfiel Graham. Protecting traditional knowledge and folklore. UNCTAD-ICTSD 2002.

Addressing the disclosure requirement at the international level: the role of the TRIPS agreement

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I. Overview

An overview of the patent system may help to understand why international recognition of disclosure requirements is necessary.

The objective of the patent system is to encourage research and innovation. Is this happening? Some patents are good examples of how research and innovation are being encouraged and of how important it is to promote this kind of research and innovation. Unfortunately, other patents offer examples of acts which should *not* be stimulated.

The patent system operates by granting exclusive rights to inventions that fulfil certain requirements. There is no valid reason for granting exclusive rights to someone who has made no contribution at all or whose contribution doesn't deserve such a reward. In other words, the patent system is not operating properly if patents are granted to inventions which are not new and do not involve an inventive step.

Moreover, the patent system works only if a balance is struck between the rights of all who have contributed to make an invention possible. The patent system is not operating appropriately if it only recognises the rights of those who have generated an invention by using the inputs and knowledge provided by others and infringing their property rights. In other words, the patent system should not validate misappropriation nor should it encourage research and innovation at any price.

It is urgent to reconsider the patent system and find mechanisms which balance the different inputs and rights vested in an invention. Including disclosure requirements in an international instrument such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), would certainly help to address these problems and to make the patent system healthier.

The current intellectual property system does little to ensure fair and equitable sharing of the benefits derived from the use of genetic resources. Two examples of patents granted in the US to inventions related to Maca *(Lepidium meyenii)* and Uña de Gato *(Uncaria tomentosa)* show why international disclosure requirements are necessary in order to prevent the intellectual property system being used to validate the misappropriation of biological resources ("biopiracy") and traditional knowledge.

II. Example 1: Patents related to Maca *(Lepidium meyenii)*

US patents 6,267,995 (extract of *Lepidium meyenii* roots for pharmaceutical applications) and 6,428,824 (treatment of sexual dysfunction with an extract of *Lepidium meyenii* roots)[29], exploit the biochemical properties of Maca, a plant that has been grown for centuries in the Peruvian Andes. It has been traditionally used by ancient Peruvians for fertility purposes, as an aphrodisiac, and to treat frigidity in women and impotence in men.

Using a purified extract of Maca roots, the inventors confirmed the traditional use of Maca as an aphrodisiac and filed patent applications in the US for (among other claims):

- An isolated composition obtained by extracting Lepidium meyenii roots;

[29] Patent applications for related inventions were also filed through the Patent Cooperation Treaty (PCT) system. For additional information, see: Document WIPO/GRTKF/IC/5/13 "Patents referring to Lepidium meyenii (Maca): Responses of Peru", submitted by the Delegation of Peru to the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore during its 5th session. See also: Venero Aguirre, Begoña. Les connaissances traditionnelles et les brevets relatifs au Lepidium meyenii: un exemple à ne pas suivre; 2003. In: Le Courrier ACP-UE, N° 201, November-December 2003.

- A method of treating sexual dysfunction in animals through the use of an isolated composition derived from an aqueous solvent extract of Lepidium meyenii root.

Prior art found by a working group created in Peru to examine these patents, shows that these inventions are either not new or do not involve an inventive step.

Moreover, the Maca roots that were used for these inventions were taken from Peru[30] and there is no evidence that the material was obtained legally or that a benefit sharing arrangement was agreed between patent holders and the Peruvian state and indigenous communities. The delivery of these patents therefore runs counter to one of the three main objectives of the Convention on Biological Diversity (CBD), which is the "fair and equitable sharing of the benefits arising out of the utilisation of genetic resources".[31]

III. Example 2: Patents related to Uña de Gato *(Uncaria tomentosa)*

US patent 4,844,901 (oxindole alkaloids having properties stimulating the immunologic system)[32] relates to a preparation containing an extract from root parts of the *Uncaria tomentosa.*

This patent claims:

1. A method for stimulating the immunological system comprising providing oxindole alkaloids from the extract of the root of *Uncaria tomentosa* (willd.), administering the extract to a subject, and measuring the rate of increase in the phagocytosis activation in the subject.

2. The method according to Claim 1 wherein the rate of increase in the phagocytosis activation in the subject is between 30-40% as a result of administering the extract.

Native Peruvians have been using this plant against tumours and inflammations for years. Klaus Keplinger, one of the inventors, mentioned in the patent and the assignee of the patent, was probably guided in his research by this traditional knowledge. However, it seems clear that he discovered something new and inventive: that this plant could also be used for stimulating the immunological system.

Keplinger's contribution deserves some kind of acknowledgement or compensation, such as that provided by the patent system. However, if we consider that Keplinger would not have been able to develop his invention if he had not been guided by the traditional knowledge of native Peruvians, it is obvious that the contribution of the native Peruvians who developed and preserved that traditional knowledge also deserves some kind of acknowledgement or compensation.

When faced with patent claims of this nature, the inadequacy of the current intellectual property system becomes apparent. If we take the first example, it is clear that the patent system was not created to grant exclusive rights to inventions that are not new and do not involve an inventive step. If we take the second example, even though the patentability requirements are apparently fulfilled, there is still a problem: the contribution of the inventor is acknowledged and recognised but the contribution of the indigenous peoples that guided him in his research is not.

What should be done to prevent these patents from being granted? National measures may help to prevent misappropriation in some cases, however, national measures alone are not sufficient, international measures too are needed.

Misappropriation measures (disclosure of origin and legal provenance of genetic resources and traditional knowledge requirements) have been adopted by the Andean Community countries through Decision 391 (on access to genetic resources) and Decision 486 (on industrial property). However, they are ineffective when misappropriation takes place in countries outside the Andean Community and which do not recognise disclosure requirements in their legislation. Peru has gone even further: a working group was convened to examine the applications filed and patents granted for inventions related to Maca; also, a national anti-biopiracy commission was recently created (Law 28216). However, so far their experience

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[30] See: Zheng, b., He, k., Kim, c., Rogers, l., Shao, y, Huang, z., Lu, y., Yan, s., Gien, l. Y Zheng, q. Effect of an extract from Lepidium meyenii on sexual behaviour in mice and rats. In: Urology 55 (4).

