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TRADITIONAL KNOWLEDGE, GENETIC RESOURCES & DEVELOPING COUNTRIES IN ASIA: THE CONCERNS

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"A man can only attain knowledge with the help of those who possess it…One must learn from him who knows."
Georges Gurdjieff (1866-1949)[1]

INTRODUCTION

The Asian region of the globe is endowed with very rich biodiversity. Asia is believed to have more than 15,000 endemic plant species, as well as being home to two out of twelve "mega-biodiversity centers."[2] This region is also the primary and secondary center of diversity for many crop plants, having large genetic diversity in these crops. Biodiversity is attributed to the way of life of peoples, which contributed to the evolution of enormous amounts of rich traditional knowledge (TK) on the conservation and sustainable use of biodiversity.[3] But unfortunately, the region has inadequate

[1] P.D. OUSPENSKY, IN SEARCH OF THE MIRACULOUS 39-40 (Tatiana Nagro 1976) (1949).
[2] Conservation International: Biodiversity Hotspots, http://www.biodiversityhotspots.org (follow "HOTSPOTS SCIENCE" hyperlink; then follow "KEY FINDINGS" hyperlink; then follow "Endemic Plant Species" hyperlink) (last visited Sept. 17, 2007).
[3] S. Bala Ravi, *Access and Benefit Sharing: Policy Concerns For South Asian Countries*, S. ASIA WATCH ON TRADE ECON. & ENV'T, No. 12, 2005, at 1, 1.

technological ability to turn the bio-resource and related TK wealth into economic strength, which can help in poverty alleviation.[4]

Prior to 1992, with no international or national laws to regulate access to genetic resources, traditional knowledge resources were considered common heritage to all mankind.[5] As a result there was a rapid increase in the commercial use of the knowledge and biological resources of technologically poor but biodiversity rich developing countries by technologically sound but biodiversity poor developed nations.[6] The developing countries, on realizing this situation, felt the need to devise a fair and equitable benefit sharing mechanism, which can be instrumental to capitalize on their bio-resources and related TK. At the international level, it was stressed in various forums; most notable are the Convention on Biological Diversity (CBD), World Intellectual Property Organization (WIPO), and the TRIPS Council (Trade-Related Aspects of Intellectual Property Rights). At the national level, various developing countries introduced, to some extent, effective legislation to desist the misuse of their biodiversity and related TK.[7]

Lying at the heart of this article is a simple question: How have the developing countries in Asia dealt with the complex and controversial nature of the legal protection of traditional knowledge? Moreover, observations will be made concerning the issues of access to genetic resources and benefit sharing, including the related intellectual property rights associated with the use of traditional knowledge. This article aims at raising some of the key issues that have occurred in the implementation of the national access legislation. It is illustrated by several case studies, namely, *Neem,*[8] *Turmeric,*[9] *Basmati,*[10] and *Arogyapaacha* (*Jeevani*).[11]

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[4] *Id.*
[5] Siddhartha Prakash, *Towards a Synergy between Biodiversity and Intellectual Property Rights*, 2 J. WORLD INTELL. PROP. 821, 821 (1999).
[6] *Id.*
[7] Biswajit Dhar, *Reconciling TRIPS and CBD: Through Disclosure Requirement*, S. ASIA WATCH ON TRADE ECON. & ENV'T, No. 11, 2005, at 1, 4.
[8] *See* Christian Bastuck, 'Biopiracy' and Patents – Developing Countries' Fears are Exaggerated 17 (Apr. 8, 2006) (unpublished LL.M. dissertation, University of Cape Town) (on file with author).
[9] *See id.* at 22.
[10] *See* Muriel Lightbourne, *Of Rice and Men: An Attempt to Assess the Basmati Affair*, 6 J. WORLD INTELL. PROP. 876, 876 (2003).
[11] Katy Moran, *Lessons from Bioprospecting in India and Nigeria*, CULTURAL SURVIVAL Q., Issue 24.4, Jan. 31, 2001, at 1, 2.

I. INTELLECTUAL PROPERTY RIGHTS, TRADITIONAL KNOWLEDGE AND GENETIC RESOURCES

It is often said that we live in a "global village," where increasing complexity makes each actor interdependent on one another. In the global markets of current age, small farmers in a remote village may be affected by import regulations on the other side of the globe. Similarly, TK holders are affected by an increasing number of factors, especially when it comes to their IP needs and expectations.[12] In addition, the traditional knowledge of indigenous societies has been linked to the debate over genetic resources, with the problems of illegal, unfair, and unlawful flow and use of genetic resources applying likewise to traditional knowledge.[13]

This section elaborates some of the key factors, processes, and conditions which shape IP needs; for example, the impact of IPRs on traditional knowledge and biodiversity, the need for the protection of TK, and an overview of genetic resources.

1. The Impact of IPRs on TK and Biodiversity

Intellectual property is playing an important role in maneuvering the lead-time advantage and business strategies of economies and industries.[14] It is a form of knowledge or intellectual activity in various ways in the value chain. One of the important factors in this value chain is extending IP rights to TK protection.[15] Technical understanding of IP is necessary for the exploration of its role in TK protection. Additionally, effective IP systems that protect and maintain TK will depend on the more thorough understanding of the various systems of innovation and intellectual property, as well as upon the participation of all stakeholders, governments, and local

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[12] World Intellectual Property Organization Report, *Intellectual Property Needs and Expectations of Traditional Knowledge Holders*, 1998-1999 REPORT ON FACT-FINDING MISSIONS ON INTELLECTUAL PROPERTY HOLDERS, at 66, 69 (2001) [hereinafter *WIPO Report*].

[13] MANUEL RUIZ, ACCESS TO GENETIC, INTELLECTUAL PROPERTY RIGHTS AND BIODIVERSITY: PROCESSES AND SYNERGIES 7 (International Union for Conservation of Nature and Natural Resources 2004).

[14] Ngo Van Lam & Thitapha Wattanapruttipaisan, *Intellectual Property Creation as Invention Patents for Development and Competitiveness in ASEAN*, 8 J. WORLD INTELL. PROP. 625, 625 (2005).

[15] *Id.*

communities in the process. It is believed that IP is not only meant for conferring property rights, but also for the recognition and respect for the contributions of human creators. In this regard, IP is crucial in protecting the dignity of holders of TK by recognizing property rights in relation to such knowledge, thus granting those holders a degree of control of its use by others.[16]

However, it is believed that IPRs (Patents) do have some negative impacts on the principle of sovereign rights of countries over their genetic resources and to some extent on sustainable use, in the form of direct and indirect misappropriation of biodiversity, genetic resources, and traditional knowledge, which is termed as "biopiracy." IPRs (Patents) are criticized for legitimizing "biopiracy" by increasing the concentration of research and development capacities in the hands of the private sector (mainly consisting of biotechnology companies, universities, and research institutions) or financially depending on private sector funds, promoting widening of the technology gaps between North and South and restricting availability of research materials. Some of the other arguments concerning the negative impacts of IPRs over biodiversity conservation are that IPRs have a tendency to homogenize agricultural diversity, tend to displace native and traditional crops, are responsible for imposing restrictions on exports of traditional medicinal plants (which leads to impacting *in situ* conservation efforts), and also impose limitations on saving, using, and selling farm-saved seeds by small farmers and indigenous communities.[17] Finally, IPRs are also critiqued for limiting the possibility of accessing relevant technology.[18]

Even if all the above criticisms are believed to be true, one cannot deny the protection afforded to TK and biodiversity by IPRs, so far, which is evident in some of the famous cases like *Hoodia,*[19] *Turmeric*, *Neem*, and *Basmati*.

The following section discusses the need for the protection of traditional knowledge.

2. Why Protect Traditional Knowledge?

Traditional knowledge, developed from experience gained over time and adapted to a local culture and environment, has always played-and still plays-an important role in the daily lives of the majority of people globally and is considered to be an essential part of

[16] *WIPO Report*, *supra* note 12, at 57.
[17] RUIZ, *supra* note 13, at 5.
[18] *Id.*
[19] Bastuck, *supra* note 8, at 31.

cultural identities. It is vital to the food security and health of millions of people in the developing, and even developed, world.[20]

According to the World Health Organization Fact Sheet No. 134, last updated in May 2003, developing countries in Africa, Asia, and Latin America use traditional medicine to meet some of the country's healthcare needs.[21]

Traditional knowledge can be defined as, "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity."[22]

It is now a well established fact that TK plays a vital role in the world economy and is valuable not only to those who depend on it in their daily lives but also to modern industry and agriculture.[23] On the international level, developing countries raised the issue of protection of TK because of their differing concerns and perspectives. A considerable number of countries, rich in genetic resources and TK, believe that the traditional communities have been deprived of the benefits accrued from the use of their knowledge, innovations, and practices, which have been monopolized by others without their approval and without rewarding them for their knowledge.[24]

These developing countries emphasize the protection of TK because it is vital for the conservation and sustainable development of the environment, "as much of the world's crop diversity has been conserved and preserved by indigenous/local peoples, which has helped in the protection and conservation of biodiversity."[25] Another apprehension is that the biological resources increasingly subjected to IPRs and patents are possibly exposed to extinction, which is a matter of concern over their exhaustibility and loss of habitat and also the loss

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[20] Bernard O'Connor, *Protecting Traditional Knowledge: An Overview of a Developing Area of Intellectual Property Law*, 6 J. WORLD INTELL. PROP. 677, 678-79 (2003).
[21] World Health Organization, *Traditional Medicine, Fact Sheet No. 134*, at 1 (2003).
[22] Convention on Biological Diversity art. 8j, June 5, 1992, 1760 U.N.T.S. 79 [hereinafter *CBD*].
[23] Marcelin M. Tonye, Sui Generis *Systems for the Legal Protection of Traditional Knowledge and Biogenetic Resources in Cameroon and South Africa*, 6 J. WORLD INTELL. PROP. 763, 763-69 (2003).
[24] Martin A. Girsberger, *Transparency Measures under Patent Law regarding Genetic Resources and Traditional Knowledge*, 7 J. WORLD INTELL. PROP. 451, 451-54 (2004).
[25] Surinder Kaur Verma, *Protecting Traditional Knowledge. Is a* Sui Generis *System an Answer?*, 7 J.WORLD INTELL. PROP. 765, 769 (2004).

of lifestyles and livelihoods to indigenous communities, which can severely affect food security.[26]

