

PRIOR INFORMED CONSENT AND ACCESS TO GENETIC RESOURCES

Paragraph 19 of the Doha Ministerial Declaration instructs 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). Work in the TRIPS Council has particularly focused on whether and how disclosure requirements would contribute to a more coherent and supportive relationship. One of the key provisions of the CBD is the requirement that access to genetic resources be subject to prior informed consent (PIC). As a result, ensuring the intellectual property system adequately considers and implements PIC is one of the fundamental elements being addressed in the context of Paragraph 19 negotiations.

The objective of the brief is to contribute to these and other ongoing negotiations by succinctly analyzing the PIC principle and the challenges faced by 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 briefly examine the relationship between intellectual property and the recognition and implementation of PIC. Finally, Section V will offer some concluding thoughts on ways the implementation of PIC could be supported in the World Trade Organization (WTO) context on the road to Hong Kong.

Background: evolution of the concept of PIC

PIC has developed into an essential principle in international relations as a necessary corollary to the permanent sovereignty of States over their natural resources.¹ It has also become more and more important to sustainable development as global interdependencies, both economic and environmental, increase. Beginning in 1989 with the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, multilateral environmental agreements, for instance, consistently acknowledge 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 recognized in various contexts, including the transboundary movements of hazardous and toxic materials, genetically engineered organisms, and persistent organic pollutants.²

The application of the PIC principle to the rights of indigenous peoples and other local communities is also increasingly appreciated. 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 Economic, Social, and Cultural Rights, indicate that prior

¹ Article 3 of the CBD recognizes “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....”

² 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>.

informed consent of indigenous peoples is central to effectuating rights within these conventions, including the right to non-discrimination and the right to property.³ PIC is indeed viewed by indigenous and other local communities as central to securing their rights in the context of logging, mining, resettlement, dam building, and access to genetic resources activities. As a result, over the last few decades, PIC has also been promoted by voluntary guidelines, social and environmental codes, contractual agreements and political referendums.⁴

PIC in the context of access to genetic resources

In the context of access to genetic resources, the relevance of PIC is particularly significant due to 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 and holders. Several cases of misappropriation, including cases for which patents have been obtained in “user” countries, have been documented.⁵ In the context of access to genetic resources, therefore, PIC does not focus on preventing adverse impacts of movement of materials into a country, as in the hazardous wastes or genetically engineered organisms contexts. Rather, the emphasis is on preventing exploitation and movement out of the country of potentially beneficial materials, as well as ensuring that benefits derived from use of the materials accrue to the provider country.

A. Rights of States to PIC

Article 15 of the CBD recognizes the right of national governments to PIC as an integral element to create adequate conditions for access to genetic resources in an environmentally sound manner. Moreover, the

³ 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 Economic, Social and Cultural Rights, Dec. 16, 1966, 993 U.N.T.S. 3, available at http://www.unhcr.ch/html/menu3/b/a_cesr.htm. For example, within the last two 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 interpreting the American Convention on Human Rights, the Inter-American Court of Human Rights determined that an indigenous community’s right to property was violated by the failure of the State to ensure that prior informed consent had been obtained from the community prior to logging.

⁴ For example, in 2000, the World Commission on Dams issued a set of voluntary PIC guidelines recognizing 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.

⁵ 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.

lack of PIC impedes the fulfillment 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 utilization of genetic resources, including by appropriate access to genetic resources."

Though, as mentioned, PIC in the context of access to genetic resources has particularities, activities to elaborate PIC requirements in other contexts can inform its development. Though in the biodiversity framework, it is the country out of which substances are transported that faces potential harm and has the right to provide PIC, information concerning what PIC means, when the information should be provided, how responsibilities for developing and providing information are allocated, and how due process concerns are addressed may be extremely valuable. In addition, the Sixth Conference of the Parties of the CBD developed the Bonn Guidelines, which provide direction on elements of the procedure to obtain PIC. For instance, the Bonn Guidelines envisage mechanisms to involve stakeholders; suggest reasonable timing and deadlines, specification of the type of use, and linkage with mutually agreed terms; and detail procedures for obtaining consent as well as a description of the general procedure for access.⁶

B. Rights of indigenous people and other local communities to PIC under the CBD

In regard to PIC for indigenous and other local communities, distinction between the context of genetic resources and others are much less pronounced.⁷ In all cases, PIC is a necessary corollary of the rights of indigenous and other local communities to participate in the management of resources on the lands they occupy. As a result, though the CBD does not refer expressly to PIC of indigenous and other local communities, recent discussions have also focused on this aspect. According to article 8 of the CBD, 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 utilization. PIC is currently seen as critical to securing these rights.

