

Access, Benefit Sharing and Intellectual Property Rights:

Report of the TWG¹

Introducing the Issues

Conservation and sustainable utilisation of biological resources, the two key objectives that the Convention on Biological Diversity (CBD) seeks to realise find themselves delicately balanced in view of the ever-increasing exploitation of these resources for commercial gains. In recent years, the developing countries, in particular have come alive to the issues of biopiracy as also misappropriation of traditional knowledge system that forms an integral part of the utilisation of these resources. This has led to initiatives being taken to address three core concerns. The first relates to the mechanism(s) that need to be adopted to regulate access to the biological resources that are available in the countries concerned. The second relates to the nature of benefit sharing arrangements that must be put in place in the event of commercialisation of the biological resources. And, finally, what are the mechanisms that are needed for protecting traditional knowledge and its holders.

These initiatives have been taken in several regions of the world and by organisations operating at the multilateral, regional or national levels. This report of the Thematic Working Group (TWG) on Access, Benefit Sharing and IPRs evaluates the initiatives and makes recommendations on the way ahead for India.

Methodology adopted by the TWG

The TWG on Access, Benefit Sharing and IPRs met twice and discussed the areas of investigation that it should take up. Members of the Group agreed to look into specific issues and to submit their inputs. Dr. Veena Jha of UNCTAD, a member of the TWG, proposed that UNCTAD and the TWG jointly take up a study “Traditional Medicinal Knowledge of India: An Overview on Commercialisation and Benefit Sharing”². The Executive Summary of the study is appended. The Group

¹ Coordinated by Dr. Biswajit Dhar, Research and Information Service for Non-Aligned and Other Developing Countries, New Delhi.

² The TWG provided travel grants to the Consultant appointed by UNCTAD to undertake the study.

members placed three documents before the TWG. These documents are also appended.

The coordinator prepared the final report of the TWG with inputs from several members.

I. Arrangements for Regulating Access to Biological Resources

Countries implementing Article 15 of the CBD that aims at regulating access to biological resources have proposed/adopted two alternative approaches in their legislations. While in one case the traditional communities would be involved in the process of gaining access to biological resources, in the other, this power would be given to an exclusively to an official body having a wide representation, which includes major stakeholders.

A third approach for regulating access of biological resources has been suggested by the United States in its submission to the WTO TRIPS Council³. According to the US, the objectives set out in Article 15 of the CBD can be met through contracts between those granting access to the resources and those to whom access is granted. Such contracts should spell out the terms and conditions and other details that would be critical to effectively using these contracts.

Besides the above-mentioned approaches, customary laws too have an important role to play in many cases. However, like the other approaches that have been suggested, this approach has remained relatively unexplored despite there being independent studies highlighting the importance of customary laws⁴.

The first system has been proposed/adopted by most of the countries that have taken initiatives to implement the CBD. These include countries belonging to the Andean Pact, the members of the Organisation of African Unity (OAU) and some of the countries in South-East Asia⁵. The second system has been proposed in the biodiversity legislation adopted by India. The third approach has found some acceptance in the establishment of benefit sharing arrangements, an issue that would be discussed in a later section.

³ WTO (2001) and WTO (2002).

⁴ In the present study, the role of customary laws has been discussed in the section on benefit sharing.

⁵ A framework for a sui generis legislation has been proposed by Dr. N.S. Gopalahrishnan, one of the members of the TWG. This framework is included in Annex I of the report.

The involvement of the traditional communities in the process of gaining access to biological resources as proposed by different countries/regions has at least three variants. The first, which forms the basis of the guidelines for bioprospecting adopted by the Philippines in its Executive Order No. 247⁶, puts the traditional communities in the key decision-making role as regards access to biological resources. The OAU Model Law⁷ provides the second variant of the access legislation access to biological resources, knowledge and or technologies of traditional communities can be obtained subject to the written PIC of the concerned traditional communities apart from the National Competent Authority set up to implement the legislation. The third variant is the one that has been provided in Decision 391 of the Andean Community⁸. This framework adopted by the Andean Community provides that the Competent National Authority appointed by each of the member countries to carry out the activities provided for in the common regime, would not only determine access but also enter into contractual arrangements with the prospective users of the biological material. But while the contract is being entered into, the interests of the traditional communities would have to be explicitly taken into consideration. In other words, the traditional communities are part of the decision making when biological resources are used in the Andean Community.

It has however been seen that participation of the government and its agencies in becoming more common as access laws are being implemented.⁹

The Indian legislation, the Biodiversity Act, too does not explicitly bring the traditional communities in the decision-making regarding access. Access to biological resources can be obtained by referring to the National Biodiversity Authority (NBA) the setting up of which has been provided for in the legislation. The 14-member NBA would have representatives of conservers, creators and knowledge holders of biological resources among its 5 non-official members.

⁶ 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, adopted in 1995.

⁷ African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources. For a discussion see, Ekeperu (2000).

⁸ Common Regime on Access to Genetic Resources, 1996.

⁹ Columbia University (1999).

It is quite obvious that the Indian legislation provides for the least participation of the traditional communities in the process involving access to biological resources as compared to the other cases discussed above. However, if it the NBA takes the views of the representatives of the traditional communities fully into consideration, the Indian legislation could provide the best mechanism for effectively utilising biological resources. The other legislative apparatus provided by the other countries could involve high transactions cost arising out of the series of approvals that would have to be taken from the traditional communities before the biological resources are utilised. There is thus a distinct possibility of the access legislations of the latter variety to become major road-blocks towards utilisation of biological resources.