The movement of traditional communities from their natural habitat and their increasing amalgamation with modern society has also necessitated the protection of TK, as this movement can lead to its total extinction and thus affect biodiversity.[27] For instance, in Nepal it has been shown that some indigenous environmental management systems are not "traditional," but rather have evolved recently in response to rapidly changing ecological conditions in the face of modern development pressures.[28] Lack of motivation in the younger generation to learn the traditions is yet another reason cited for the protection of TK, as it is believed that TK will suffer extinction with the death of the elders of the community.[29] There is also a dire need to make these communities control TK for their economic uplift and growth.[30]

Given the varied reasons for protecting TK and the broad nature of the subject matter, there is no single procedure through which it can be protected or promoted. Therefore, the protection of TK raises a whole series of questions which can be considered common to the protection of established forms of intellectual property and some which are not so common, and thus need separate consideration.[31] Current IPR regimes are believed to be the most active in providing protection to TK, but have faced criticism:

> [S]ome indigenous peoples have reiterated that such regimes may in effect discriminate against their interests, amounting to a "new form of colonization," linked to "indigenous knowledge piracy." A basic dilemma is that some indigenous communities may consider inclusion of traditional knowledge in IP regimes as unethical by encouraging commodification of such knowledge. [32]

Some of the technical problems which can possibly be encountered in the extension of IPRs to traditional knowledge include

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[26] *Id.*
[27] *Id.*
[28] Benjamin J. Richardson, *Indigenous Peoples, International Law and Sustainability*, 10 REV. EUR. COMMUNITY & INT'L ENVTL. L. 1, 10 (2001).
[29] Verma, *supra* note 25, at 769-70.
[30] Daniel Gervais, *TRIPS, Doha and Traditional Knowledge*, 6 J. WORLD INTELL. PROP. 403, 404 (2003).
[31] O'Connor, *supra* note 20, at 697.
[32] Richardson, *supra* note 28.

the following issues. First, IP rules demand establishment of individual or joint authorship so as to confer protection, which may cause problems in relation to indigenous communities where TK has been passed from generation to generation and may be collectively owned.[33] It is cumbersome to delineate the indigenous knowledge due to considerable "blurring" and "permeability" of the knowledge and cultural boundaries between indigenous and dominant society. Second, the indigenous knowledge is dynamic and evolving, and it is most likely that IPRs will restrict and inhibit the sharing of information among indigenous communities, which can hinder evolving patterns. Third, indigenous knowledge and products are considered part of an existing body of knowledge and practice and thus do not meet the novelty criterion of certain IP laws (e.g., patents). Finally, the restricted duration of IP protection to knowledge processes and products is also a reason for concern. After the expiration of IPR, TK would be freely available to everyone.[34]

Despite the continuing controversy, it is feasible that IP regimes could be controlled or reworked to extend protection to the indigenous peoples' knowledge. Community based rights to cultural and intellectual property can be a suitable solution.[35] The establishment of a common system for the protection of TK and the creation of rights, which give benefits to their holders, may speed up innovation and the spread of knowledge from regional communities to the international community.[36] In practice, the establishment of such a common system has been decided by states in *ad hoc* ways. This common system is generally termed as the "new" or *sui generis* form of protection. The main features consist of prior informed consent and arrangements for sharing of benefits from commercialization of genetic resources and traditional knowledge.[37] This system is thoroughly discussed in the following section.

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[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] O'Connor, *supra* note 20, at 698.
[37] Somesh K. Mathur, *Trade-Related Aspects of Intellectual Property Rights and Copyright Provisions. Some Issues with Special Reference to Developing Countries*, 6 J. WORLD INTELL. PROP. 65, 84 (2003).

3. Overview of Genetic Resources

It is an established fact that most of the major agricultural crops were domesticated over a period of thousands of years in the areas which are currently considered developing countries. It took hundreds and thousands of years for those genetic resources to flow from these developing countries to Europe and North America, and undoubtedly it provided much of the early biological foundation for agriculture in today's developed countries. The current hot debate in most of the international forums involves the economic and developmental benefit of early crop transfers to "gene poor" Europe and North America, and unequal benefits offered to Asian and African donors of this genetic material.[38]

It is pertinent to clarify the term "*genetic resources*" before highlighting the current state of affairs regarding its appropriation by the developed world and the demands of developing countries. The term "*genetic resources*" builds upon the definition of "*genetic material*," which is "any material of plant, animal, microbial or other origin containing functional units."[39] Genetic material includes all biological material where there are functional units of heredity.[40] Being both reproducible and highly portable, genetic resources exist within natural habitats (termed as *in-situ* conditions) and outside such ecosystems (*ex-situ*). States in possession of genetic resources with *in-situ* conditions (countries of origin) can be differentiated from States supplying such resources either from *in-situ* or *ex-situ* sources (providing countries) and States using these resources (user countries).[41]

Throughout the negotiation of the CBD, the issue of genetic resources generated a great amount of negotiating "heat" because developing countries were adamant that they would not be able to desist continuing misappropriation of their genetic resources. Somehow in the latter stages of the CBD talks this issue was resolved, in part as the result of the inclusion of a provision that confirmed the authority of national governments over their genetic resources (i.e., genetic resources were the common concern but not the common

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[38] Cary Fowler, Melinda Smale & Samy Gaiji, *Unequal Exchange? Recent Transfers of Agricultural Resources and Their Implications for Developing Countries*, 19 DEV. POL'Y REV. 181, 181-82 (2001).

[39] *See CBD*, *supra* note 22, art. 2, §§ 9-10.

[40] Morten Walløe Tvedt, *Elements for Legislation in User Countries to Meet the Fair and Equitable Benefit-Sharing Commitment*, 9 J. WORLD INTELL. PROP. 189, 194 (2006).

[41] Stephen Tully, *The Bonn Guidelines on Access to Genetic Resources and Benefit Sharing*, 12 REV. EUR. COMMUNITY & INT'L ENVTL. L. 84, 88 (2003).

heritage of mankind).[42] This agreement is clearly mentioned in Article 15 of the CBD, which provides that the authority to determine access to genetic resources lies with national governments and is subject to national legislation. The genetic resources being provided are only those from contracting parties who are countries of origin or parties who have acquired those resources in accordance with the Convention. The text also stressed the need for benefit-sharing obligation (ABS), focusing on sharing "the benefits arising out of the utilization of genetic resources."[43] Prior informed consent (PIC) would form the basis for transactions involving genetic resources.

Some observers have termed the agreement mentioned above as "the grand bargain," where developing countries would provide access to their genetic resources in return for resulting economic benefits derived from developed countries' use of these genetic resources, describing this as the "equity issue."[44] It is in this light that the subsequent development of the ABS regime and PIC regarding protection of genetic resources and related TK may be instructively viewed.

II. *SUI GENERIS* PROTECTION OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE

Sui generis is a Latin phrase which means "of its own kind." It is a system which has been designed specifically to address the needs and concerns of a particular issue. It is patterned on completely different lines than the current IP system. Some observers also use the term to refer to new IP or IP-like rights. Calls for a "*sui generis* system" of protection of TK and genetic resources (GRs) are heard very frequently.[45]

Developing countries would like to see faster progress toward an international regime for better protection of the holistic character of TK and to tackle the problem of illegal acquisition of GRs, and a *sui generis* system, according to these countries would be the most

[42] LYLE GLOWKA ET AL., A GUIDE TO THE CONVENTION ON BIOLOGICAL DIVERSITY 3 (Int'l Union for Conservation of Nature and Natural Resources 1994).
[43] *CBD*, *supra* note 22, art. 1.
[44] Timothy J. Hodges & Anne Daniel, *Promises and Pitfalls: First Steps on the Road to the International ABS Regime*, 14 REV. EUR. COMMUNITY & INT'L ENVTL. L. 148, 148 (2005).
[45] *WIPO Report*, *supra* note 12, at 24.

appropriate option to address the issue.[46] This option has focused almost entirely on reaffirming the principle of national sovereignty over genetic resources. It has recognized the role of the state in the preservation and protection of TK and the complementary nature of defensive and positive measures relating to the protection of GRs.[47]

As of February 2002, at least twenty-two countries and certain regional integration organizations had made or were in the process of making available a *sui generis* form of legal protection for TK related subject matter.[48] The initiatives that have been taken at the national level have taken two forms. First, various countries through an official decree have recognized the rights of the traditional communities over the resources they have been using, including knowledge, technologies, and practices. Second, countries have taken steps to implement the commitments that they have made as signatories to the CBD. These initiatives are in two important forms. The first is that they provide for the prior informed consent of traditional communities for exploration of the biological resources. The second initiative is that they recognize the need to develop an organized institutional set up, which can ensure fair and equitable sharing of benefits with the traditional communities, should the resources be exploited commercially.[49] Both of these initiatives are discussed hereinafter.

1. Prior Informed Consent

The PIC concept was originated in the medical field, where patients give consent to treatment based on information provided by a doctor or surgeon. In international law, it was used earlier concerning trans-boundary movements of hazardous wastes.[50] The issue of PIC is not new even to the patent regime, which in the case of joint inventors and employees' inventions requires evidence of their consent for the grant of patent. Making this requirement compulsory in the case of biological inventions related to TK therefore is not a demand alien to

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[46] Biswajit Dhar & R.V. Anuradha, *Access, Benefit-Sharing and Intellectual Property Rights*, 7 J. WORLD INTELL. PROP. 597, 626-28 (2004).
[47] Verma, *supra* note 25.
[48] World Intellectual Property Organization, *Review of Existing Intellectual Property Protection of Traditional Knowledge* 6 (2002).
[49] Dhar & Anuradha, *supra* note 46, at 626.
[50] Anne Perrault & Maria Julia Olivia, Prior Informed Consent and Access to Genetic Resources, WTO Public Symposium, Dialogue on Disclosure Requirements: Incorporating the CBD Principles in the TRIPS Agreement on the Road to Hong Kong 1 (April 21, 2005).

patent law.[51] However, making PIC a condition of patentability calls for certain important threshold questions, which need to be addressed. How may PIC be achieved? How can it be implemented in order to provide better protection to TK and related genetic resources? What kind of hurdles may be encountered in its implementation?

According to CBD, the legal Providing Contracting Party (PCP) of the genetic resources is the national government or their authorized agencies. The PCP is required to define a framework, which will facilitate provision of relevant and adequate information on the material to the Accessing Contracting Party (ACP).[52] The CBD also states that access to resources is subject to the prior informed consent of the provider of such resources. In this regard paragraph 31 of the Bonn Guidelines requires that the PIC "should be obtained…" from such local communities, "in accordance with their traditional practices, national access policies and subject to domestic laws."[53] However, in the case of access to TK, innovations, and practices of indigenous and local communities, the Conference of the Parties (CoP) emphasized obtaining PIC approval of holders of such knowledge, innovations, and practices.[54]

The question of how "prior informed consent" may be achieved is best answered by CBD, which mandates PIC for access only in respect to the "country of origin," but at the same time it has been argued that it should also operate at the level of the local community when its knowledge, innovations, and practices are to be accessed by outsiders. Indeed, it is authorized by Article 8(j), which used the language "approval" and "involvement of communities for such use."[55] For instance, the relevant law in the Philippines recognizes this by providing basic elements in consensus building in

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[51] Christopher Heath & Sabine Weidlich, *Intellectual Property: Suitable for Protecting Traditional Medicine*, 2003 INTELL. PROP. Q. 69, 76.