[31] CBD, article 1.

[32] For additional information see: Venero Aguirre, Begoña. Mitos y verdades sobre la biopiratería y la propiedad intelectual. In: Anuario Andino de Derechos Intelectuales, Año I, N° 1, Lima, enero 2005.

has shown that challenging patents such as those described above is not an easy task. Despite the efforts of the working group (since July 2002) and the national commission (since august 2004), no results have been obtained yet. Furthermore, challenging patents granted to inventions that are actually new and do involve an inventive step, such as Keplinger's on *Uncaria tomentosa* root, is even more difficult.

Developing a *sui generis* system to protect traditional knowledge and/or adopting provisions to regulate access to genetic resources have been, until now, results of isolated national efforts.[33] However, the experience of Andean Community countries shows that in order to be effective these national measures must be complemented by international measures such as disclosure requirements.

IV. Role of different international forums

Several international forums have played host to discussions and activities related to disclosure requirements.

The CBD's Ad Hoc Open-Ended Working Group on Access and Benefit Sharing, Ad Hoc Open-Ended Working Group on Article 8(j) and Conference of the Parties have influenced WIPO and even the WTO, to take into account issues such as protection of traditional knowledge and access to genetic resources that were not originally linked to the intellectual property system.

In addition, WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore has contributed significantly to the understanding of protection of traditional knowledge and access to genetic resources from an intellectual property perspective. It has produced comprehensive documents that have been very useful for moving the debates further.

Moreover, influencing WIPO's working group on the reform of the PCT should not be sidelined. The PCT system applies to 126 countries and may have important practical implications in relation to the protection of traditional knowledge and access to genetic resources from a disclosure perspective.

However, the WTO remains the most relevant forum for discussion of disclosure requirements, and the inclusion of disclosure requirements in the TRIPS Agreement is vital. Although the progress achieved in different international forums such as WIPO and CBD should not be overlooked and these organisations should continue to address these issues, such discussions should not be taken as an excuse not to advocate for progress in the WTO context.

As a matter of fact, even if WIPO had a mandate for leading negotiations, developed countries may choose not to sign an instrument which includes an obligation for disclosure. Therefore, the objective of making the disclosure requirements mandatory at an international level would not be achieved. This choice would not be possible in the WTO context. If the TRIPS Agreement was modified to include mandatory disclosure requirements, this would legally bind all its member states.

Additionally, if we consider that the TRIPS Agreement needs to be rebalanced, it is clear that this can only be achieved through a modification of the TRIPS Agreement itself.

V. Nature, format, and elements of disclosure requirements in the TRIPS agreement

Much has been written about the disclosure requirements that should be included in the TRIPS Agreement.[34] However:

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[33] In doing so, countries should establish clear and reasonable rules. They should take into account that those interested in their resources or in the traditional knowledge of their indigenous peoples have more than one choice and option, most of the time (given the shared nature of resources and traditional knowledge). Interested parties can also choose countries where simpler laws on access or traditional knowledge are in place.

[34] See: Correa, Carlos. Establishing a Disclosure of Origin Obligation in the TRIPS Agreement. Occasional Paper No. 12, QUNO, Geneva, 2003. See also : Correa, Carlos. The Politics & Practicalities of a Disclosure of Origin Obligation. In: South Bulletin 97/98, February 2005. Also review: Sarnoff, Joshua. Compatibility with existing international intellectual property agreements of requirements for patent applicants to disclose origins of genetic resources and traditional knowledge and evidence of legal access and benefit sharing, available in PIIPA's website (www.piipa.org) and Commission on Intellectual Property Rights. Integrating Intellectual Property Rights and Development Policy, Report of the Commission on Intellectual Property Rights, London, February 2003.

- No consensus has been reached on whether these requirements should take the form of simple formalities, an additional requirement of patentability, a component of the disclosure requirement or an additional substantive condition on entitlement to apply for patent rights;

- No consensus has been reached on whether these requirements should be mandatory or facultative, or about the consequences of non-compliance with these requirements (for example, denial or rejection of the application, invalidation or revocation of the patent, unenforceability of the patent);

- No consensus has been reached either about how these requirements should be discharged (via a statement, submission of evidence, submission of a certificate of origin), about how far the applicant of a patent should go in order to comply with these requirements, or about how the patent office should proceed in order to verify compliance with these requirements;

- Last but not least, no consensus has been reached about what is meant by disclosure requirements, about the terms that should be used to define these disclosure requirements, or in which cases these requirements should apply (inventions directly based on biological resources or traditional knowledge, inventions developed using biological resources or traditional knowledge).

In order to move debates forward, basic agreements need to be reached. The following ideas may contribute to attaining certain levels of consensus:

- These requirements may be considered formal or substantive, but they should be mandatory[35] and there should be a sanction for non-compliance with these requirements before and after the grant of a patent;

- Agreements should be reached between the patent applicant or patent holder and the holders of rights to the genetic resources or traditional knowledge before sanctions are applied. This could contribute to a win-win situation;

- Simplicity should be a paramount consideration when defining how these requirements are to operate;

- Expectations about what a patent office may really be capable of doing in order to verify the compliance of these requirements, should be realistic;

- Clear rules about when these requirements apply (the relationship between the invention and the resource or knowledge) and about what is required (disclosure of the country of origin or of the source or both) are of great importance.

VI. Conclusions: next steps towards introducing disclosure requirements and a misappropriation regime in the TRIPS Agreement

First, the checklist of issues submitted to the WTO by Brazil, Cuba, India and Peru, among others, and the submissions that followed[36] provide a good example of the kind of documents that are needed to move discussions about disclosure forward.