There above discussion indicates that there is a need to evolve a mechanism providing for access to biological resources that provides a balance between the two systems that countries have proposed/adopted in their legislations. Given this imperative, it that could be suggested that the NBA as provided for by the Indian legislation could include more stakeholders from amongst the traditional communities so as to improve its representative nature. In the ultimate analysis, the nature of the NBA could play a critical part in the benefit sharing arrangements.

II. Evolving Benefit Sharing Arrangements

A number of issues need to be considered while addressing the second set of concerns. These can be divided into three broad sets. These are (i) using the conventional forms of intellectual property rights to provide benefits to the owners of traditional knowledge, (ii) developing sui generis systems to protect the interests of traditional knowledge, (iii) using customary laws, and (iv) establishing contractual arrangements for benefit sharing in case traditional knowledge was commercially exploited. The first approach suggests using various forms of intellectual property rights that the Western legal tradition has employed over centuries to reward the creators, which includes patents, copyrights, trademarks and the like. The second, an alternative suggestion to the first, has been to develop a distinct form of intellectual property rights, the so-called sui generis system, for protecting traditional knowledge. The third approach suggests various contractual arrangements that may be used to ensure that the holders of traditional knowledge

can claim benefits when commercial exploitation of their knowledge takes place. The following discussion provides a critical appraisal of the three approaches.

1. Use of Intellectual Property Rights

Two approaches, which are not mutually exclusive, have been suggested in this context of using conventional forms of intellectual property rights to provide arrangements for benefit sharing. The first is to protect the holders of traditional knowledge using one of the conventional forms of intellectual property rights so that they can use the monopoly rights that they would enjoy as a result for extracting the rents arising from the use of the knowledge by third parties. The second approach is to allow for benefit sharing arrangements in case commercial interests have used patents to protect a product or process that have used either the biological material or the associated traditional knowledge. The issues involved in each of the two approaches are discussed below.

(i) Protecting Traditional Knowledge through Intellectual Property Rights

The issue of using conventional forms of IPRs for protecting traditional knowledge has seen the emergence of three sets of views. The first of these support the use of forms of IPRs, including patents, for protecting traditional knowledge¹⁰. The second advances the view that specific forms of IPRs may be more appropriate for the purpose. The third view is that conventional forms of IPRs are inappropriate for protecting traditional knowledge.

The use of conventional forms of IPRs, more particularly patents, have found support with the participants in the debate who argue that the individuals in local communities can be singled out for the contributions they make as creators or inventors of knowledge¹¹.

The proponents of the view that Conventional forms of intellectual property rights should be used for protecting traditional knowledge have argued that the concept of

¹⁰ It may be pointed out that a variant of the first approach has also been suggested. This involves creation of property rights to protect traditional knowledge, the so-called traditional intellectual property rights (TIP-Rights), in the framework of the TRIPS Agreement. These rights would have to be adapted to the characteristics of traditional knowledge and designed to answer its specific protective needs. TIP-Rights would not rely on novelty but would encompass pre-existing traditional knowledge and know-how relating to plant and animal genetic resources. For a discussion on this issue, see, Biber-Klemm (2000).

traditional knowledge is not a static, but dynamic one. Thus view, in other words, emphasises on the evolutionary nature of traditional knowledge as being one of its features. A Canadian report elaborates this perspective thus:

What is 'traditional' about traditional knowledge is not its antiquity, but the way it is acquired and used. In other words, the social process of learning and sharing knowledge, which is unique in each indigenous culture, lies at the very heart of its 'traditionality'. Much of this knowledge is actually quite new, but has a social meaning, and legal character, entirely unlike the knowledge of indigenous peoples acquires from settlers and industrialized societies...¹²

Based on this understanding, some organizations, including SRISTI and the Council of Scientific and Industrial Research (CSIR), have been taking patents on behalf of the identified owners of traditional knowledge¹³.

There have, however, been suggestions that some forms of intellectual property rights, which have either loosely defined criteria of novelty or none at all, can be used for protecting traditional knowledge¹⁴. Two forms of intellectual property rights have been specifically been mentioned in this context. These are: (i) the system of plant breeders rights as provided for under the International Convention for the Protection of New Varieties of Plants, more commonly known as the UPOV Convention, and (ii) geographical indications.

According to the UPOV Convention a plant variety could be considered as new if two criteria were met. One, the variety must not have been offered for sale or marketed in the country in which protection was being sought for more than one year. And, two, the variety must not have been offered for sale or marketed in any other country for more than four years in case of all plant varieties except for vines, forest trees, fruit trees and ornamental trees. In the latter set of plant varieties, the corresponding period was to be not more than six years. However, the protection that UPOV Convention affords to plant varieties is for a limited duration and is

¹¹ Gupta (1992), quoted by Downes (1997).

¹² Submission to the Executive Secretary from the Four Directions Council, Canada, 15 January 1996, quoted from Convention on Biodiversity (1996), p. 19.

¹³ Gupta provides the evidence on SRISTI. See, Gupta (n.d.). The CSIR has been taking patents on traditional knowledge on behalf of individuals in the communities possessing the knowledge in the United States.

¹⁴ See for example, Correa (2001).

hence unsuitable as an instrument for traditional knowledge for the reasons elucidated above.