[52] Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Fifth Meeting, Decision V/16, at 140, U.N. Doc. UNEP/CBD/COP/5/3 (May 15-26, 2000).

[53] Secretariat of the Convention on Biological Diversity [CBD], *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization*, *delivered to the CBD*, at 10, U.N. Doc. UNEP/CBD/COP/6/20 (2002).

[54] Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Sixth Meeting, Decision VI/24, at 270, U.N. Doc. UNEP/CBD/COP/6 (Apr. 7-19, 2002).

[55] R.V. Anuradha, *IPRs: Implications for Biodiversity and Local and Indigenous Communities*, 10 REV. EUR. COMMUNITY & INT'L ENVTL. L. 27, 30 (2001).

the community, which include information dissemination to all members of the concerned people, assessment of the concerns and issues by appropriate assemblies in accordance with customs and traditions, and recognition by a council of elders and affirmation of such decision by all members of the community.[56]

Mugabe opines that a country's PIC legislation is only as effective as the institutional and technical capacities available to implement it. These factors analyze the complexities involved in the creation of national PIC legislation.[57] The main impediment is to get the government to introduce the legislation and then enforce it, which often is a time-consuming process. Hence, more refinement of the current laws is suggested so as to create a sequential approach, such as initiating with a general law or policy, which can be followed by more thorough legislation. It is likely to be passed speedily and to meet with less criticism from different interest groups. Another of Mugabe's suggestions is the "imposition of a temporary prohibition on all genetic exports until full national legislation is set up and all parties comply."[58]

The major hurdle to implementation at the national level is the intricate nature of the relationship between governments and indigenous societies. Some observers and non-government organizations (NGOs) have pointed out certain tensions that have arisen between them. In a situation where the government claims complete sovereignty, how does one ensure that any benefits accrued from the use of such traditional sources will be granted to the original communities? These are the issues which require more consideration.[59]

2. Access and Benefit-Sharing (ABS)

When world leaders signed the Convention on Biological Diversity in 1992, they agreed to its third objective: "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all

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[56] An Act to Recognize, Protect, and Promote the Rights of Indigenous Cultural Communities/ Indigenous Peoples, Creating a National Commission on Indigenous Peoples, Establishing Implementing Mechanisms, Appropriating Funds Therefor, and for Other Purposes, Rep. Act No. 8371, § 3(g), (July 28, 1997) (Phil.).
[57] Melanie Nakagawa, *Overview of Prior Informed Consent from an International Perspective*, SUSTAINABLE DEV. L. & POL'Y, Summer 2004, at 4, 4.
[58] *See* Prakash, *supra* note 5, at 828 n.12.
[59] *Id.* at 828.

rights over those resources and to technologies, and by appropriate funding."[60]

In the early 1990s, when the CBD was being negotiated and ratified, numerous developing countries were expecting their biodiversity and genetic resources to be a "green gold" which they could use to fund conservation and development. Unfortunately, these expectations remained a dream. However, these expectations have now shifted towards elaborating the meaning of fair and equitable benefit sharing, *inter alia*, obligations of user countries.[61]

Benefit sharing is a process that follows access (based on PIC) to biodiversity and associated TK by parties external to the holder community or country. The main objective of the concept of benefit sharing lies in the fair and equitable manner in which it is done.[62] Several questions need to be answered regarding the complex nature of the protection of TK and related genetic resources through benefit sharing from the perspective of developing countries. For instance, in what ways can the timings of the benefits be stipulated? What mechanism should be devised for effective enforcement, and what problems might be faced by developing countries and indigenous communities? Is the concept of benefit sharing really fair and equitable? Is it evolving in a manner which is in the best interests of the local communities?

The timing of the benefits may be stipulated and scheduled on a case-by-case basis, including short-term, medium-term, and long-term bases, in the form of upfront payments, milestones, and royalties, and non-monetary benefits, as mutually agreed.

Mechanisms for benefit sharing need to be flexible within the framework satisfying fairness and equity. It is believed that such mechanisms give importance to capacity building in scientific research and technology development, building trust funds and joint ventures, and granting preferential licenses.[63] In several countries, the national legislation includes a list of required or potential benefit sharing provisions. There is also a common use of a written agreement or

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[60] *CBD*, *supra* note 22, art. 1.

[61] *See generally* Kerry ten Kate & Sarah A. Laird, *Bioprospecting Agreements and Benefit Sharing with Local Communities*, *in* POOR PEOPLE'S KNOWLEDGE 133, 148, 155-56 (J. Michael Finger & Philip Schuler eds., 2004).

[62] David. J. Faye, *Bioprospecting, Genetic Patenting and Indigenous Populations*, 7 J. WORLD INTELL. PROP. 401, 410 (2004).

[63] Rachel Wynberg, *Rhetoric, Realism and Benefit Sharing*, 7 J. WORLD INTELL. PROP. 851, 873-74 (2004).

contract that sets out the benefit sharing agreements as well as the establishment of penalties or sanctions in cases of non-compliance. "In some countries the IPR system is used as a compliance mechanism and IPRs are refused or revoked if the applicant did not comply with ABS provisions."[64] It is estimated that since CBD came into force in 1993, efforts to implement the provisions on benefit sharing have resulted in development of national access and benefit sharing legislation in more than fifty countries. A majority of developing countries in Asia has responded to CBD provisions and the Bonn Guidelines in their national policies and legal framework. Some of the examples are:

> Bangladesh (*Draft Biodiversity and Community Protection Act of Bangladesh, 1998*)…
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> India (*Biological Diversity Act, 2002; Biodiversity Rules, 2004*)…
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> Malaysia (*Sarawak Biodiversity Center Ordinance, 1997; Sarawak Biodiversity* (*Access, Collection and Research*) *Regulations, 1998; Sabah Biodiversity Enactment, 2000*)…
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> Pakistan (*Draft Legislation on Access to Biological Resources and Community Rights, 2004*)…
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> Philippines (*Executive Order No. 247, 1995; Department of Environment and Natural Resources Administrative Orders 96-20, 1996; Wildlife Resources Conservation and Protection Act, Republic Act No. 9147, 2001*)…[65]

Despite all these efforts, one of the major problems faced by local communities and countries entering into ABS contracts is the difficulty of monitoring the implementation of these contracts and enforcing their terms and conditions. For example, if a research organization has agreed to share the benefits of any findings from its research, but then leaves the country with the biological samples, it becomes very difficult for the country providing these resources to inquire about the further happenings. Do the resources lead to new

[64] KATHRYN GARFORTH ET AL, OVERVIEW OF THE NATIONAL AND REGIONAL IMPLEMENTATION OF ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING MEASURES, CISDL STUDY 50 (3d ed. 2005), *available at* http://www.cisdl.org/pdf/ABS_ImpStudy_sm.pdf.

[65] Mohamad bin Osman, Issues of Bioprospecting, and Implementation of ABS Legislation at National and Regional Levels, International Expert Workshop on Access to Genetic Resources and Benefit Sharing 3 (Sept. 20-23, 2005).

insights and understanding? Do they become the subject of intellectual property protection? Do they start to generate income for that particular organization? These are the areas which need to be covered by the terms in ABS contracts; terms which it will be essential for the provider country to effectively monitor and enforce once the activity moves outside its borders.[66]

Furthermore, some of the critics believed the ABS contracts to be unfair and inequitable. When an IPR is sought over a product developed from biological resources and through the local community's knowledge regarding the resource, the IPRs thus obtained are exclusive rights over the developed products. There is no obligation on the holder of the IPR to share the benefits, material or otherwise, with the provider of the knowledge, regardless of the latter's contributions to the development of the patentable subject matter. Moreover, it is argued that although society receives the benefit of having technology developed, originally it is the government which receives the direct benefits in the form of fees and charges levied for registration of IPRs.[67]

Finally, there has been a fair amount of skepticism over the manner in which the concept of benefit sharing has been evolving. The basis for this skepticism is that the tool of benefit sharing has little or no value when analyzed against the series of historically committed wrongs against these local communities. In the context of the piecemeal processes of alienation of local communities from their land and resources, displacement, and the subsequent disintegration of several of these communities, a phenomenon that is caused by the active support of the State, the question that comes to mind is the value of sharing a minor percentage of royalties with such peoples. The question whether benefit sharing, in such an inequitable situation can ever achieve fairness and equity, cannot be easily answered.

A. The Case of Aarogyappacha

Despite a great deal of criticism that has come in for the concept of "access and benefit sharing," a number of benefit sharing

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[66] Marie-Claire Segger, *Laying the Foundations: CISDL Summaries of Legal Working Papers: for Release in the Third Meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing* 8 (2005), *available at* http://www.cisdl.org/pdf/LtF_side%20event_ doc%20ABS-WG3.pdf.

[67] Dhar & Anuradha, *supra* note 46, at 630.

experiments have already been carried out successfully. The case of *Aarogyappacha* is one of the examples, which the Indian government heralded as a case study on benefit sharing, and which has been presented to the Secretariat of the CBD.[68]

The *Kani* people of southern Kerala were convinced by some biologists to share with them some of their knowledge regarding a plant called *Aarogyappacha* or *trichopus zeylanicus travancoricus*.[69] Although it was widely used by local people, the plant itself was unknown to the outer world until 1987.[70] The Tropical Botanical Garden and Research Institute (TBGRI), having one of the largest botanical gardens in Asia, carried out research on the plant and identified its active ingredients.[71] Later a drug was developed with anti-fatigue properties called *Jeevani*.[72] The rights to manufacture Jeevani were transferred to a private manufacturer for a license fee of about $25,000 (U.S.) for seven years.[73] TBGRI decided to give half of the fee and half of any royalties to the *Kanis*.[74] The deal was also accepted by a majority of the community, which had significant interactions with TBGRI, including the people who shared the knowledge; this has been hailed as a model for future transactions.[75]

B. The Way Forward for Developing Countries

With respect to the realization of the objectives in regard to prior informed consent and fair and equitable benefit sharing, it has been said that the suggested national-based approach could have the following features:

> contractual arrangements could be used to establish the rights and obligations of the communities involved prior to any access to genetic resources; this would ensure that prior informed consent is achieved;

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[68] Philippe Cullet, *Revision of the TRIPS Agreement concerning the Protection of Plant Varieties. Lessons from India concerning the Development of a* Sui Generis *System*, 2 J. WORLD INTELL. PROP. 617, 647 (1999).
[69] R.V. Anuradha, Sharing with the Kanis 5 (Jan. 1998) (unpublished manuscript), *available at* www.cbd.int/doc/case-studies/abs/cs-abs-kanis.pdf.
[70] *Id.*
[71] *Id.*
[72] *Id.* at 6.
[73] *Id.*
[74] *Id.*
[75] *Id.* at 11.