A new submission with concrete proposals that take into account reactions of developed countries to the checklist and the submissions that followed would be extremely useful, especially if it was endorsed by developing countries.

Secondly, more practical examples of misappropriation would be useful to understand why the disclosure requirements should be introduced in the TRIPS Agreement and how. For example, the delegation of Peru intends to submit a new document about the problems the national anti-biopiracy commission continues to face in its attempt to confront biopiracy.

Third, many arguments have been provided to justify the inclusion of disclosure requirements in the TRIPS Agreement. However, one argument that should be stressed is that it would benefit the intellectual property system itself. It is clear that the intellectual property system was not created with the aim

[35] Optional or voluntary requirements would probably be as useful as not having any disclosure requirements at all at an international level (precisely because of their voluntary nature).

[36] See: Documents IP/C/W/420, IP/C/W/429, IP/C/W/438 and IP/C/W/442.

of regulating access to genetic resources or protecting traditional knowledge. However, the system can contribute to and support regimes to protect access to genetic resources and traditional knowledge. By doing so, it would legitimise itself and leave those totally opposed to patents *per se* with fewer arguments with which attack the system.

This may help to overcome the endless discussions about whether TRIPS and the CBD are compatible or not. No matter what each delegation thinks about this specific issue, all delegations may be more inclined to reach some kind of consensus about how to make the intellectual property system more fair and, therefore, stronger.

Fourthly, considering that in the framework of the mandate contained in Paragraph 19 of the Doha Declaration the relationship between the TRIPS Agreement and the CBD has to some extent been examined, it is time to move to a next level of discussions. This should be the aim of the Hong Kong Ministerial Meeting: to obtain a specific and clear negotiating mandate to modify the TRIPS Agreement in order to include mandatory disclosure requirements.

Finally, careful consideration should be given as to where will be the best place to introduce these requirements. One of the options that could be contemplated would be to include a new paragraph in Article 27 (a new 27.4) and a third paragraph in Article 29 (as a new 29.3). The disclosure of evidence of prior informed consent and benefit sharing requirements could be included in Article 27, bearing in mind that exclusions from patentability are related to inventions that may be new, involve an inventive step and be capable of industrial application but shouldn't be granted patents because of reasons that go beyond the logic of the patent system itself. On the other hand, Article 29, which actually addresses disclosure of information in patents, could also be a good place to include the disclosure of origin requirement.

These steps are essential if the international patent regime is to be reformed in a sustainable and fair manner. The current system recognises only the contribution made by those developing inventions on the basis of biological materials or traditional know-how. However, it is also necessary to recognise the contribution made by countries that supply the biological materials and by the indigenous peoples who supply their traditional knowledge.

Switzerland's proposals for disclosure of the source of genetic resources and traditional knowledge in patent applications; and views on prior informed consent and benefit sharing in patent applications

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I. Overview

Switzerland submitted its proposals on the disclosure of the source of genetic resources and traditional knowledge in patent applications to the WIPO Working Group on Reform of the Patent Cooperation Treaty (PCT) in May 2003.[37]

In a nutshell, Switzerland suggested amending PCT Regulations to include a new Rule 51bis.1(g) explicitly enabling states to incorporate into national patent legislation the requirement to declare the source of genetic resources and traditional knowledge in patent applications, if the invention is based directly on such resources or knowledge. In order to further advance discussions of its proposals,[38] Switzerland presented two further submissions with more detailed explanations to the WIPO Working Group on PCT Reform in May 2004 and October 2004, respectively. These submissions address the use of terms, the concept of the "source" of genetic resources and traditional knowledge, the scope of the obligation to declare this source in patent applications, the possible legal sanctions for failure to declare the source or wrongful declaration of the source, and its optional vs mandatory introduction at the national level.

Switzerland does not ask for disclosure of the source in patent applications; rather, Switzerland submitted its proposals in order to support the process and because it is interested in ensuring equitable patent protection for biotechnological inventions.

Switzerland also presented its proposals to the WTO/TRIPS Council,[39] and to the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC).[40] Finally, Switzerland presented a summary of its proposals to the 3rd session of the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing of the Convention on Biological Diversity (CBD) in February 2005.[41]

II. Switzerland's proposals

(1) Policy objectives
Switzerland believes that disclosing the source of genetic resources would enable four policy objectives to be achieved: transparency, traceability, technical prior art, and mutual trust (in short, "the four T's"):

(a) Transparency: a requirement to disclose the source of genetic resources in national and international patent applications, would increase transparency in access to and benefit sharing of genetic resources and traditional knowledge.

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[37] See WIPO-document PCT/R/WG/4/13 and, with identical contents, PCT/R/WG/5/11/Rev. (available at <http://www.wipo.int/pct/en/meetings/reform_wg/pdf/pct_r_wg_5_11_rev.pdf>)

[38] See WIPO-documents PCT/R/WG/6/11 (available at <http://www.wipo.int/pct/en/meetings/reform_wg/pdf/pct_r_wg_6_11.pdf>) and PCT/R/WG/7 Paper No. 7 (available at <http://www.wipo.int/pct/reform/en/draftdocs/wg7/pct_r_wg_7_paper_7.pdf>).

[39] 3 See WTO-documents IP/C/W/400/Rev.1 (available at <http://www.ige.ch/E/jurinfo/documents/IP-C-W-400.pdf>), IP/C/W/423 (available at <http://docsonline.wto.org/DDFDocuments/t/IP/C/W423.doc>), and IP/C/W/433 (available at <http://www.ige.ch/E/jurinfo/documents/j110114e.pdf>).

[40] 4 See WIPO-document WIPO/GRTKF/IC/7/INF/5 (available at <http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_7/wipo_grtkf_ic_7_inf_5.pdf>).

[41] 5 See CBD-document UNEP/CBD/WG-ABS/3/INF/7 (available at <http://www.biodiv.org/doc/meetings/abs/abswg-03/information/abswg-03-inf-07-en.pdf>).