In addition, though PIC procedures necessarily have culturally specific variations, a number of commonalities or "best practices" can already be identified and many communities have indeed articulated PIC procedures.⁸ Some lessons from these instruments include: a) the person seeking access must obtain consent from every affected community in the traditionally recognized manner; b) before seeking consent, the person seeking access should distribute and hold community discussions regarding all relevant information 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.

⁶ Several parties are currently working to develop national legislation in response to these guidelines. The Seventh Conference of the Parties of the CBD recognized "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.

⁷ It generally constitutes a consultation process – an open dialogue between the community and the individuals interested in conducting activities on their territory. Differences do exist, however. These include, for example, differences in the abilities of communities to be aware of and physically control the activities and in the complexities of legal structures that govern use of the resources.

⁸ Laird, Sarah, ed., (2001), *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice*, ed. Sarah A. Laird, and World Commission on Dams guidelines

International Treaty on Plant Genetic Resources

The International Treaty on Plant Genetic Resources (ITPGR) adopted on 3 November 2001, entered into force on 29 June 2004. The treaty, negotiated under the auspices of the FAO, responds to concerns over the increasing privatization and monopolization of plant genetic resources for food and agriculture and the potentially negative impacts this trend may have on agricultural biodiversity. The ITPGR, which is in harmony with the Convention on Biological Diversity, thus provides for the special needs of plant genetic resources for food and agriculture. In particular, it establishes a multilateral system of facilitated access and benefit sharing for selected plant genetic resources. Because the nature of the plant breeding process calls for a broad range of plant genetic resources as inputs into any one product, creating 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, 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 regards 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.

C. Intellectual property and the recognition and implementation of PIC

Despite the growing recognition and development of the PIC principle, its implementation in the genetic resources context still presents several difficulties. These include those related to lack of laws and regulations, burdensome procedures and excessive costs, non-articulated community procedures, the lack of desire of many communities and some governments to facilitate access, and, perhaps, unrealistic expectations. Additionally, questions remain about what mechanisms are available for enforcement of PIC requirements and how effective these mechanisms are. 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 pursuant to which PIC requirements could be enforced.

Many parties to the CBD, as well as local communities, believe that a fundamental enforcement mechanism should be the intellectual property system. In this regard, coherence with the objectives of the CBD and, in particular, the requirements for PIC, is seen to compel international intellectual property norms to require evidence of PIC in the process of acquisition of rights. Mechanisms to implement PIC in patent filing and patent granting procedures, for instance, have been developed at the national and regional levels. These mechanisms include voluntary and mandatory PIC requirements, and incorporate various approaches to enforcement. The view by 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 describing how this might be accomplished, either through a new international instrument developed through, and perhaps as a protocol to, the CBD, or through amending the TRIPS Agreement.

IV. Conclusions

As the TRIPS Council hastens its work on ensuring the mutual supportiveness between the TRIPS Agreement and the CBD, an element that must not be overlooked is PIC. PIC is an essential principle in international relations and, in the context of genetic resources, is fundamental for the fulfillment the objectives of the CBD. Moreover, even though PIC is currently required in patent applications at the

national and regional levels, it is only through a mandatory international requirement that an effective recognition and implementation will be achieved.

The recognition of PIC is also essential from the perspective of the legitimacy of the intellectual property system. In intellectual property law, equitable principles require the refusal to grant or to enforce intellectual property rights when they would be or have been procured by fraud or deception. The contrary would allow the intellectual property system to assist and reward the 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.