> countries could also establish permit systems that impose civil or criminal penalties for extracting genetic resources without a permit, while the permit would serve as evidence of prior informed consent;
>
> a contract-based system would provide a mechanism to transfer benefits as it could be used to effectively control the collection of resources and ensure the sharing of benefits from their use;
>
> contracts could also include a compulsory disclosure of any future commercial application using the relevant traditional knowledge or genetic resource, whether or not a patent is filed or granted over the relevant application…
>
> within the contract, a party could require the researcher or other party accessing the genetic resources and traditional knowledge to report regularly to the point of contact regarding progress of his research.[76]

III. OVERVIEW OF THE IPR AND TK DEBATE IN INTERNATIONAL NEGOTIATIONS

The need for the protection of genetic resources and related TK can be described as a horizontal concern, as several multilateral institutions are involved in discussing it from different perspectives and in different contexts. However, this section will limit itself to the institutions and processes which have a particular relevance for TK and GRs within an intellectual property context.

It is pertinent to discuss the concerned issue in the context of various international forums (Agreements), as they are the driving force for the protection of such knowledge and resources at the international level. Once a country becomes a signatory to such an Agreement, the legislatures of these member states have to keep in view all the binding rules in such an Agreement, while making laws

[76] Council for Trade-Related Aspects of Intellectual Property Rights, *Note by the Secretariat: The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity*, at 14-15, IP/C/W/368/Rev.1 (Feb. 8, 2006).

for the protection of these resources and knowledge at the national level.

The three principal forums where the issues pertaining to TK protection, GRs, and IPRs have figured prominently are WIPO, CBD, and the TRIPS Council of the World Trade Organization (WTO).

1. Developments at the World Intellectual Property Organization

WIPO, whose forerunner was actually the International Bureau that administered the Paris and Berne Conventions, came into being in 1970 once the 1967 Stockholm WIPO Convention took force.[77] Under a 1974 agreement, WIPO became a specialized United Nations agency, with its prime mandate being to promote the use and protection of intellectual property. [78] WIPO's current membership is 179 States, with the majority of them being developing countries.[79] Despite providing an "umbrella framework for the organization, however, the WIPO Convention is, in actuality, merely an administrative treaty.[80]

WIPO's Standing Committee on the Law of Patents (SCP) held its third session in September 1999, devoting the session primarily to discussing a draft Patent Law Treaty (PLT) that would hopefully further harmonize various aspects of patent laws.[81] The PLT was concluded in June 2000.[82]

Prior to that, in 1999, the Colombian delegation submitted a Proposal entitled "Protection of Biological and Genetic Resources" which argued that the PLT should comprise provisions linking the filing of patent applications with access and benefit-sharing regulations. The basic demands made in the Proposal were that:

> "All industrial property protection shall guarantee the protection of the country's biological and genetic heritage. Consequently, the grant of patents or registrations that relate to the elements of that

[77] Carlos M. Correa & Sisule F. Musungu, *The WIPO Patent Agenda: The Risks for Developing Countries* 2 (Trade-Related Agenda, Development, and Equity, Working Paper No. 12, Nov. 2002).
[78] *Id.*
[79] *Id.*
[80] *Id.*
[81] Graham Dutfield, *Sharing the Benefits of Biodiversity*, 5 J. WORLD INTELL. PROP. 899, 914-15 (2002).
[82] Dhar & Anuradha, *supra* note 46, at 608.

> heritage shall be subject to their having been acquired legally."; and
>
> "Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof where the goods or services for which protection is sought have been manufactured or developed from genetic resources or products thereof, of which one of the Member countries is the country of origin."[83]

This idea of patent filing with ABS regulations gained the support of many of the developing countries, including India, China, Bolivia, Chile, Cuba, Kenya, Costa Rica, and Barbados. But predictably it was staunchly opposed by the United States, the European Union, and Japan as being an element of substantive patent law that should not be included within the PLT.[84] As things turned out, Colombia's proposal did not fail completely because the concerns behind it were given other opportunities for expression within WIPO.[85] Thus another meeting was arranged on Intellectual Property and Genetic Resources, which took place in April 2000 and reached a consensus that "WIPO should facilitate the continuation of consultations among Member States in co-ordination with the other concerned international Organizations, through the conduct of appropriate legal and technical studies and through the setting up of an appropriate forum within WIPO for future work."[86]

> "The WIPO Secretariat invited Member States to consider the establishment of an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore (IGC) in the year 2000."[87] Three themes on which the IGC could focus were "[i]ntellectual property issues that arise in the context of: (i) access to genetic resources and benefit sharing; (ii) protection of TK, whether or not associated with these resources; and (iii) the protection of expressions of folklore."[88]

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[83] *Id.* at 608-09.
[84] *Id.* at 609.
[85] *Id.*
[86] *Id.*
[87] *Id.*
[88] *Id.*

This suggestion was strongly supported by a large number of developing countries and was approved without formal opposition.[89] Later, in the IGC sessions of 2001 and 2002, discussions revolved mostly around how patent law could prevent misappropriation of TK and promote benefit sharing.[90] The third IGC discussion mainly focused on two possible approaches, the first being to require patent applicants to disclose the origin of genetic resources and related TK in patent applications.[91] Some delegations further added that such applications should also provide documentary evidence of prior informed consent and compliance with the ABS regulations of provider countries.[92] The U.S. representative expressed concern that these requirements would create an additional substantive condition on patentability beyond those already in place, thus causing a conflict with TRIPS.[93] Meanwhile, developing countries like India and Brazil consistently asserted that such a measure was needed in order for patents to be supportive of the CBD.[94]

In April 2006, the ninth session of the IGC was held, where the Committee commissioned the drafting of an outline of policy options and legal mechanisms for the protection of TK. The Committee first requested this outline at its sixth session and extensively reviewed an initial draft at its seventh session. It was reaffirmed that if the objectives and principles for protection of TK were established internationally, it would still be necessary to determine how they are implemented at the level of national and regional laws. Thus, this outline gave updated information on the actual policy options and legal mechanisms that national and regional legal systems have already employed to give effect to the kind of draft objectives and principles set out in document WIPO/GRTKF/IC/9/5, the main working document on TK for this ninth session of the Committee.[95]

Analysis

The IGC deliberations indicated several differences among the countries regarding the need, scope, and nature of legal protection of

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[89] Dutfield, *supra* note 81, at 916.
[90] *Id.*
[91] *Id.*
[92] *Id.*
[93] *Id.*
[94] *Id.*
[95] *See* World Intellectual Property Organization, *The Protection of Traditional Knowledge Revised Outline of Policy Options and Legal Mechanisms*, at 2, WIPO Doc. WIPO/GRTKF/IC/9/INF/5 (Mar. 27, 2006), *available at* http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=59333.

TK and its format. Notwithstanding these differences, the Member States have agreed that WIPO should produce the elements for a model *sui generis* system of protection for TK, though the developed countries stress that any legally binding international *sui generis* system at this stage is premature and unnecessary and that such attempts should first be made at the national level to determine feasibility. On the other hand, developing countries demand that intensive work be taken in this regard.[96]

Generally speaking, while the IGC's work has not produced any tangible results other than being a forum for discussion of legal, economic, and policy issues related to the protection of GRs and related TK, including the *sui generis* form of protection, it helped spark the awareness among the developing countries to safeguard their valuable knowledge assets. To date, the WIPO has proposed a bottom-up approach under which developing countries first analyze how existing national mechanisms of IPRs could be more effectively used to protect TK before introducing protection at the international level.[97]

2. Convention on Biological Diversity

The relationship between IPRs and the CBD tends to be treated as most relevant to the regulation of access to genetic resources and the development of measures to ensure fair and equitable benefit sharing with States and the holders of traditional knowledge.[98]

The CBD asserts the sovereign rights of nations over their national resources, and their right to determine access according to national legislation with the aim of facilitating the sustainable use of these resources, promoting access and their common use.[99] It contains provisions which ensure that the genetic resources and knowledge associated with these cannot be treated as "free goods," and that there is a scope for each State party to frame regulations for controlling access to such resources in the interests of the national and local

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[96] Paul Kuruk, *Bridging the Gap Between Traditional Knowledge and Intellectual Property Rights Is Reciprocity an Answer?*, 7 J. WORLD INTELL. PROP. 429, 436 (2004).
[97] *Id.* at 429.
[98] Philippe Cullet, *Property Rights Over Biological Resources India's Proposed Legislative Framework*, 4 J. WORLD INTELL. PROP. 211, 211 (2001).
[99] Eugẽnio Da Costa e Silva, *The Protection of Intellectual Property for Local and Indigenous Communities*, 17 EUR. INTELL. PROP. REV. 546, 546 (1995).

community.[100] The most notable provisions of the Convention are Articles 8(j), 15, and 16.