(b) Traceability: disclosing the source in patent applications would allow the providers of genetic resources and traditional knowledge to keep track of the use of their resources or knowledge in any research and development resulting in patentable inventions.

(c) Technical prior art: disclosing the source of genetic resources and traditional knowledge in patent applications would assist patent examiners and judges to establish the existence of prior art with regard to inventions that relate to these resources or this knowledge. In particular, it may facilitate the establishment of prior public use, or help to establish a lack of novelty or inventive step, as in the case, for example, of the so-called "neem tree oil" patent (European Patent 0,436,257). This applies in particular to prior art regarding traditional knowledge, where disclosing the source would simplify a search of the databases of traditional knowledge that are increasingly being established at the local, regional and national level.

(d) Mutual trust: disclosure of the source would increase mutual trust among the various stakeholders involved in access and benefit sharing, including among developing and developed countries, indigenous and local communities, private companies and research institutions. All of these stakeholders may be providers and/or users of genetic resources and traditional knowledge. Accordingly, disclosing the source would help to build mutual trust between North and South. Moreover, it would strengthen mutual support between the access and benefit sharing system and the patent system.

(2) Amendment of the Patent Cooperation Treaty and the Patent Law Treaty
Switzerland proposes to amend PCT Regulations to explicitly enable the Contracting Parties to the PCT to require patent applicants to declare the source of genetic resources and/or traditional knowledge, if an invention is directly based on such resources or knowledge. Under the Swiss proposals, applicants would have the possibility of satisfying this requirement either when they file a national application for an international patent or at a later stage when the application is considered by international patent granting bodies, and to include the declaration of the source in the international publication of the patent application. In the event that an international patent application does not include the required declaration, national law may include provisions to halt the processing of the national phase of the application until the patent applicant has furnished the required declaration.

Based on the reference to the PCT contained in Article 6.1 of WIPO's Patent Law Treaty (PLT), the proposed amendment to the PCT would also apply to the PLT. Accordingly, the Contracting Parties of the PLT would be able to require in their national patent laws that patent applicants declare the source of genetic resources and/or traditional knowledge in national patent applications.

(3) Use of terms
The Swiss proposals use the terms "genetic resources" and "traditional knowledge related to genetic resources" to ensure consistency with the CBD, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilisation (Bonn Guidelines), and the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty) of the Food and Agriculture Organization (FAO). Under patent law, the focus is on traditional knowledge that can be used in a technical invention.

(4) Concept of the "source" of genetic resources and traditional knowledge
Switzerland proposes that patent applicants be required to declare the "source" of genetic resources and traditional knowledge. The term "source" should be understood in its broadest sense, because a multitude of entities may be involved in access and benefit sharing.

The source is defined as the entity that is competent (1) to grant access to genetic resources and/or traditional knowledge; or (2) to participate in the sharing of the benefits arising out of their utilisation.

Depending on the genetic resource or traditional knowledge in question, it is possible to distinguish:

- primary sources, including Contracting Parties providing genetic resources,[42] the Multilateral System of FAO's International Treaty,[43] indigenous and local communities;[44] and

- secondary sources, including in particular *ex situ* collections and scientific literature.

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[42] See Articles 15, 16 and 19 CBD.
[43] See Articles 10-13 FAO International Treaty.
[44] See Article 8(j) CBD.

Accordingly, there is a "cascade" of possible primary and secondary sources. Patent applicants must declare the primary source to fulfil the requirement, if they have information about this primary source at hand, whereas a secondary source need only be declared if patent applicants have no information at hand about the primary source. Therefore, if, for example, the patent applicant knows that the source of a genetic resource is the Contracting Party providing this resource, this Contracting Party must be disclosed as the source; in contrast, if the patent applicant received the genetic resource from a botanical garden, but does not know the Contracting Party providing the genetic resource, the botanical garden must be disclosed as the source.

(5) Scope of the obligation to declare the source
As far as genetic resources are concerned, the proposed new Rule 51bis.1(g)(i) of the PCT Regulations makes clear that:

- the invention must make immediate use of the genetic resource, that is, be dependent upon the specific properties of this resource; and

- the inventor must have had physical access to this resource, that is, possession or at least contact which is sufficient to identify the properties of the genetic resource used in the invention.

As far as traditional knowledge is concerned, proposed new Rule 51bis.1(g)(ii) of the PCT Regulations makes clear that the inventor must know that the invention is directly based on such knowledge, that is, the inventor must consciously derive the invention from this knowledge.

(6) Optional vs mandatory introduction of the requirement at the national level
Switzerland proposes to amend the PCT Regulations to explicitly *enable* national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications, if they so wish. The proposals thus leave it up to the national legislator to decide whether such a requirement is to be introduced in national patent legislation.

Switzerland has suggested that this be optional because it believes that by doing so it offers four main advantages:

(a) At present, greatly divergent views exist on transparency measures, and ongoing discussions have not yielded any final results. Much faster progress, however, can be expected from an optional approach as proposed by Switzerland, than can be expected from any mandatory approach.

(b) The optional introduction of the disclosure requirement would enable those states interested in introducing such a requirement to do so. Additionally, it would allow national governments and the international community to gain experience with the disclosure requirement, without prejudice to further international efforts.

(c) The proposed establishment of the list of competent government agencies just described, and the inclusion of the declaration of the source in the publication of the patent application, would yield almost identical results as a mandatory approach. It is important to note that Switzerland[45] and most European countries plan to introduce a disclosure requirement in their national patent laws. This would create the critical mass needed to make the proposed disclosure of the source an effective measure.

(d) The approach proposed by Switzerland would not oblige developing countries, especially the least developed countries, to introduce the disclosure requirement in their national laws. Introducing such a requirement would generally bring little advantage to these countries. In contrast, a mandatory approach would oblige all countries to introduce such a requirement in their national patent laws.