The uses of geographical indications (and also trademarks) for protecting traditional knowledge as an alternative to the better-known forms of intellectual property rights e.g., patents, have been explored¹⁵. Geographical indications have been recognised as one of the forms of intellectual property rights under the Agreement on TRIPS, which can be used to prevent unauthorised use of any product that is known to have originated in a specific geographical location. The alternative of using geographical indications promises at least two advantages over patents. While the geographical indications can be used to grant protection in perpetuity, the patent system allows protection of the product or process only a specific period of time. Moreover, geographical indications do not confer a monopoly right over the use of certain information but simply limit certain categories of people who can use the product that is protected.

The use of geographical indications is however not free from problems, particularly when the subject matter of protection is traditional knowledge. It can be argued that this form of protection only provides protection to the product, and not to the embodied technology, thus limiting to usefulness¹⁶. Furthermore, this form of intellectual property rights still does not address the fundamental problem that traditional knowledge is often unbound by space and thus may not be confined to a geographical location in which case geographical indications cannot be used for its protection.

The inappropriateness of the existing intellectual property laws for protecting traditional knowledge has been discussed quite extensively in the past couple of decades. The nub of the arguments presented thus far has been that the existing intellectual property laws have been the products of Western capitalism, which has glorified the virtues of individual efforts in furthering the knowledge systems. Thus, the patents and copyright laws were designed to safeguard the interests of the individual inventor or the authors and creators of article works. The temporary monopoly that was provided to both the inventors and the authors and other creators

¹⁵ See for example, Downes (1997) and Rangnekar (2002).

of artistic works through the grant of intellectual property rights was aimed at providing them with the incentive to further hone their skills. By nature, therefore, intellectual property rights, as we understand them now, are designed to prevent anyone other than the inventor or the creator to use these products of human intellect.

These monopolistic and exclusionary characteristics of intellectual property rights are not suited for the protection of traditional knowledge on at least two counts. The first is that the existing intellectual property laws have not been applied to knowledge that is mostly collectively held. Traditional knowledge has come to be collectively held primarily because of the fact that it has generally been free flowing, unbound by the limits of time and space. It is this nature of traditional knowledge that has given the system the strength not only to survive the millennia but also to establish the point that it could play an important role in ensuring the sustainability of human civilization.

The second issue, albeit a conceptual one, is the veracity of using certain forms of intellectual property rights to protect knowledge that is essentially in public domain. The major forms of intellectual property rights, viz., patent and copyrights, can only be used to protect knowledge that has not fallen into public domain. This, in other words, means that the patents and copyrights can only be used to protect an invention in case of the former and a literary or artistic work, in the case of the latter only if the embodied knowledge was novel.

In this context, it may however be pointed out that none of the above mentioned suggestions have been put into practice and this does raise some doubts about their applicability.

Alongside the so-called market-based approach for protecting traditional knowledge by using existing intellectual property laws there have been several attempts to devise alternative approaches. These approaches have tried to emphasise the rights of the communities and farmers over the genetic resources and knowledge they have customarily used over generations through the so-called *sui generis* options. The details are provided in the following discussion.

¹⁶ Dutfield (2000).

(ii) Using Intellectual Property Rights to Extract Benefits

It has been argued that intellectual property rights could encourage access and benefit-sharing, if applications for such rights required: (i) identification of the source of genetic material used in the development of subject matter which is to be protected by intellectual property rights; and (ii) proof of the prior informed consent of the competent national authority of the provider country, if the genetic resource was acquired after the entry into force of the Convention on Biological Diversity and does not fall within the scope of a possible multilateral system for plant genetic resources for food and agriculture.

The importance of these requirements lies in the fact that once the origin of the biological resource utilised in a patents technology is identified, the country in which the resource originates can claim benefits arising out of communal exploitation of the technology. It is with this interest that the provision for disclosing the source of the biological resource has been included in the second amendment of the Patents Act that was carried out recently.

The disclosure requirement is significant from yet another perspective. One of the most significant of the immediate threats that traditional knowledge holders have faced over the years arises from the misappropriation of their knowledge. This has happened when for instance a company or an individual has taken patent rights on a product or process that is based on traditional knowledge. Thus, traditional knowledge that has largely remained in public domain could end up being a private property, the use of which can subsequently be controlled by its owner.

This threat posed by the intellectual property system to the holders of the traditional knowledge system arose primarily because of differing standards for assessing “prior art” by the intellectual property offices in various countries¹⁷. The term “prior art” refers to the body of knowledge, which is in public domain at the time when the application for a patent, utility model or industrial design is made. In case the patent applicant claims priority, the period before the priority date would be considered while considering whether or not the invention in question can be considered as “prior art”. The knowledge of prior art is of critical importance for undertaking

¹⁷ WIPO (2001a).

substantive examination of the applications for grant of the above mentioned forms of intellectual property rights, since novelty of the subject matter for protection would have to be proved before the intellectual property rights can be granted.