Article 8(j) provides the basis for the establishment of rights of the local communities over the biological resources of which they are custodians and the knowledge systems they have developed with regard to these resources. The outstanding question in this provision is "Who is meant to be included?" The provision implies that local communities embodying traditional lifestyles possess an equal status to indigenous peoples. Indigenous peoples' organizations have argued for an interpretation of Article 8(j) that refers not only to indigenous peoples who live within their traditional territories, but also those who have been forcibly relocated to other territories but who still hold claim to their original territories.[101] "Article 15 recognizes the sovereign rights of States over their natural resources and their authority to determine access to genetic resources and provides that access, where granted, shall be on mutually agreed terms and subject to prior informed consent of the provider party (contracting party)."[102] Article 16, on access to and transfer of technology, requires parties to the Convention to undertake to provide and facilitate access and transfer of technologies to other parties under fair and most favorable terms. Article 16 is concerned with any technologies "that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment."[103] Article 16.5 is more controversial, requiring the parties to co-operate to ensure that patents and other IPRs "are supportive of and do not run counter to" the CBD's objectives.[104] This sparked severe disagreement during the negotiations between those who believed that IPRs conflict with the CBD's objectives, and others that saw no contradiction.[105]

Analysis

Like other international environmental law instruments, the CBD also has a tendency to consolidate the role of government in protecting and maintaining resources and reaffirms that States have sovereign rights over their own biological resources. However, terms

[100] Rajesh Sagar, *Intellectual Property, Benefit Sharing and Traditional Knowledge How Effective is the Indian Biological Diversity Act, 2002?*, 8 J. WORLD INTELL. PROP. 383, 384 (2005).
[101] Richardson, *supra* note 28, at 8.
[102] Verma, *supra* note 25, at 775.
[103] *CBD*, *supra* note 22, art. 16, para. 2.
[104] Verma, *supra* note 25, at 775.
[105] *Id.* at 781-82.

such as "as far as possible" and "as appropriate" are vulnerable to being used by States as an excuse for non-action because of cited financial or other constraints of a similar nature. The CBD is believed to be more problematic because it does not contain "any explicit non-derrogable requirement for the consent or participation of indigenous peoples in access to resources or knowledge."[106]

A. The Bonn Guidelines

In 2002, some 2000 government and non-government officials, from 166 countries, attended the Sixth Session of the CBD Conference of the Parties (CoP-6) at The Hague.[107] At the Conference, the government officials responded to a shift away from policy formulation by resolving "to develop and implement effective and innovative mechanisms."[108] Thus, in May 2002, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization were officially adopted.[109] The Guidelines consist of a set of voluntary rules to assist in the drafting and progress of national biodiversity legislation or administrative regulation, by providing "a transparent framework to facilitate access and ensure benefit-sharing at national or regional levels."[110] The Guidelines state parties should consider adopting "measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights."[111] In biodiversity-rich countries, the Guidelines provide a mechanism to "advance the harmonization of the steps for adequate access and benefit-sharing."[112]

One of the remarkable features of the Bonn Guidelines is that, for the first time in the CBD context, there is an agreed and expressed reference to the need for users of genetic resources, especially in the case of developed countries with biotechnological capacities

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[106] Richardson, *supra* note 28, at 9.
[107] Tully, *supra* note 41, at 84.
[108] *Id.*
[109] *Id.*
[110] O'Connor, *supra* note 20, at 685.
[111] Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Sixth Meeting, Decision VI/24, ¶ 16(d)(ii), at 268, U.N. Doc. UNEP/CBD/COP/6/20 (Apr. 7-19, 2002).
[112] O'Connor, *supra* note 20, at 685.

traditionally making use of genetic resources for research and development, to adopt measures that ensure that the interests of providing countries are respected and considered.[113] The Guidelines include "adoption of measures that ensure prior informed consent has been provided for the use of resources (16.b. i – ix) and measures to encourage disclosure of origin in IPR applications (16.d.ii)."[114] Furthermore, the Guidelines ensure that countries of origin have the right to regulate ABS, and also that "countries in which these resources are used should adopt certain actions to assist in the implementation of the CBD ABS principles and complement regulatory actions by providing countries."[115]

Criticism

Certain environmental NGOs criticized that the Guidelines could not substitute for legally binding national instruments.[116] The International Indigenous Biodiversity Forum also criticized the Guidelines by stating that, "consistent with self-determination, indigenous peoples should be duly recognized as rights-holders and not merely stakeholders over genetic resources."[117] Several legally binding instruments provide that "indigenous peoples shall 'wherever possible' participate in the benefits associated with resource exploitation pertaining to their lands."[118]

Analysis

Despite criticism, the importance of the Guidelines for developing countries is that they are a vital step towards the harmonization of the regime of access and benefit sharing.[119] In the context of the CBD,

> emphasizing national sovereignty and the authority of governments to regulate access to GRs cannot rule out bilateral negotiations between the biodiversity-rich but technologically poor countries and those seeking access to these resources. In other words, the CBD promotes bilateral

[113] RUIZ, *supra* note 13, at 10.
[114] *Id.*
[115] *Id.*
[116] Tully, *supra* note 41, at 85.
[117] *Id.* at 85-86.
[118] *Id.* at 86.
[119] Verma, *supra* note 25, at 777.

> agreements between the providers and users of resources, whereas a multilateral approach would be mutually beneficial by laying down the framework of fair terms because in bilateral negotiations the biodiversity-rich countries quite often are not in a strong position to negotiate a fair deal.[120]

3. TRIPS, Traditional Knowledge, and Genetic Resources

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO) provides minimum standards that Member countries agreed to, regarding protection of intellectual property.[121] It came into effect at the end of the Uruguay Round of trade negotiations.[122] These negotiations ended in 1995.

The TRIPS Agreement addresses traditional concepts of intellectual property but does not address the protection of TK specifically.[123] The Agreement excludes TK "by virtue of Article 70(3), which considers it as a part of the public domain."[124] The relevant provisions in this regard could be Article 39 (protection of undisclosed information), if the TK is kept as secret knowledge, and Article 22 (protection of geographical indications).[125] However, these Articles are of limited scope and application and fail to meet the concerns of developing countries.[126]

The issue of protection of TK was brought before the General Council of WTO, in the context of Article 27.3(b) of the TRIPS Agreement in 1999, which allows exclusion from patentability of plants and animals and essentially biological processes for their production, but obliges the protection of micro-organisms and micro-biological or non-biological processes for their production.[127] This

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[120] *Id.*
[121] CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES 1 (2000).
[122] *Id.*
[123] Verma, *supra* note 25, at 779.
[124] *Id.*
[125] *Id.*
[126] *Id.*
[127] JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES

Article is severely opposed by developing countries. On August 6, 1999, the African Group of countries warned that "by mandating or enabling the patenting of seeds, plants and genetic and biological materials, Article 27.3(b) is likely to lead to appropriation of the knowledge and resources of indigenous and local communities."[128]

The developing countries also argued that the exclusions in Article 27.3(b) should be clarified and that "life forms should be excluded from patentability, that information relating to the origins of a biological invention should become part of the patent application process, and that the principle of prior informed consent under the CBD should be incorporated into the TRIPS Agreement."[129]

As a contribution to this examination, several developing countries in Asia, including China, Pakistan, India, and Thailand, together with other groups of developing countries, submitted a paper to the Council for TRIPS in June 2002. The paper proposed that WTO Member States must require:

> that an applicant for a patent relating to biological materials or to traditional knowledge shall provide, as a condition to acquiring patent rights:
>
> (i) disclosure of the source and country of origin of the biological resource and of the traditional knowledge used in the invention;
>
> (ii) evidence of prior informed consent through approval of authorities under the relevant national regimes; and
>
> (iii) evidence of fair and equitable benefit sharing under the national regime of the country of origin.[130]

The United States and Japan have raised the primary objections to the above. These countries have argued that:

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131 (2001).

[128] Preparations for the 1999 Ministerial Conference, *Kenya – The TRIPS Agreement*, ¶24, at 5, WT/GC/W/302 (August 6, 1999).

[129] Verma, *supra* note 25, at 780.

[130] Council for Trade-Related Aspects of Intellectual Property Rights, *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity*, at 1, IP/C/W/356 (June 24, 2002).

> [the] amendments would not be consistent with the TRIPS Agreement and would violate the principle of non-discrimination between fields of technology;
>
> expanding the norms of disclosure would amount to a legal and administrative nightmare and an unnecessary burden on the patent applicant and the Patent Office.[131]

Analysis

These deliberations at the WTO Council for TRIPS clearly indicate that no appreciable achievement has been registered on the issue of legal protection of TK and that sharp differences exist between the member States, as it is observed that some countries seem to be more concerned with avoiding the misappropriation of traditional knowledge and with the implementation of the "sharing of benefits" principle than with the development of an intellectual property rights regime for traditional knowledge (most notably the U.S. and Japan). Others seem to aim at preserving the room existing at the national level to legislate on the matter.[132]

> [O]ut of 147 parties to the TRIPS Agreement, three-fourths are developing countries, which are the chief holders of TK, and they want to correct the balance of TRIPS, which, according to them, is heavily tilted towards the interests of industrialized countries. Consequently, they have demanded the inclusion of TK in the TRIPS Agreement to get a fair return on their resources. The WTO may, however, be considered to be the most appropriate forum, with its dispute settlement mechanism and binding obligations and the procedure of negotiation (based mainly on reciprocity). Furthermore, the United States, which is not a party to the CBD so far, would be negotiating on some of the

[131] Dhar & Anuradha, *supra* note 46, at 608.
[132] Verma, *supra* note 25, at 781-83.

> contentious provisions of the CBD in the TRIPS forum.[133]

Currently, a challenging agenda of research and policy still lies ahead. The issues raised include the extensiveness and potential uses of GRs and indigenous knowledge of countries; the potential economic value of these resources; the means of restoring proprietary protection to names in the public domain; and how to create a proprietary right that is enforceable internationally and which can reward agents, including traditional communities, for preserving and creating such resources and knowledge. In all these areas, a credible international negotiation can be built if these protective systems are going to be implemented in a more workable manner, and in order to reduce the deadlocks between the Member States.[134]

Final Comments

Winding up the discussion, determination of positive synergies between various international regimes in the context of IPR, *vis a vis*, protection of GRs and related TK is a politically and technically intricate and challenging endeavor, although enormous progress has been made over the past few years. However, as has been demonstrated by briefly addressing some of the key issues under discussion and some of the most important international forums where this discussion takes place, TK protection and benefit sharing still remains a goal and is far from achieved.[135]

Whether it be devising norms of protection for TK, entering into review processes of the TRIPS Agreement, designing an international framework for the successful ABS implementation, or thorough consideration of the provisions contained in WIPO and the CBD, policy and law will need to create and develop different tools to effectively ensure that countries of origin assert their rights over their genetic resources, to guarantee that benefits of the use of these resources are equitably shared, and to make certain that indigenous peoples' intellectual efforts are well protected.[136]

In the above section, it is shown that there are a number of parallel processes underway where many of these issues are considered. Compared to the situation that existed a decade ago,

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[133] *Id.* at 783.
[134] Somesh K. Mathur, *Domestic Challenges and the TRIPS Agreement: The Way Forward for India*, 4 J. WORLD INTELL. PROP. 337, 346 (2001).
[135] RUIZ, *supra* note 13, at 21.
[136] *Id.*

currently WIPO, the CBD, the Council of TRIPS, and numerous other national and regional processes, are engaged in finding ways to establish positive synergies among IPR and biodiversity related issues, which in itself is an important development.[137]

In the wake of heightened debates over TK protection and monopolization attempts of industrialized nations, the author is of the view that one of the effective strategies for developing countries is to combine their efforts, not only at international forums, like TRIPS, the CBD, and WIPO, but also to keep this issue the focus of discussions, held at regional levels like the Association of Southeast Asian Nations (ASEAN) and the Organization of African Unity (OAU). Particularly, the TK rich countries ought to be more vigilant and organized in future TRIPS negotiations, as the developed countries have shown profound interest in this forum because of its effective enforcement tools.