It is crucial to keep in mind that once the disclosure requirement proposed by Switzerland is implemented at the national level, it will be mandatory for patent applicants to disclose the source in patent applications. Failure to disclose or wrongful disclosure would carry severe penalties.

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[45] For more information on the draft for a revised Swiss Patent Law with regard to the declaration of the source of genetic resources and traditional knowledge in patent applications, see <http://www.ige.ch/E/jurinfo/documents/j10017e.pdf>.

(7) Sanctions
In the Swiss view, the sanctions currently allowed for under the PCT and the PLT should be invoked in the event of a failure to declare the source or a wrongful declaration of the source of genetic resources and traditional knowledge in patent applications.

Accordingly, if the national law applicable by the designated office requires the declaration of the source of genetic resources and traditional knowledge, the proposed amended Rule 51bis.3(a) of the PCT Regulations requires the designated office to invite the applicant, at the beginning of the national phase of the application, to comply with this requirement within a time limit of two months from the date of the invitation. If the patent applicant does not comply with this invitation within the set time limit, the designated office may refuse the application or consider it withdrawn on the grounds of non-compliance. If, however, the applicant submits the proposed declaration using standardised wording to describe the declaration of the source at the time the international application is lodged or later during the international phase, under new Rule 51bis.2(d) the designated office must accept this declaration and may not require any further document or evidence relating to the declared source, unless it has valid reasons to doubt the veracity of the declaration concerned.

Furthermore, if, after the patent has been granted, it turns out that the applicant failed to declare the source or submitted false information, such failure to comply with the requirement may not be a ground for revocation or invalidation of the granted patent, except in the case of fraudulent intention (Article 10 PLT). However, other penalties provided for in national law, including criminal sanctions such as fines, may be imposed.

(8) Establishment of a list of government agencies competent to receive information on declaration of source
The proposed transparency measure could be further strengthened by establishing a list of government agencies competent to receive information about patent applications that include a declaration of the source of genetic resources and/or traditional knowledge. For easy reference, this list should be made accessible on the internet. Patent offices receiving patent applications containing such declarations could inform the competent government agency that the respective state has been declared as the source. This information could be provided in a standardised letter sent to the competent government agency. Switzerland invites WIPO, in close collaboration with the CBD, to further consider establishing a list of competent government agencies.

III. Evidence of prior informed consent (PIC) and benefit sharing in patent applications

During discussions on transparency measures for access and benefit sharing in the patent system, it has been proposed that patent applicants should be required to provide evidence of prior informed consent and of fair and equitable benefit sharing in patent applications. Some of the proposals put forward have suggested that providing this evidence should be a mandatory pre-condition that must be fulfilled in order for the applicant to acquire patent rights.[46]

When assessing such proposals, relevant international law must be taken into consideration. Under Article 15 of the CBD, access to genetic resources and the sharing of the benefits arising out of their utilisation shall be on mutually agreed terms. Article 15 furthermore requires that "[a]ccess to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party". The FAO's International Treaty establishes a Multilateral System of Access and Benefit Sharing. Under this system, prior informed consent is not required for access to genetic resources. Furthermore, Article 13 of the FAO Treaty contains a finite list of the possible forms of benefit sharing. Moreover, both the CBD and the FAO Treaty make provisions for the involvement of many different entities in access and benefit sharing.

From the Swiss perspective, there are potentially a number of legal and technical problems associated with such a system, particularly if it is left to the authorities responsible for granting patents to determine the veracity and accuracy of the evidence provided. Among the potential problems, the following are worth highlighting:

[46] See explicitly document IP/C/W//438 para. 8 re. prior informed consent (PIC). Unclear remains document IP/C/W/442 regarding fair and equitable benefit sharing.

(a) According to a recent survey,[47] only a small number of Parties to the CBD have implemented a national system for access and benefit sharing, or designated relevant national authorities to oversee it. Furthermore, the few existing national systems dealing with PIC differ considerably. Some national laws provide that PIC is not necessary at all or only in certain cases, whereas other national laws may spell out in detail the elements and modalities of PIC. Such differences are also likely to arise in future national PIC systems.

(b) Authorities responsible for granting patents would need access to the various national legislations governing PIC in a language familiar to them, and would have to familiarise themselves with each of the national systems every time a patent application containing such evidence is submitted. Patent granting authorities, however, are neither designed to carry out nor do they have the necessary legal and technical competence to determine the veracity of the evidence provided.

(c) The FAO's International Treaty does not make any provision for obtaining PIC when accessing genetic resources, with the result that burdensome distinctions would have to be made.

(d) How would the authorities responsible for granting patents determine whether the sharing of the benefits in each individual case under consideration is "fair and equitable"? Moreover, usually, at the time when an application for a patent is submitted, the commercial success of the invention is generally unknown and no monetary benefits have as yet accrued. Not all patents applied for will be granted, and a large part of the patents that are granted will never be commercialised. In most instances, therefore, at the time of the application, the patent applicant will not be able to provide evidence that benefits have actually been shared in a fair and equitable way.

Based on these considerations, the task of verifying whether the national systems of PIC have been adhered to on one hand, and whether fair and equitable benefit sharing has been mutually agreed to or has taken place on the other hand, can best be done by the providers of the genetic resources or the traditional knowledge in accordance with the relevant provisions of the CBD and FAO's International Treaty.

It is the Swiss view that its proposals relating to the declaration of the source, and the establishment of a list of government agencies competent to receive information about this declaration, would allow the providers of genetic resources and traditional knowledge to verify whether the obligations regarding access and benefit sharing have been complied with. If patent applicants are additionally required to provide evidence of fair and equitable benefit sharing in their applications, it would mean that they are being asked to submit information they do not have at hand, or, if they do, it would imply that they would be required to submit the information in double or even in triplicate, information that would be of little advantage to the providers of genetic resources and traditional knowledge.