In recent years there has been growing concern about the recognition of traditional knowledge as “prior art”. Such concerns have been raised particularly after the patent on “Use of Turmeric in Wound Healing” was obtained in the United States in 1995. The subject matter of patent in this case was a well-known remedy used in the Indian Systems of Medicine. There are two facets to this problem. The first is the difference in the definition of “prior art” in relation to traditional knowledge adopted by the patent offices of various countries and the second is the availability of adequate documentation that can be easily accessed which can then be used to challenge any patent claim that uses traditional knowledge

Although the patent regime countries across the world have been harmonised to a significant extent after the adoption of the Agreement on TRIPS, definition of “prior art” differ considerably across countries. The European Patent Convention considers any information “made available to the public by means of a written or oral description, by use, or in any other way...” to comprise “prior art”. On the other hand, the US Patent Act accepts the following criteria to examine an application for a patent to decide whether or not it can be considered a “prior art”: (a) the invention was known or used by others in the United States, or patented or described in a printed publication in the United States or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in the United States or a foreign country or was in public use or on sale in the United States, more than one year prior to the date of the application for patent in the United States. The differences in the standards adopted for assessing whether or not patent application includes a product or a process represents “prior art” in the two patent laws maintained above quite clearly signifies the extent of problem that traditional knowledge could face on this account in the United States as compared to Europe. While in Europe, oral description could be used as evidence to prove the fact of “prior art” the same standards would not be applicable in the United States where only printed publication would be admissible.

There is thus an urgent need to take up the issue of harmonisation of guidelines to be followed by the patent examiners in so far as “prior art” is concerned¹⁸.

The problem caused by inadequacy of information was experienced when CSIR challenged the patent taken on the wound healing properties of turmeric. The challenge mounted by the CSIR brought to light the fact that this knowledge was a part of the oral tradition and that documentary evidence was hard to come by. It was an ancient scripture that eventually came to the rescue of the CSIR in defending its position¹⁹.

The experience gained from the challenge to the turmeric patent prompted the government and the civil society organizations in India to carry out extensive documentation of traditional knowledge, related to biodiversity, and traditional knowledge in particular. At the international level, the World Intellectual Property Organization (WIPO) took up the issue documenting traditional knowledge as a part of the work programme under the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

Two sets of issues have been raised in the context of the documentation of traditional knowledge in the discussions that have taken place in WIPO’s Intergovernmental Committee. The first is the issue of developing quality databases and digital libraries in order that the relevant information can be easily accessed. The second is the classification of traditional knowledge so as to facilitate efficient retrieval of the information contained in the databases.

In both these issues, India has taken the lead among the developing countries. A Traditional Knowledge Digital Library (TKDL) has been established by the Government²⁰ which can provide the wherewithal to the patent examiners in developed countries where patenting of products and processes based on traditional knowledge has continued to take place despite the dispute over the turmeric patent.

¹⁸ Some steps towards this end has been taken by the WIPO through the proposed Substantive Patent Law Treaty. For details see WIPO (2002).

¹⁹ Orbit magazine quotes Dr. R.A. Mashelkar, Director General, CSIR: “We submitted all the evidence, including texts from our ancient Sanskrit literature, and eventually the Americans revoked the patent”. For details see, Orbit magazine, issue 83, www.vso.org.uk/publications/orbit/83/article1.htm.

²⁰ The National Institute for Science Communication (NISCOM) is the implementing organization.

Further, it has been suggested that a traditional knowledge resources classification (TKRC) be adopted alongside. The initiatives mark significant progress towards ensuring that the traditional knowledge system can be protected from misappropriation.

The efforts that the Government of India has taken in this direction is being complemented by the considerable amount of work that civil society organisations have put together in documenting traditional knowledge²¹. Preparation of Community Biodiversity Registers (CBRs) (also called People's Biodiversity Register or PBRs) represents an initiative taken by several civil society organisations in India for promoting sustainable use and equitable benefit sharing while conserving the biological diversity²². As a loosely knit nationwide movement, it aims to generate village level biodiversity and knowledge stock maps as well as management plans. The objectives of the programme broadly stated are as follows:

- (i) Documentation of people's knowledge, practices of sustainable use and conservation of bioresources, both wild and domesticated; to help in protecting their IPRs (benefit sharing rights) besides traditional usage practices.
- (ii) Participatory planning for its sustainable and equitable use, besides conservation.
- (iii) Resolution to approve this document as a village resource, at meeting of the gram sabha (village community) or panchayat (village council), so as to help in institutionalisation of the CBRs.
- (iv) Giving wide publicity to this process and products in popular as well as scientific media, to stimulate debate and encourage improvements and replication.

Besides the CBRs, attempts are also being made by a few civil society groups to develop digital libraries of local innovations, using the advances in technology to preserve and protect traditional knowledge and their holders.

²¹ The National Innovation Foundation (NIF) and Indian Institute of Science have been engaged in major programmes for documenting traditional knowledge. The innovations database of the former (www.nifindia.org) and biodiversity registers developed by the latter (<http://ces.iisc.ernet.in/hpg/cesmg>) provide the details in this regard.

²² Ghate (2001).

These efforts at documenting traditional knowledge are singularly important, as they would lead to a better understanding of the knowledge system. In fact these initiatives should be considered at the first steps towards finding the most appropriate system for the protection of traditional knowledge and their holders. But while these initiatives represent the right way forward, it needs to be mentioned that the databases that are thus being developed can also become the easy conduits for the large scale biopiracy to take place. It is therefore important that the government and the civil society organisations coordinate their activities in order that the objective of providing benefits to the holders of traditional knowledge can indeed be realised.

The other threat that these databases that are being prepared in countries like India can come from the proposed sui generis protection of databases. Protection of databases is currently covered by the copyright laws, which are, in turn governed by the Berne Convention. However, the nature and scope of protection that databases can be provided are proposed to be substantially re-written as is evident from the Draft Treaty that the WIPO has been considering for the past few years²³.