IV. PRESERVING AND PROTECTION GRS & RELATED TK AT NATIONAL LEVELS: EXPERIENCES IN SELECTED DEVELOPING COUNTRIES OF ASIA

National measures are the primary source of protection of genetic resources and related traditional knowledge, as the international measures will only be able to protect the economic aspects of GRs and TK if they are put into commercial use. International regimes would be limited to protection and not concerned with further development, diffusion, and preservation tasks, which can only be done at national levels.[138]

The preservation, protection, and promotion of the traditional knowledge, innovations, and practices is of key importance for developing countries around the globe. Their rich endowment of GRs and TK plays a crucial role in their health care, food security, culture, religion, identity, environment, sustainable development, and trade. In this regard, like Latin America, several Asian countries have been at the forefront of creating and implementing effective legislation at local and national levels.[139]

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[137] *Id.*

[138] *See* Assafa Endeshaw, *Asian Perspectives on Post-TRIPS Issues in Intellectual Property*, 8 J. WORLD INTELL. PROP. 211 (2005).

[139] *See* Thomas Cottier, *The Protection of Genetic Resources and Traditional: Towards More Specific Rights and Obligations in World Trade Law*, 1 J. INT'L ECON. L. 555 (1998).

This section reviews the national and local measures for the preservation and legal protection of genetic resources and related traditional knowledge by selected developing countries in Asia.

1. The Philippines Experience

The Philippines is home to a vast variety of traditional knowledge, which still influences the lives of Filipinos.

> The TK of the Philippines is mostly concentrated in the areas of health care, agriculture, forestry systems, mining, arts and crafts, music, dance, and literature. Among the best-known embodiments of the country's TK are the world-renowned rice terraces of the Ifugaos….
> Awareness of the need to protect TK was spurred by economic development at the end of the twentieth century. Massive logging and large-scale mining in the Philippines were among the main activities that caused the displacement of indigenous people from their ancestral domains, thus adversely affecting the TK of many indigenous communities.[140]

Several provisions were incorporated into the Constitution of the Philippines in 1987, so as to address the problem of rapidly vanishing TK of the country. In this context, Section 17 of Article XIV encourages the State to respect and protect the rights of indigenous cultural communities and to preserve and develop their cultures, traditions, and institutions.[141] Thus, after the ratification of the CBD in 1993, the Philippines became one of the first countries to enact laws protecting the rights of indigenous peoples when the Indigenous People's Rights Act of 1997 and its regulation, Executive Order No. 247, were officially adopted.[142]

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[140] Jocelyn L.B. Blanco, *Harnessing Traditional Knowledge for Development and Trade: The Philippines Experience*, *in* PROTECTING AND PROMOTING TRADITIONAL KNOWLEDGE: SYSTEMS, NATIONAL EXPERIENCES AND INTERNATIONAL DIMENSIONS 293, 293 (Sophia Twarog & Promila Kapoor eds., 2004).
[141] CONST. (1987), Art. XIV, (Phil.).
[142] Mattias Leistner, *Analysis of Different Areas of Indigenous Resources, in* INDIGENOUS HERITAGE AND INTELLECTUAL PROPERTY: GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE 99, 100 (Silke von Lewinski ed., 2004); Agnès Lucas-Schloetter, *Existing Legal Remedies Regarding the Protection of Folklore*, *in* INDIGENOUS HERITAGE AND INTELLECTUAL PROPERTY: GENETIC

Executive Order No. 247 (EO 247), "Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, Their By-Products and Derivatives, for Scientific and Commercial Purposes, and for Other Purposes," entered into force on May 18, 1995.[143] Later, in 1996, the Department of Environment and Natural Resources (DENR) issued Administrative Order No. 20 (DAO No. 20), for implementing rules and regulations under EO 247.[144] Due to the broad scope and certain procedures regarding prior informed consent, there were some hurdles experienced in implementing EO 247. To remedy these problems, the Philippines Legislature, on July 30, 2001, enacted the Wildlife Resources Conservation and Protection Act (Wildlife Act), a general environmental legislation that codifies existing wildlife laws.[145]

EO 247 protects the rights of indigenous communities in TK in general, including "the right to limit the access of researchers in their ancestral domains/lands or territories and to receive royalties from the income derived from any of the researches conducted and from resulting publications. Access to bio-resources and GRs would be subject to prior informed consent…"[146] In this regard, the Wildlife Act is an effective tool which defines bioprospecting as the research, collection, and utilization of biological and genetic resources for purposes of applying the knowledge derived therefrom to solely commercial purposes.[147] In order to engage in bioprospecting, a proponent must enter into a "Bioprospecting Undertaking." The applicant must have received prior informed consent from the concerned indigenous cultural communities or management board under Republic Act No. 7586 or a private individual or entity. During this process the concerned communities can negotiate benefit-sharing terms with the applicant.[148]

Chapter VII of the proposed Guidelines describes how bioprospecting will be monitored. The user must submit annual

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RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE 266, 337-39 (Silke von Lewinski ed., 2004).

[143] REVISED FORESTRY CODE, E.O. No. 247, as amended.

[144] ADMINISTRATIVE CODE, D.A.O. No. 96-20, as amended.

[145] GARFORTH ET AL., *supra* note 64, at 19-20.

[146] Verma, *supra* note 25, at 795.

[147] An Act Providing for the Conservation and Protection of Wildlife Resources and Their Habitiats, Appropriating Funds Therefor and for Other Purposes, Rep. Act. No. 9147, § 5(a), (Mar. 19, 2001) (Phil.).

[148] Verma, *supra* note 25, at 777.

progress reports covering the status of the procurement of PIC, progress of the collection of samples, the status and results of benefit-sharing negotiations, and progress on payment of benefits or other provisions of the undertaking. The Department of Foreign Affairs and the Department of Science and Technology can assist in overseas monitoring including monitoring inventions and commercialization in foreign countries. According to the report of the currently-dissolved Inter-Agency Committee on Biological and Genetic Resources, between 1996 and early 2004 it processed eight applications for Commercial Research Agreements and seventeen applications for ARA under EO 247. Only one CRA and one ARA were granted during that time.[149]

One of the important pieces of legislation is "The Traditional and Alternative Medicine Act (TAMA) of 1997," or "Republic Act 8423." It institutionalizes the ownership by indigenous societies of their knowledge of traditional medicines. According to this Act, when outsiders use TK, the indigenous societies require the permitted users to acknowledge its source and demand a share of financial return that may come from its authorized commercial use.[150]

Legislation may also provide guidelines at the local level. "Samoa has the Village Fono Act 1990 which provides for an institutional structure within the village communities "Village Fono" (Village Council) and which, although indirectly, effectively protects Samoa's traditional form of governance."[151]

In the context of compliance with the international regimes, for instance, the TRIPS Agreement, the Philippines has an Intellectual Property Code, i.e., Republic Act No. 829300.[152] Patents, trademarks, copyrights, and other economic rights are covered by this Code.[153]

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[149] *See* United Nations Conference on Trade and Development, *The Role of Intellectual Property Rights in Protecting Traditional Knowledge (The Philippine Experience)*, (Apr. 3-5, 2002) (*prepared by* Marga C. Domingo-Morales), *available at* http://www.unctad.org/trade_env/test1/meetings/delhi/Countriestext/Philipinestext.doc [hereinafter *UNCTD*].

[150] An Act Creating the Philippine Institute of Traditional and Alternative Health Care (PITAHC) to Accelerate the Development of Traditional and Alternative Health Care in the Philippines, Providing for a Traditional and Alternative Health Care Development Fund for Other Purposes, Rep. Act. No. 8423, § 2, (July 28, 1997) (Phil.).

[151] O'Connor, *supra* note 20, at 692.

[152] Blanco, *supra* note 140, at 296.

[153] *Id.*

Analysis

Laws regulating access to genetic and biological resources (IPRA and EO 247) were foreseen to pave the way for collaborative research efforts.[154] However, the local scientific community argues that these laws instead proved restrictive and hindered the development of their research efforts.[155] It is believed that restricting access to local research institutions will reduce the chances of obtaining maximum benefits from biological and genetic resources of the indigenous people.[156]

Moreover, there are also apprehensions regarding how the policy-making processes for protecting TK and their implementation modalities will evolve.[157] Most of the program failures have been associated with "the insufficient capacity and capability of the implementers, notwithstanding their sincerity and the receptiveness and involvement of the beneficiaries."[158] The time factor is also crucial, as protection is necessary only when there is something to protect, keeping in view the rapid depletion of biodiversity.[159] The policymakers should ensure that the emerging policies are acceptable, and the concerned section of the society is involved at the very beginning of the policy-making process.[160]

2. The Use and Protection of GRs & TK in Vietnam

"With its diverse climate, fertile plains, forests, mountains, and ecosystems, Vietnam is endowed with rich and unique biodiversity…. The country is ranked sixteenth in the world in terms of biological diversity."[161] The economy of Vietnam depends mainly on its natural

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[154] *UNCTD*, *supra* note 150, at 6.
[155] *Id.*
[156] *Id.*
[157] Blanco, *supra* note 140, at 297.
[158] *Id.*
[159] *Id.* at 296-97.
[160] *Id.*
[161] Le Quy An, *The Use and Commercialization [sic] of Genetic Resources and Traditional Knowledge in Vietnam: The Case of Crop and Medicinal Plants*, *in* PROTECTING AND PROMOTING TRADITIONAL KNOWLEDGE: SYSTEMS, NATIONAL EXPERIENCES AND INTERNATIONAL DIMENSIONS 7, 7 (Sophia Twarog & Promila Kapoor eds., 2004).

resources.[162] Agriculture contributes significantly to the gross domestic product, as compared to other countries in the region.[163] Biological resources play a vital role in agriculture, forestry, and fisheries for ensuring the food security of the nation.[164]

"In Vietnam's WIPO Survey Response, it was reported that there are very few legislative efforts in the area of genetic resources and almost none in the protection of traditional knowledge."[165]

However, the Government Decree No. 7-CP of February 1996 elaborates the following measures:

> • The overall policy of the Government is to invest for building national capacity in conserving, selecting, producing and carrying on the business of developing seed varieties (Art.4).
> • Plant genetic resources are to be considered as national property and managed by the State. All organizations and individuals are encouraged to prospect for, collect, preserve, utilize, and enrich genetic resources for the benefit of the national economy and social welfare (Art. 8). The Ministry of Agriculture and Rural Development (MARD) is the main government body responsible for the management of development of seed varieties by the State.
> • The State encourages and protects the legal rights of all Vietnamese and foreign organizations and individuals in their scientific research and business activities (Art. 3) and facilitates international cooperation (Art. 13) on seeds and plant breeds. Such activities must nevertheless be licensed and put under the control of MARD (Art. 14) and must strictly follow the stipulated technical process (Art. 11).
> • It is stated that newly produced, selected or imported seed varieties are subject to tests or pilot production before recognition and wider use (Art. 9).