IV. The role of the TRIPS Agreement

In the discussions on the disclosure requirement, reference is made to Articles 27.1, 29.1 and 62.1 of the TRIPS Agreement. In Switzerland's opinion, these provisions can be interpreted as follows: Article 27.1 does not preclude Members from introducing additional formal requirements in their national patent laws. Such requirements, however, must be in line with Article 62.1; this provision allows Members to require, as a condition of the acquisition or maintenance of patents, compliance with procedures and formalities, as long as these procedures and formalities are "reasonable". Article 29.1 states that inventions must be disclosed in the patent application "in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art". The disclosure of the invention as required by Article 29.1 is thus of a different nature from the disclosure of the source of genetic resources and traditional knowledge as proposed by Switzerland. Consequently, it can be said that Article 29.1 does not affect the introduction of the requirement to disclose the source. In Switzerland's opinion, the provisions of the TRIPS Agreement provide for adequate flexibility with regard to a formal requirement to disclose the source. Accordingly, Switzerland does not consider it necessary to amend the TRIPS Agreement.

These legal considerations not withstanding, the approach proposed by Switzerland to amend the PCT and the PLT has two considerable advantages over any TRIPS-based approach. First, the simple amendment of the Regulations under the PCT could be carried out in a very short period of time. In contrast, any amendment of the TRIPS Agreement would probably require considerable time in order to achieve

[47] See Valerie Normand, "National Implementation", paper presented to the International Expert Workshop on Access to Genetic Resources and Benefit Sharing (Mexico, Oct. 04), available at: <http://www.canmexworkshop.com/documents/papers/I.1.pdf>.

consensus. Second, an amendment of the PCT can be decided by a three-quarters majority of the PCT's Contracting Parties, whereas an amendment of the TRIPS Agreement requires consensus among the WTO's Members.

V. Conclusions

The Swiss proposals submitted to WIPO aim to present a simple and practical way forward. These proposals could be introduced in a timely manner and would not require extensive changes to the provisions of the relevant international agreements, the PCT and the PLT. As the proposed transparency measures do not require modifications to the TRIPS Agreement, they are further evidence of the flexibility that this agreement provides for. The proposals are also intended to enhance cooperation between the competent international forums and the mutual supportiveness of the relevant international agreements.

Disclosing the source can be seen as the "entry point" for access and benefit sharing in the patent system. Disclosing the source would help to build mutual trust between North and South. Moreover, it would strengthen mutual support between the access and benefit sharing system and the patent system.

The proposed declaration of the source of genetic resources and traditional knowledge in patent applications would allow states that are party to a contract on access and benefit sharing to verify whether the other contracting party is complying with its obligations arising under that contract. This transparency measure would not only assist in and simplify the enforcement of these obligations, but would also enable a verification of whether the prior informed consent of the country providing the genetic resources has been obtained and whether provisions have been made for fair and equitable benefit sharing.

The Swiss proposals would thus enable the Contracting Parties of relevant international agreements, including the TRIPS Agreement, the PCT, the PLT, the CBD and the FAO IT, to fulfil their respective obligations. This applies in particular to the Articles 27.1 and 62.1 of the TRIPS Agreement as well as Articles 8(j), 15.4, 15.5, 15.7 and 16.5 of the CBD. These proposals aim to provide the means to ensure that international agreements on intellectual property and the CBD can be implemented in a mutually supportive way. Furthermore, the Swiss proposals would enable the Contracting Parties of the CBD to implement the provisions of the Bonn Guidelines, in particular their Paragraph 16(d), as well as several of the decisions adopted by the CBD's COP6 and COP7. And finally, requiring the declaration of the source would also support the determination of prior art with regard to traditional knowledge, as it would simplify searches of databases of traditional knowledge that are increasingly being established at the local, regional and national level.

Appendix: Switzerland's proposed amendments to PCT-Regulations[48]

Rule 4: The Request (Contents)

Rule 4.17: *Declarations Relating to National Requirements Referred to in Rule 51bis.1(a)(i) to (v) and Rule 51bis.1(g)*

The request may, for the purposes of the national law applicable in one or more designated states, contain one or more of the following declarations, worded as prescribed by the Administrative Instructions:

> (vi) a declaration as to the source of a specific genetic resource and/or traditional knowledge related to genetic resources, as referred to in Rule 51*bis*.1(g).

Rule 48: International Publication

Rule 48.2: *Contents*

(a) The pamphlet shall contain:

> (xi) any declaration referred to in Rule 4.17(vi), and any correction under Rule 26*ter*.1, which was received by the International Bureau before the expiration of the time limit under Rule 26*ter*.1.

Rule 51bis: Certain National Requirements Allowed Under Article 27

Rule 51*bis*.1: *Certain National Requirements Allowed*

(g) Subject to Rule 51*bis*.2, the national law applicable by the designated Office may, in accordance with Article 27, require the applicant to furnish:

> (i) a declaration as to the source of a specific genetic resource to which the inventor has had access, if the invention is directly based on such a resource;
> (ii) a declaration as to the source of traditional knowledge related to genetic resources, if the inventor knows that the invention is directly based on such knowledge;
> (iii) a declaration that the source referred to in (i) or (ii) is unknown to the inventor or applicant, if this is the case.

Rule 51*bis*.2: *Circumstances in Which Documents or Evidence May Not Be Required*

(d) Where the applicable national law requires the applicant to furnish a declaration as to the source (Rule 51*bis*.1(g)), the designated Office shall not, unless it may reasonably doubt the veracity of the declaration concerned, require any document or evidence:

> (i) relating to the source of a specific genetic resource (Rule 51*bis*.1(g)(i) and (iii)) if, in accordance with Rule 4.17(vi), such declaration is contained in the request or is submitted directly to the designated Office;
> (ii) relating to the source of traditional knowledge related to genetic resources, (Rule 51*bis*.1(g)(ii) and (iii)) if, in accordance with Rule 4.17(vi), such declaration is contained in the request or is submitted directly to the designated Office.