The proposed sui generis protection of databases is particularly significant given the fact that large corporate interests have developed in Western Europe and the United States in the production of databases. Following the decision in 1991 in the Feist Publications Inc. vs Rural Telephone Services Co., the database community has consistently argued that the protection afforded to databases through the Copyright law provides little or no protection against piracy.

Support for these arguments was lent by the EU Directive on database protection of 1996. The EU initiative in turn was given a further direction by the WIPO when it brought before the copyright community the proposal for the sui generis protection of databases the same year.

However, with the databases treaty on the anvil, there is a perceptible danger of the CBRs going out of the public domain and forming parts of protected databases. In the worst case scenario, the owners of databases would use the "non-disclosure to public" clause proposed in the databases treaty to protect the databases. With such

²³ Dhar and Chaturvedi (2001).

restrictions on the access to information about their biodiversity in place, countries like India can be prevented from taking advantage of the benefits that may arise from commercial use of biodiversity.

2. The Sui Generis Options

The sui generis options have been seen as the alternatives to protecting traditional knowledge through the existing intellectual property laws. These options have focused almost entirely on defining the rights of the communities over the genetic resources that have been using. In the more specific context of agriculture, the concept of “Farmers Rights” has been put forth. These concepts are still evolving through the various initiatives taken at the national and multilateral levels, mostly involving the developing countries.

The initiatives that have been taken at the national level have taken two forms. One, the rights of the traditional communities over the resources they have been using, including knowledge, technologies and practices, have been recognised by various countries through an official fiat. Two, countries have taken steps to implement their commitments that they have made as signatories to the Convention on Biological Diversity. Most of these legislations are still being finalised and this includes the Indian Biodiversity Act. These initiatives have two key elements. The first is that they provide for PIC of traditional communities for exploitation of the biological resources. The second feature of these initiatives is that they recognise the need to develop an institutional structure, which can ensure fair and equitable sharing of benefits with the traditional communities in case the resources are exploited commercially. Box 1 gives a brief account of the recognition that different countries have granted using official fiat.

Box 1: Communities' Rights in National Constitutions and Laws

The Constitution of the Philippines of 1987 says: "The State shall recognize, respect and protect the rights of the indigenous cultural communities to preserve and develop their cultures, traditions and institutions" (Section 17, Article XIV).

Thailand's Constitution of 1997 states: "Persons so assembling as to be a traditional community shall have the right to conserve or restore their customs, local knowledge, arts or good culture of their community and of the nation and participate in the management, maintenance, preservation and exploitation of natural resources and the environment in a balanced fashion and persistently as provided by law." (Section 46).

The Constitution of Ecuador (1998) recognises "collective intellectual property rights" on communities' ancestral knowledge (Article 84). The Intellectual Property Law (No. 83, 1989) establishes a *sui generis* system of collective intellectual rights of indigenous and local communities (Article 377).

According to the Constitution of the Federative Republic of Brazil of 1998: "The Indians shall be accorded recognition of their social organization, customs, languages and traditions and the original rights in the lands that they occupy by tradition, it being the responsibility of the Union to demarcate them, protect them and ensure respect for all their property" (Article 231).

The Constitution of the Republic of Venezuela of 1999 says: "The collective intellectual property of indigenous knowledge, technology and innovations is guaranteed and protected. Any work on genetic resources and the knowledge associated therewith shall be for the collective good. The registration of patents in those resources and ancestral knowledge is prohibited" (Article 124).

The Costa Rican Biodiversity Law establishes that: "The State expressly recognises and protects, under the common denomination of *sui generis* community intellectual rights, the knowledge, practices and innovations of indigenous peoples and local communities related to the use of components of biodiversity and associated knowledge. This right exists and is legally recognised by the mere existence of the cultural practice or knowledge related to genetic resources and biochemicals; it does not require prior declaration, explicit recognition nor official registration; therefore it can include practices which in the future acquire such status. This recognition implies that no form of intellectual or industrial property rights protection regulated in this chapter, in special laws and in international law shall affect such historic practices" (Article 82).

In Brazil, the Provisional Measure 2.052-6 (21.12.2000) provides that the State recognises the indigenous and local communities' rights to decide on the use of traditional knowledge associated to genetic resources. This knowledge is protected against "illicit exploitation" and other unauthorised uses (Article 8 (1) and (2)). This Measure has been subsequently renewed (and partially amended) by acts of the Brazilian Executive Power. (Provisional Measure No. 2.126-11, 26 April 2001).

Decision 391 of the Andean Group (1996) recognises the rights of indigenous, Afro-American and local communities to decide on their knowledge, innovations and traditional practices associated with genetic resources and derived products.

Source: Correa (2001).

At the global level, several initiatives for the development of an alternative framework for protecting traditional knowledge have been taken. These initiatives have been taken by three sets of organizations: (i) multilateral bodies, (ii) Regional organizations and (iii) non-governmental organizations.

At the multilateral level, several organisations have taken initiative to address the issue of protecting traditional knowledge. These include, the Food and Agriculture Organisation (FAO), the World Intellectual Property Organisation (WIPO), the Convention on Biological Diversity (CBD) and the World Trade Organization (WTO).