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[162] *Id.*
[163] *Id.*
[164] *Id.*
[165] JJ Disini, *Survey of Laws on Traditional Knowledge in South East Asia* (2003), http://cyber.law.
harvard.edu/openeconomies/okn/asiatk.html.

> • Seed varieties, when sold as goods in the market, should be sold under trademark with a certificate of quality. All illegal and unfair dealings in the production of and trade in seed varieties are forbidden (Art.13).
> • Plant breeders own the copyright on new seed varieties (Art.10).[166]

Moreover, the "[g]eographical indications protect traditional knowledge to some extent as in the case of 'Phu Quoc,' a fish soya sauce, and 'Shan Tuyet Moc Chau,' a variety of tea."[167] Patent protection is also available for a traditional preparation of medicinal plants used in stopping drug-addiction, while a trademark has been registered for a traditional balm made of medicinal plants, called "Truong Son."[168]

A. Vietnam and International Regimes

There is a need in the country to grasp the contents of the CBD and TRIPS to elaborate a national legal framework for TK and GR protection.[169] In this regard, MARD is drafting legislation for the protection of genetic resources and related TK.[170]

> Since the draft regulation has not yet been examined and approved, there is no formal interpretation of its contents. However, through workshops and discussions during the process of its elaboration, it might have made an attempt to reconcile the conflict between the CBD and TRIPS – for example, by recognizing the rights of the patent holder and at the same time denying patents in certain cases, such as (a) personal and non-commercial use of seed varieties; (b) using the product of the harvest obtained by planting the protected variety for propagating purposes on one's

[166] An, *supra* note 161, at 10-11.
[167] Disini, *supra* note 165.
[168] *Id.*
[169] An, *supra* note 161, at 11.
[170] *Id.* at 12.

> own holdings; and (c) using the protected material to develop new varieties and for scientific purposes. However, genetic resources differ according to their uses, and TK is often associated with particular genetic resources.[171]

"Vietnam has to take [maximum] advantage of the grace period allowed by TRIPS to devise appropriate IPR laws taking into account its national interests."[172]

3. The TK Protection in Indonesia

"Indonesia has reported to WIPO the absence of any specific legal protection for traditional knowledge, but some protection may be available through copyright, distinctive signs (including geographical indications) and trade secret law."[173] Some of these laws were further amended in order to provide effective protection, such as Amended Law No. 12 of 1997 on Copyrights, Amended Law No. 13 of 1997 on Patents, and Trademark Law No. 14 of 1997.[174] The Indonesian National News Agency also reported that the government is now making an inventory of the Indonesian folklore and traditional knowledge to prevent it from being patented by others.[175]

The top hierarchy of government officials and intellectuals in Indonesia has learned to value the importance of standard IPR. Especially with the implementation of the TRIPS Agreement, they became aware of the IPR regime and hence of the importance of traditional knowledge. The draft of a new IPR regulation has been submitted to the People's Consultative Assembly.[176]

Considering the provisions of the TRIPS Agreement, Indonesians are striving to devise legal measures for the legal protection of TK, in particular in the field of biodiversity. Some institutions and non-governmental organizations have organized several meetings on this pattern; however, systematic activities on a

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[171] *Id.*
[172] *Id.*
[173] Disini, *supra* note 165.
[174] *See* Sulaeman Kamil, *The Protection of Traditional Knowledge in Indonesia*, *in* PROTECTING AND PROMOTING TRADITIONAL KNOWLEDGE: SYSTEMS, NATIONAL EXPERIENCES AND INTERNATIONAL DIMENSIONS, 193, 193 (Sophia Twarog & Promila Kapoor eds., 2004).
[175] *See* Disini, *supra* note 165.
[176] Kamil, *supra* note 174, at 195.

national scale for the protection of TK are still in the planning stages.[177]

4. Control over Knowledge and Resources: The Indian Experience

"India is one of the 12 megabiodiversity centres in the world. It has a wide diversity of ecological habitats like forests, grasslands, wetlands, coastal and marine ecosystems. Based on the available data, India ranks tenth in the world and fourth in Asia in plant diversity."[178]

Like many other developing countries, India is at a crossroads with regard to the development of a new legal regime concerning the management of its vast biological resources and related knowledge. In pursuance of this, the Indian Parliament enacted the Biological Diversity Act 2002 in order to implement and give effect to the CBD. The Act was passed on February 5, 2003, and is an important step towards incorporating the CBD's policy framework at the national level, and was considered long overdue by various intellectuals and NGOs (non-governmental organizations) active in the field of IPRs and biodiversity conservation. Their demands and concerns were mainly spurred by the global hijack of Indian biodiversity and associated TK. The patenting of Neem and Turmeric by foreign firms initiated a public unrest not only in India, but also abroad, thus compelling the government to enact legislation to protect and regulate access to genetic resources and traditional knowledge.[179]

Under § 36(5) of the Biological Diversity Act, it is provided that the Central Government shall endeavor to respect and protect the knowledge of local people relating to biological diversity through such measures as recommended by the National Biodiversity Authority (NBA). That could include registration of the knowledge and/or creation of a *sui generis* system for protecting such knowledge.

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[177] *See* World Intellectual Property Organization, *What is Traditional Knowledge? Why Should it be Protected? Who Should Protect it? For Whom? Understanding the Value Chain*, ROUNDTABLE ON INTELLECTUAL PROPERTY AND TRADITIONAL KNOWLEDGE (Nov. 1-2, 1999) (*prepared by* Michael Blakeney), WIPO/IPT/RT/99/3.

[178] R.V. Anuradha, *In Search of Knowledge and Resources: Who Sows? Who Reaps?*, 6 REV. EUR. COMMUNITY & INT'L ENVTL. L. 263, 267 (1997).

[179] *See* Peter Drahos, *Developing Countries and International Intellectual Property Standard-Setting*, 5 J. WORLD INTELL. PROP. 765 (2002).

According to § 3, persons who are not citizens of India, or associations or organizations which are not registered in India or which have non-Indian citizen participation in equity or management, would be prohibited from obtaining any biological resource originating within the country, and associated knowledge, without the prior approval of the National Authority. This prohibition is also applicable on citizens of India who live abroad. Some provisions are available to ensure monetary compensation to the providers of knowledge where the commercial exploitation of biological resources or knowledge was a result of access given by a specific individual or group of individuals. This will be achieved in four different ways. First, at the time of granting approvals under §§ 19 and 20 of the Act, the NBA can secure equitable benefit sharing for benefit claimers. Second, a venture capital fund for aiding the cause of benefit claimers may be set up. Third, an association of Indian scientists, benefit claimers, and indigenous peoples may be set up to carry out research and development in biological resources. Fourth, the NBA can order that benefit sharing be carried out by way of the payment of monetary compensation directly to these individuals, groups, or organizations, in accordance with the terms of any agreement for benefit sharing and in such a manner as the NBA deems fit.[180]

Analysis

The Act is the first statute that has been enacted in India in order to achieve the objectives of the CBD. Though it establishes a regulatory and enforcement mechanism within India, nevertheless critics have pointed out several shortcomings from both the regulatory and enforcement viewpoints. Practically, it does not provide effective measures for the protection of genetic resources and related TK and is heavily biased against the interests of tribal and local communities who are the original guardians of the associated knowledge. This is perhaps because there was no direct participation of local communities and tribes in the consultation process for drafting the Biodiversity Bill. Their interests were mainly reflected by some representative NGOs and not directly by themselves. Moreover, the regulations prescribed for Indian nationals and organizations even seem to encourage commercial exploitation of resources rather than giving impetus to the conservation of biodiversity or to benefit sharing with the local communities.[181]

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[180] *See* Anitha Ramanna & Melinda Smale, *Rights and Access to Plant Genetic Resources under India's New Law*, 22 DEV. POL'Y REV. 423 (2004).
[181] Sagar, *supra* note 100, at 400.

Even from the perspective of its compatibility with international regimes, there are also some frictions reported. According to the Act, Indian applicants for access to genetic resources are not subject to the same constraints as foreign or international biological diversity prospectors. These restrictions, which apply only to foreign bio-prospectors, stand in problematic relation to Article 15(2) of the CBD, which obliges the Member States of the Convention to mutually facilitate access to genetic resources.

Cullet also observes that, since the permission of the National Biodiversity Authority would be required for patent applications outside India, the Authority may theoretically oppose the grant of intellectual property rights, not only in national patent procedures, but in any foreign country, as long as the subject matter is based on a biological resource obtained from India or on knowledge associated with such a biological resource. Thus, the Authority's competence to impose this may not be compatible with the TRIPS Agreement.[182]

A. Case Studies

As stated earlier, the need for effective legislation for the protection of GRs and associated TK was sparked due to several cases of misappropriation (biopiracy) of TK from India. In the well-known cases of Neem & Turmeric (Haldi), the issue arose from the granting of patent protection to inventions relating to traditional knowledge, which was already in the public domain. In these cases, patents were issued because the patent examiners were not aware of the relevant traditional knowledge.

(i) The *Neem* Case

The *Neem* case was noteworthy because, for the first time, a patent based on the traditional knowledge of a developing country was successfully challenged.[183]

As long as 4,000-4,500 years ago, various parts of the neem tree were used in beauty and medicinal products by the ancient Harappa. Evidence of these uses exists in the remains excavated in the region where the Harappa formerly lived – present day northwestern

[182] Cullet, *supra* note 98, at 215-17.
[183] O'Connor, *supra* note 20, at 681.

India, Pakistan, and Afghanistan. Neem is also famous for its properties as a natural medicine, pesticide, and fertilizer.

"In 1994, the European Patent Office granted a European patent to the U.S. Corporation W.R. Grace and the U.S. Department of Agriculture for a 'method for controlling fungi on plants by the aid of a hydrophobic extracted neem oil.'"[184] In June 1995, legal opposition against the grant of this patent was filed by the Green Group in the European Parliament and by Dr. Vandana Shiva, on behalf of the Research Foundation for Science, Technology, and Natural Resource Policy, New Delhi.[185]

> On 15 June 1999, the Opposition Board of the European Patent Office held that due to the fact that "all features of the present claim [of the patent] have been disclosed to the public prior to the patent application during field trials in the two Indian districts Pune and Sangli" of Maharashtra, Western India, in summer 1985 and 1986, it appeared to be "mere routine work for a skilled person to add an emulsifier in an appropriate amount" and that therefore "the present subject-matter was considered not to involve an inventive step." The patent, therefore, was revoked by the European Patent Office in May 2000.[186]

(ii) The *Turmeric* Case

In spite of the fact that the decision on the *Turmeric* case appeared later than the revocation of the neem patent, this case attracted even more attention from the public.