Rule 51*bis*.3: *Opportunity to Comply with National Requirements*

(a) Where any of the requirements referred to in Rule 51*bis*.1(a)(i) to (iv), and (c) to (e), and (g), […] is not already fulfilled during the same period within which the requirements under Article 22 must be complied with, the designated Office circumstances, shall invite the applicant to comply with the requirement within a time limit which shall not be less than two months from the date of the invitation. […].

[48] Wording of the proposed amendments is underlined.

Disclosure of origin: time for a reality check?

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I. Overview

Strategically, disclosure of origin has been extremely useful for those developing countries that have advocated it, particularly those keen to delay or block the adoption of a Substantive Patent Law Treaty based on the most protectionist patent rules of the developed world. Nothing in this brief paper should be construed as a criticism of the strategy as it has been deployed so far. But it is nonetheless suggested that for countries wishing to expand their freedoms under international law to tailor their intellectual property regimes in furtherance of their economic, social and cultural interests, it may be better to target intellectual property rulemaking in other areas of the law where the stakes are likely to be much higher than to push aggressively for the introduction of an international disclosure of origin rule that may in fact offer little practical benefit to any national economy or population.

Specifically, this paper draws attention to (a) the limitations of disclosure of origin as a practical measure to reform patent law in a way that favours the interests of bio-culturally diverse developing countries; and (b) to the lack of clarity in the whole disclosure of origin concept.

II. What should be the underlying objectives of disclosure of origin?

It is often unclear what should be the underlying objectives of disclosure of origin. While it is of course entirely up to the countries advocating the disclosure of origin requirement, it is contended that the objectives put forward tend either to be lacking in ambition or alternatively are based on unsubstantiated assumptions.

One common motive appears to be to prevent "biopiracy". The problem here is that the term, like "intellectual property piracy", is a political one that is "strategically vague", which is to say that coinage and advocacy of the term are intended to embrace to the maximum possible extent business practices that may be perceived rightly or wrongly as being exploitative of developing countries and/or indigenous peoples. The problem is that by lumping together behaviour that runs from extreme ends of a continuum, including the highly exploitative and illegitimate at one end (e.g. allegedly the plant patent on ayahuasca and the patents on the "enola bean"), to the perfectly legitimate (e.g. Eli Lilly's commercialisation of the vinca alkaloids derived from the rosy periwinkle) at the other, policy made on the basis of preventing "biopiracy" could actually hinder economic activities that should be encouraged. So what we need to do is to come to an agreement on where to draw the line between the exploitative and illegitimate and the acceptable and legitimate, and then to consider more deeply whether disclosure of origin would actually prevent the former types of activity without necessarily hindering the latter. (Or do we want to stop the latter as well?) One helpful way to achieve this balance may be to investigate some past "biopiracy" cases and to see whether disclosure of origin would have made any difference. Another is to find out objectively how much genuine "biopiracy" actually takes place. It is assumed by many that there is some kind of "global pandemic". But it is contended that there is probably a great deal of exaggeration. In short, how you define "biopiracy" goes a long way towards determining what, if anything, you should do about it. But disclosure of origin should be more ambitious than preventing unfair practices by foreigners. If biological and cultural diversity are sources of high economic value, surely those countries rich in these assets should be seeking to maximise their own effective exploitation of them, while of course recognising the rights of indigenous peoples and local communities that have legitimate property claims over them. Or to put it another way, countries should seek to add value to their own biogenetic and cultural resources. If collaboration with foreign institutions and scientists can help in this respect, patent reforms to regulate access to genetic resources and benefit sharing should surely not prevent equitable collaborative research partnerships but rather encourage them.

III. Should we continue to use the term disclosure of origin? Or are there better alternatives?

The origin of a given resource may be very difficult to establish, and there may be many countries of origin. The distinction between provider or source country on the one hand, and origin country as defined in

the Convention on Biological Diversity (CBD) on the other, is significant. Given that a great many species are not endemic to a single country, the origin of a given resource according to the CBD definition may be several or many countries. For the sake of practicality, it may be better to use the word “source” rather than “origin”. Alternatively, the term “legal provenance” may be the most appropriate term to use since the country of source may not have acquired the resource legally anyway.

IV. What should be the relationship between the genetic material and the claimed invention, and what terminology should be used?

This is a tricky question. Clarification is badly needed of the relationship between the invention and the biogenetic resource and/or associated traditional knowledge that would make the disclosure of origin requirement applicable. In many cases, knowledge and material relevant to an invention may be manifold. Should all sources of knowledge and material be compensated no matter how distant and tangential? This would be hard to justify. The following terms have been suggested, including “based on”, “used in” and “derived from”. Each may have specific practical and legal implications. This is far from being a trivial issue and requires an honest and informed debate. Ideally, it ought to be discussed in a multi-stakeholder setting which includes biotechnology firms and patent practitioners as well as providers.

V. What should be the consequence of failure to disclose origin or of disclosing origin falsely?

Possibilities may vary from returning the patent application, to rejecting or revoking the patent, to granting the patent but enforcing fines and criminal sanctions for non-compliance or fraudulently disclosing origin. The author of this paper has no strong views either way but sooner or later proponents may have to agree on this if for no other reason that it may have implications for the TRIPS-compatibility of the requirement.

VI. How should disclosure of origin be incorporated into international law, and what might be the implication of the different possible decisions on this?