The FAO considered the issue of farmers' rights as a step towards adopting a framework for the management of plant genetic resources needed for food and agriculture. This initiative resulted in the adoption of the International Treaty on Plant Genetic Resources for Food and Agriculture²⁴.

The WIPO has been dealing with the issue in a broader context in its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. Since its establishment in 2000, this Committee has been discussing matters relevant to three primary themes. These themes concern intellectual property issues that arise in the context of: (i) access to genetic resources and benefit-sharing; (ii) the protection of traditional knowledge, innovations and creativity; and (iii) the protection of expressions of folklore.

The Conference of Parties (COP) to the Convention on Biological Diversity has been engaged in issues that are central to the implementation of the treaty. One of the key decisions of COP 5 was the establishment of the Ad Hoc Working Group in Access and Benefit Sharing as a part of its decisions²⁵. The Working Group adopted the draft Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, which was aimed at giving

²⁴ For details see later discussion.

²⁵ Decision V/26 A of COP 5.

directions to the Parties to the CBD to evolve effective mechanisms for implementation of access and benefit sharing arrangements²⁶.

Finally, the World Trade Organization (WTO) was given the mandate to examine the issues relating to protection of traditional knowledge as a part of its work programme on the Agreement on TRIPS at the conclusion of the Fourth Ministerial Conference that was held in Doha in November 2001. The Ministers instructed “the Council for TRIPS ... to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore ...” as a part of its post-Doha work programme.

At the regional level, two significant required initiatives need to be mentioned in this context. The first is the Common Regime for the Access to Genetic Resources of the Andean Community of Nations (Decision 391 of 1996). The second is the initiative taken by the Organisation of African Unity (OAU) to develop a Model Law for the protection of the rights of traditional communities, farmers and breeders and for the regulation of access to biological resources. At the multilateral level, at least four organisations have been engaged in the process of developing frameworks for protecting holders of traditional knowledge. In November 2001, the FAO successfully concluded the International Treaty on Plant Genetic Resources for Food and Agriculture, which provided explicit recognition to farmers’ rights. The third is the recognition granted to farmers’ rights in the International Treaty on Plant Genetic Resources for Food and Agriculture that has recently been concluded under the aegis of the FAO.

The initiative taken by the Andean Community of Nations to define an access regime for genetic resources provides that the rights and the interests of the providers of the genetic resources and derived subject matter and also intangible elements must be considered when these are used. The intangible elements, according to this framework, comprise of individual or collective knowledge, innovation and practice having actual or potential value that is associated with the genetic resource, or derived products. In case a resource has an intangible

²⁶ Convention on Biological Diversity (2001). The Bonn Guidelines were adopted by COP 6 through Decision VI/24.

component, viz. knowledge, Decision 391 requires: (i) identification of the provider of the genetic resource and its derived subject matter having an intangible component, and (ii) incorporation of an appendix to the access contract (with the potential user of the resource or its intangible component) in which provision has been made for the equitable distribution of the benefit resulting from access to the resource and the associated elements²⁷.

The OAU Model Law provides a comprehensive framework for protecting the rights of traditional and local communities and has several interesting elements (see Box 2). This Model Law is currently being used by the Namibian Government to bring forth a domestic legislation.

²⁷ Correa (2001).

Box 2: The OAU Model Law

The OAU Model Law is based on two principles. In the first place the Model Law seeks to maintain the status given in so far as the traditional communities and their rights and responsibilities over their genetic resources are concerned. Secondly, the Model Law provides guidelines for access of genetic resources, which includes provisions requiring prior informed consent of the communities that have traditionally used those resources.

An important objective of the Model Law is to ensure the maintenance and protection of the open systems of exchange and reciprocity that have been the underlying strength of traditional systems of access to and the use and exchange of biological diversity, knowledge, innovations and practice. This system has evolved, accumulated and has been refined over time by the traditional communities in accordance with their environment and biodiversity. The Model Law seeks to provide support to this system by upholding the customary rights of farmers to save, use, exchange and sell seed and other planting material as these rights have been the cornerstone of agricultural practices of the farming communities.

The OAU Model Law is based on the premise that biodiversity related knowledge, innovations and practices of local communities are a result of the tried and tested practices of the past and present generations. Keeping in view the need to maintain the continuity of their system, the Model Law has emphasised that no one has the right to appropriate, sell or monopolise any component of biological resources and the associated knowledge, innovations and practices of the local communities. Community rights are considered inalienable and imprescriptible.

Flowing from the understanding of community rights, the OAU Model Law has provided a framework for regulating access to biological diversity and to community knowledge and technologies. This has been proposed as the duty of the state and its people.

The provision on prior informed consent (PIC) of the local communities forms the basis of the access regime proposed in the OAU Model Law. Specific provisions for consultation with the communities on applications being made for access have been provided for. A competent National Authority has been identified for undertaking the consultation process. Access to biological resources would be considered invalid if no PIC has been granted.

The OAU Model Law recognises that the local communities have a right to fair and equitable sharing of benefits arising out of any commercial exploitation of the genetic resources, knowledge, technologies, innovations and practices which they have customarily used over generations. Towards this end, the Model Law provides that a minimum of 50 per cent of any financial benefits returns to the local community. The benefits that would thus accrue would be deposited in a community Gene Fund, which would be established as an autonomous trust.

Source: Ekepere (2000).