Turmeric is a plant of the ginger family. It has been used as a dye, flavoring, and medicine (to treat stomach and liver ailments) since 600 B.C. In 1280, Marco Polo described it as "a vegetable with the properties of saffron, yet it is not really saffron."[187]

In March 1995, two expatriate Indians at the University of Mississippi Medical Center were granted a U.S. patent for turmeric to be used to heal wounds.[188]

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[184] *Id.*
[185] *Id.*
[186] *Id.* at 682.
[187] *Id.*
[188] *Id.*

The Indian Council for Scientific and Industrial Research (CSIR) filed a case with the U.S. Patent Office challenging the patent on the grounds of "prior art," i.e., existing public knowledge. The CSIR argued that turmeric has been used for thousands of years for the healing of wounds and rashes and, therefore, its medicinal use was not novel. The CSIR went so far as to present an ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association. The U.S. Patent Office upheld the CSIR's objections and revoked the patent in August 2002.[189]

5. Protection of Genetic Resources and Traditional Knowledge in Pakistan

> Pakistan has a rich bio-wealth and vast natural resource base, covering various ecological and climatic zones; hence the country has great potential for producing all types of food commodities. Agriculture is the backbone of Pakistan as in most of the developing countries and the majority of people are depending on agricultural production to sustain their livelihood and food security.[190]

The recent advances in modern biotechnology make possible the increased use of genetic resources and traditional knowledge related to these resources in science and industry.[191] This raises a number of questions in the context of access to such GRs and related TK and the sharing of the benefits arising from their use. Pakistan is well aware of the current developments in the field of intellectual property and there are certain measures devised at the national level for the protection of such resources and knowledge.[192]

A. Draft Law on Access to Biological Resources and Community Rights 2004

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[189] *Id.*
[190] Abdul Hafeez & Qasim Ali Shah, Access and Benefit Sharing: Options After TRIPs 1 (March 13, 2005) (unpublished paper, Islamabad, Pakistan) (on file with author).
[191] *Id.*
[192] *See generally, id.*

The Pakistani Ministry of Food, Agriculture, & Livestock is working on draft legislation to establish fundamental grounds for an ABS mechanism within that nation.[193] The drafted legislation will protect and support the rights of local (and traditional) communities over biological resources and their related knowledge, innovations, and practices.[194] This draft has been developed, keeping in view the obligations of CBD, as the preamble shows commitment to implement the relevant provisions of the CBD, in particular Article 15 on access to genetic resources and Article 8(j) on the preservation and maintenance of knowledge, innovations, and practices of indigenous and local communities.[195] It will ensure the conservation and sustainable use of biological resources and knowledge, and provide an appropriate system of access based upon mutually agreed terms and subject to the prior informed consent of the State and the concerned local communities.[196] Article 4(3) prohibits import or export of any genetic resources unless the competent national authority confirms that prior informed consent has been obtained from the country of origin.[197] Article 6 provides appropriate mechanisms for a fair and equitable sharing of benefits arising from the use of biological resources, knowledge, and technologies.[198]

B. Biodiversity Action Plan for Pakistan (BAP)

The Pakistani Ministry of Environment, Local Government, and Rural Development, working alongside the World Wide Fund for Nature, Pakistan, and IUCN-The World Conservation Union, submitted the BAP 1999, in addition to the first and second country reports, to the CBD Secretariat.[199] It is an endeavour to roll into one the three sequential processes called for under the CBD: the country study, the national strategy, and the action plan.[200] Action 4.11 of the BAP discusses "access issues" in detail.[201] Action 2.7 reaffirms Pakistan's commitments to the CBD to develop access legislation as a matter of priority to comply with Article 15 (genetic resources), Article 16 (technology), and Article 19 (handling of biotechnology and

[193] *Id.* at 5.
[194] *Id.*
[195] *Id.* at 6.
[196] *Id.*
[197] *Id.*
[198] *Id.*
[199] *Id.*
[200] *Id.*
[201] *Id.*

distribution of its benefits).[202] Similarly, Action 22.5.1 suggests providing a legal ABS framework, so as to "establish a clear system for the fair and equitable distribution of benefits derived from the use of genetic resources."[203]

C. The Way Forward

Trained human resources and infrastructure have to be put in place coherently for the effective implementation of the legislation. In Pakistan, neither the legislation nor the systems of implementation are in place. This is perhaps because of the lack of technical know-how and resources. Therefore, at the national level, there is a need to create awareness among local communities, and efforts should be made forthe promulgation of draft legislation on access to biological resources and community rights. The civil societies and real stakeholders (including farmers and local communities) should persuade the government to take necessary measures to implement various conventions like the CBD. At the same time, capacity building activities like training to create human resources and infrastructure should be put in place for the effective implementation of the legislation.[204]

D. The Basmati *Case*

The *Basmati* rice case concerned the protection of traditional knowledge and geographical indications.

Rice is the second-place major crop in Pakistan in its contribution to export earnings from raw material, an annual foreign exchange return of $250.6 million (U.S.) (1999-2000).[205] Pakistan exports one million tons of rice annually, which is about 10% of the world rice trade.[206]

In 1997, the Texas based RiceTec, Inc., was granted a patent on basmati rice lines and grains by the U.S. Patent Office (USPTO).[207] These "new" strains of rice could be sold under the name "Basmati."

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[202] *Id.*
[203] *Id.*
[204] *Id.* at 11.
[205] *Id.* at 16.
[206] *Id.*
[207] U.S. Patent No. 5,663,484 (filed Sep. 2, 1997).

Both Pakistan and India showed concerns over this issue, as this could have grave repercussions for the agricultural communities in both of those countries.[208] The basmati variety, on which RiceTec claimed a patent, has been derived from Indo-Pak Subcontinent (Punjab) basmati crossed with semi-dwarf varieties.[209] After the protests of India and Pakistan against the use of the name "Basmati," the USPTO disallowed the patent holder from using the name "Basmati," as that name was not considered to be a generic name but denoted specific qualities of the famous basmati rice from the Punjab provinces of India and Pakistan. The rice can now be sold only as "*Texmati*" or any other name that clearly informs the consumer that the rice is not from the Punjab region.[210]

It is important to mention that it is highly expensive to challenge cases of biopiracy on a case-by-case basis. American lawyers demanded a deposit of £300,000 from Pakistan to fight the basmati case.[211]

E. The Chapatti *Case*

"*Chapatti*" is another issue which demands immediate attention from the public and government both in Pakistan and India. The grant of a patent has spurred the leading NGOs and public in India to persuade the government to stop the bid which, according to them, is misappropriation of their traditional knowledge.[212]

This latest gene-theft is of a wheat variety used for making chapatti. The patent was obtained by Monsanto, which is the world's largest genetically modified seed company.[213] The patent was awarded by the European Patent Office (EPO) in Berlin, which gives the U.S. multinational exclusive ownership over Nap Hal, a strain of wheat whose gene sequence makes it particularly suited to producing crisp breads.[214] The activists argue that this act of biopiracy of important plant genetic resources could block cultivation of all related varieties in India.[215]

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[208] Lightbourne, *supra* note 10, at 891-92.
[209] *Id.* at 876-77.
[210] *Id.* at 885, n. 43.
[211] Hafeez & Shah, *supra* note 190, at 16.
[212] Ashfak Bokhari, *It's 'Chapati' Now*, DAILY DAWN (Karachi, Pakistan), March 8, 2004, (Economic & Business Review), at 5, *available at* http://www.dawn.com/2004/03/08/ebr5.htm.
[213] *Id.*
[214] *Id.*
[215] *Id.*

Academics in Pakistan are equally concerned about the issue as, according to them, if Monsanto's bid is successful, it can adversely affect Pakistani farmers because this is the same wheat variety from which chapatti is prepared in Pakistan, as well.[216] Unfortunately, none in Pakistan – the government, farmers, or the NGOs – have taken notice of the development and its effects.[217]

To put it in a nutshell, Nap Hal's qualities are the result of the efforts of several generations of farmers in the Indo-Pakistan subcontinent who spent years crossbreeding the crops. Monsanto is simply interested in monopolizing the profits from a wheat variety which has a vast market and on which the lives of millions depend.[218]

CONCLUSION

Over the past decade, the issue of protection of genetic resources and associated traditional knowledge has received worldwide attention. The activities in this regard can be observed, not only in the framework of international organizations, but as several developing countries have also made efforts for introducing effective legislation for promoting and conserving genetic resources and traditional knowledge. Factors contributing to this include the recognition of TK's importance in the lives of the majority of the world's population and in the conservation of biodiversity, concerns about the rapid loss of TK, little or no sharing of resulting benefits with the original holders of TK, interest in harnessing the potential of TK for local sustainable development, and increasing attention to indigenous rights.[219]

Though considerable work has been done for the protection of such knowledge and resources, a challenging agenda of research and policy still lies ahead. How extensive are genetic resources and indigenous knowledge of countries, and to what uses can they be put? How important is the potential economic value of these resources? Most importantly, how do providing countries tackle the misappropriation of such knowledge and resources? In all these areas, the developing countries can build a credible international negotiating position.

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[216] *Id.*
[217] *Id.*
[218] *Id.*
[219] *See* Leistner, *supra* note 124.

As far as the smooth and successful adoption of international provisions and regimes into domestic laws is concerned, developing countries need to consider the following issues:

> the degree to which the provisions required changes in domestic legislation;
>
> the degree to which the required changes conflict with existing laws of obligations under other agreements; and
>
> the ability of the developing countries to adjust their institutions where the two issues outlined above do not hinder the implementation process.[220]

For developing countries, the adoption of a *sui generis* system, which rewards the contribution of all actors involved and which also seeks to foster their sustainable management, is of great importance at this juncture. The developing countries need to create consensus among each other to promote a *sui generis* system of protection, not only in the TRIPS Council, but in other international forums as well.

Keeping in view the rigid stance of developed countries of not tolerating any hindrance to access to such knowledge and resources, the developing countries need to make joint efforts in all international negotiations so as to secure their economic interests. Moreover, they need to develop a consensus upon a solution which should be mutually beneficial and in the wider interest of humanity by utilizing such knowledge and resources.

[220] Mathur, *supra* note 37, at 95.