Article 29 of TRIPS would probably be the most logical place for incorporating the requirement. But amending TRIPS will likely entail a high cost. Strategically speaking it may be worth mentioning that disclosure of origin is a reform targeted at patent activity in the field of biotechnology and biochemistry. Advocating disclosure of origin therefore implies accepting the practice of patenting in these fields. And yet some countries in favour of disclosure of origin seem to be opposed to—or at least highly sceptical of—the patenting of life forms and natural products. If a sound negotiating strategy requires clarity, the fact that this seems rather contradictory is cause for some reflection. To repeat what was said at the outset, for countries wishing to expand their freedoms under international law to tailor their intellectual property regimes in furtherance of their economic, social and cultural interests, it may be better to target intellectual property rulemaking in other areas of the law where the stakes are likely to be much higher, than to push aggressively for the introduction of an international disclosure of origin rule that may in fact offer little practical benefit to any national economy or population.

VII. Conclusions: what practical difference would disclosure of origin make anyway?

This is difficult to answer. At a practical level, most biogenetic material used for commercial research does not lead to a patented invention, even less to a valuable product, and most biotech-related inventions are not closely related to imported biogenetic material. So the requirement may be relevant to a tiny proportion of income-generating life science products.

More fundamentally, the burden of proof should be placed on those advocating reform. So far, advocates of disclosure of origin have not made a convincing case that disclosure of origin will do anything to improve the social and economic conditions of developing countries or of their indigenous peoples. If it is merely a moral issue rather than an economic one, then this should be made clear.

Conclusions

1. Requirements for the disclosure of origin and legal provenance of genetic resources and traditional knowledge in intellectual property applications (especially patents and plant breeders rights) currently offer the most transparent and practical solution to generate positive synergies and mutual support between the access and benefit sharing (and protection of traditional knowledge) regime being negotiated under the CBD and the international intellectual property system and the TRIPS Agreement in particular.

2. Arguments in favour of the disclosure of origin and legal provenance requirements are solid and consistent in their legal and technical foundations. From developing and developed countries alike, numerous technical and academic papers have assessed the legal viability and validity of these requirements in the light of international intellectual property law and standards as set by the TRIPS Agreement in particular. Additional exchange of national experiences on the practical application of this mechanism at the national and regional levels was considered as an area for further research.

3. While there may be some variances with regard to the scope, consequences and practical operations of these requirements, most experts agree that, in general, the requirements for disclosure do not run counter to international intellectual property law, agreements and the TRIPS Agreement in particular. It is worth noting that whereas some proponents advocate for disclosure of legal provenance as a key aspect of disclosure debates, others focus more on the disclosure of geographical origin as the means through which misappropriation may be prevented.

4. Specific issues – with practical implications – regarding disclosure of origin and legal provenance requirements include: determining what is the trigger for the disclosure requirements and whether it is mandatory or voluntary in nature; what are the legal consequences of not disclosing – prior to the granting of a right (during the application process) or after the right (e.g. patent) has been granted; what are the costs of implementing a disclosure system, particularly with regard to possible burdens on already stretched (in terms of personnel and resources) national authorities especially in developing countries; what is disclosed –information on specific genes? Information on biological specimens upon which inventions originally derived? Traditional knowledge in a specific form? Should disclosure also be required in the case of synthetic products? And how should derivatives be defined? Would derivatives also trigger disclosure requirements?

4. It is important to note that disclosure of origin and legal provenance requirements will not solve nor address all of the concerns related to illegal or irregular access to and use of genetic resources and traditional knowledge (misappropriation and “biopiracy”). However, these requirements, if supported by other instruments, such as a certificate of origin and enforcement measures, could lead to increased transparency and the formulation of a mechanism which would be part of a broader set of measures geared towards preventing misappropriation and biopiracy in all of its forms. Other measures may, among others, include the development of effective laws to regulate access to genetic resources and protection of traditional knowledge; and the development of policy, legal or administrative measures in countries using genetic resources and traditional knowledge (user measures) to support actions by countries providing resources. These measures may also help to make prior informed consent operational at the national and international levels.

5. Disclosure of origin (and legal provenance) requirements do not run counter to international intellectual property agreements nor to the TRIPS Agreement in particular. It is however important to stress that efforts should be made to avoid entering into bilateral or multilateral intellectual property agreements (for example in the context of Free Trade Agreements) that may curtail the opportunities and leeway that the TRIPS Agreement provides for policy and legislative implementation at the national level by impeding the inclusion of disclosure requirements in national or even regional legislation.

6. One possible alternative may be to consider disclosing origin and legal provenance of biological specimens (and related traditional knowledge) in all cases where inventions may have – at some point in time, even if years back – originated from these specimens or their biological or genetic materials.

7. For developing, biodiversity rich countries (traditionally providers of biological and genetic resources) it is important to ensure that, if disclosure of origin and legal provenance requirements are to be successful, effective national legislation governing access to genetic resources and traditional knowledge are in place to legitimise access to and use of these resources and knowledge. Furthermore, these countries

should also be prepared to ensure that their national intellectual property authorities are in a position and have the capacity to apply and enforce disclosure requirements.

8. Disclosure implies commitments and compromises both in the case of countries acting as users of resources and as providers of resources. Most policy and legal developments and efforts have been made by countries acting as providers of resources (e.g. through access laws). However, in order to achieve the realisation of the CBD objectives (in the area of ABS), similar but different commitments are required from countries using resources and traditional knowledge. Rather that complicating the intellectual property system, disclosure requirements could help to endow it with fairness, transparency and added legal certainty, especially in areas of innovation where genetic resources and traditional knowledge may be directly or indirectly used in research and development processes.

9. Some experts and countries also advocate minor adjustments to the Patent Cooperation Treaty and the Patent Law Treaty as a means to include disclosure requirements. According to this view there is no need to make the requirement mandatory, advocating instead for a voluntary system. This perspective also considers that linking the mechanism to an international examination process could improve patent examination quality and provide an international response to the misappropriation problem.

10. Once this is achieved (including references to the disclosure requirement in the Hong Kong Declaration), it may be necessary to work on specific analyses of how the disclosure of origin and legal provenance requirements could materialise in national and international law. Drafting model provisions in model legislation could serve to evaluate whether and how the conservation, sustainability and benefit sharing goals of the CBD could be realised.

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