Although the above-mentioned initiatives are quite significant from the point of view of addressing the concerns of traditional communities, only one among the ones mentioned in the foregoing, viz., FAO's ITPGR, has been accorded formal

recognition by the comity of nations. The ITPGR, in fact complements the national and regional initiatives that have been taken for recognising Farmers' Rights. First proposed in 1989²⁸, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) has succeeded in developing a broad consensus on various aspects of managing plant genetic resources including, on the "Farmers' Rights" issue. This marks a significant step and should serve as signals for a larger cross-section of developing countries to take legislative action that can protect the rights of farmers²⁹ (see box).

Box 3: Farmers' Rights

9.2 ...each Contracting Party should... take measures to protect and promote Farmers' Rights, including: (a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture; (b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and (c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

9.3 Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate.

Source: FAO (2001).

The Indian legislation on plant varieties protection and farmers rights, the Protection of Plant Varieties and Farmers' Rights (PPVFR) Act, is the singular attempt made by a developing country to give effect to the concept of farmers' rights as provided for in the ITPGR³⁰. Although this Act has several limitations³¹, it nonetheless provides a model of an effective sui generis system for the protection of plant varieties protection that WTO members are expected to put in place in fulfillment of their commitment to the Agreement on TRIPS.

The non-governmental organisations have been active in proposing sui generis options for the protection of traditional knowledge. Two of these initiatives, taken

²⁸ FAO (1989). For details see Bragdon and Downes (1998).

²⁹ See Government of India (2001).

³⁰ For details, see Dhar (2002).

by the Third World Network and Gene Campaign are described in Annex 1.

Role of Customary Laws

Customary laws have been an integral part of the management of traditional communities. These laws have been seen as “the standing codes of behaviour sanctioned by the society, the preservation and continuation of which is the social obligation of all its members”³².

Customary laws have remained largely uncodified, a feature that has contributed to both its strength and weakness. Its strength is observed from the fact that these laws have constantly evolved over time and have thus remained relevant even with the changes taking place in the society at large. The weakness of customary laws arising from its uncodified character is its limited applicability in situations that may merit the use of such laws.

Documentation on the use of customary laws for access and benefit sharing show that these laws can be used in a limited manner to achieve the objectives set out in the CBD³³. However, what also needs to be explored is the extent to which these laws can be modified to take care of the concerns that the CBD seeks to address in its various provisions, including Article 8(j).

4. Contractual Agreements for Access to Genetic Resources and Benefit Sharing

The increased focus on “Community Rights” and “Farmers Rights” as a step towards ensuring that the traditional knowledge holders are recognised for the contribution they have made in making available the biodiversity and the associated knowledge for the betterment of the present generation has generated interest in contractual agreements between the suppliers and the users of the knowledge. This interest has been seen at two levels. One, steps that have been taken by governments to put in place a legislative framework that would allow benefit sharing along the lines provided for by the Convention on Biological Diversity (CBD)³⁴. And, two,

³¹ For a critique of the legislation, see Kothari ().

³² Singh (2000), quoted by Mukhopadhyay (2002).

³³ Mukhopadhyay (2002).

³⁴ Article 1, elaborating on the objectives states that the objectives of the CBD "are the conservation of biological diversity, the sustained use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic

using the successful cases of benefit sharing to better understand the issues involved which can in turn contribute towards development of a consistent framework.

There are by now several cases where contractual agreements have been entered into for utilisation of genetic resources and the associated knowledge which also include elements of benefit sharing. Three cases are discussed here to give an indication of the nature of these arrangements.

Case I The INBio–Merck Agreement

This case involves the National Institute of Biodiversity of Costa Rica (INBio) and the pharmaceutical major, Merck Sharp and Dohme headquartered in the United States³⁵. The agreement entered into by the two organisations in 1991 was the first formal attempt to include benefit sharing arrangements while commercialisation of genetic resources took place. The parties to the contract agreed to collaborate in the investigation of the existent biodiversity in Costa Rica's tropical forests in order to establish its potential applications to human and animal health.

Under the terms of the agreement INBio had the following obligations: (i) to establish the necessary facilities in Costa Rica for the collection and processing of plants, insects and environmental samples, (ii) to provide Merck sharp and Dohme with the specific number of plants, insects and environmental samples for a period of two years, and (iii) to provide for processing of the samples of plants and insects in a laboratory established by INBio at the University of Costa Rica. The corresponding obligations of Merck Sharp and Dohme were the following: (i) Merck was to provide INBio with a research fund of US \$ 1 million during the first two years of the Agreement and was to contribute to the establishment of laboratories needed for processing of the sample at INBio and at the University of Costa Rica (ii) Merck was to make an assessment of the samples provided by INBio through biological experiments owned by Merck to detect potential activity of compounds for use on human and animal health and agriculture, and (iii) Merck was to give unique numeric identification to all samples sent by INBio and was to keep an

resource and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies ...".

³⁵ Government of Costa Rica (2000).

identification system which would allow the parties to the contract to identify all products from which there was a possibility of obtaining royalties.

The INBio–Merck Agreement provided that all inventions arising from the samples supplied by INBio would belong to Merck. Consequently, the patents on these inventions were also to be taken by the Merck. INBio was to be compensated for its contribution to any inventor through the payment of royalties in the sale of products. The rate of royalties was however not decided a priori.

Although the INBio–Merck case was the first significant case of benefit sharing involving the supplies of genetic resources and the commercial interests, the single most noticeable lacuna was the absence of any involvement of local communities. Not only were the local communities not involved in the process of formalisation of the Agreement, there was no explicit arrangement to share the benefits accruing to INBio with the communities.

Case II Collecting Traditional Medicines in Nigeria

In 1992, three US agencies undertook a programme to collect and experiment on plants and traditional medicines throughout the world. The agencies, National Cancer Institute, National Science Foundation and the US Agency for International Development joined together to form an International Cooperative Biodiversity Group (ICBG) programme³⁶. The ICBG focussed on traditional medicines and plants as a source for cures and while so doing it also took into consideration the issues of biodiversity conservation, sustainable economic development and the protection of intellectual property of the local communities.

One of the project teams under the ICBG programme working in Nigeria devised an interesting arrangement for sharing the benefits arising out of the bio prospecting that the programme had undertaken. The team members agreed to a three-part arrangement for compensating the local people for the traditional knowledge. One, the team was to ensure that specific monetary benefits went to the communities at each stage of its research, two, representatives from these communities were to decide how this money would be spent and three, a legal trust was to be created to ensure that the decisions taken by the representatives were actually implemented.

The monetary benefits to the local communities were to be provided initially from the project funds. Subsequently, the royalty earned by the project by making the technologies available to commercial enterprises were to be shared with the communities, with the latter getting a 25 per cent share. 50 per cent of this share of the local communities was to be provided to the local government in whose jurisdiction the project lay with the other half going to the town or village where the project was located. Besides these arrangements the team was to also provide 5 per cent of all commercial drug profits to all projects in the particular region of Nigeria where the project under discussion was based in order to promote rural health, traditional medicines and biodiversity conservation. The drug company had also to agree to provide the drug at affordable cost to all Nigerians afflicted with the disease for which the drug was the cure.

The case of the ICBG team does appear to have provided a structure for realisation of the objective of benefit sharing even as questions may be asked about the magnitude of payments and the likely beneficiaries of this arrangement. The latter issue seems to be the most pertinent since given the structure of benefit sharing that was proposed it does seem unlikely that the communities themselves would have got any substantial monetary benefits.

Case III Benefit sharing arrangements with the Kani tribes of Kerala

This case study relates to benefit sharing arrangements arrived at between Tropical Botanical Garden and Research Institute (TBGRI) a publicly funded research institute based in Trivandrum and the Kani tribals of Kerala, involving the medicinal plant called *arogyapaacha (Trichopus zeylanicus)*³⁷. The Kani tribals were using this plant in their traditional medicine. Within the Kani tribe the customary rights to transfer and practice certain traditional medicinal knowledge have been held by tribals healers, known as *Plathis*. The knowledge related to the medicinal plant in question was divulged by three Kani tribal members to the scientists of TBGRI.

Detailed scientific investigation of the plant was subsequently carried out, including chemical screening to isolate the active principles, and pharmacological screening.

³⁶ McGowan and Udeinya (1994).

³⁷ Anuradha (2001).

The TBGRI scientists developed a drug “Jeevani” by adding three other medicinal plants as ingredients.

The Governing Body of the TBGRI authorised the TBGRI Director to transfer technology for the manufacture of “Jeevani” to interested parties on payment of an appropriate licence fee. Negotiations for the same were conducted by a committee constituted for this purpose headed by the Chairman of the TBGRI Executive Committee who is also Chairman of the State Committee on Science, Technology and Environment, Government of Kerala. This committee recommended a transfer of the right to manufacture Jeevani to a commercial firm, Arya Vaidya Pharmacy (Coimbatore) Ltd., for a period of seven years at a licence fee of Rs. 10 lakh.

TBGRI was also to receive two per cent royalty on any future drug sales. This was done as per the guidelines of Council of Scientific and Industrial Research of the Government of India. In a separate resolution approved both by the Governing Body and the Executive Committee of the TBGRI, it was decided that the Kani tribals would receive 50 per cent of the licence fee, as well as 50 per cent of the royalties obtained by the TBGRI on sale of the drug, as part of the benefit sharing arrangement for divulging the information. In November 1997 with the assistance of TBGRI, a trust was registered, named the Kerala Kani Samudaya Kshema Trust. All the nine registered members of the Trust were Kani tribals. The president and vice-president of the Trust were the two Kanis who imparted the traditional knowledge to TBGRI regarding arogyapaacha. The objectives of the Trust are: (i) welfare and development activities for Kanis in Kerala, (ii) preparation of a biodiversity register to document the knowledge base of the Kanis, and (iii) evolving and supporting methods to promote sustainable use and conservation of biological resources.

The first tranche of Rupees 5 lakh and royalties of Rupees 19,000 of the benefit sharing formula were deposited in the account of Kani Samudaya Kshema Trust at Kuttichal Union Bank. The first meeting of the Trust after the transfer was held at the Kallar Mattammodhu Kani tribal settlement on March 19, 1999. In the meeting it was decided to grant as special incentives, Rs. 20,000 to Mallan Kani, Rs. 20,000 to Kuthy Mathan Kani and Rs. 10,000 to Eachen Kani, who passed on the information to the scientists.

The above mentioned case involving the Kanis appeared to be the solution towards the evolution of a framework for benefit sharing with traditional communities at the first instance. However, this case threw up its usual share of problems. The first and the most important of these was that the claims for their share in the benefits that were made by the Kani tribals located in other districts of Kerala. This brought to light the fact that all the stakeholders had not been included as beneficiaries of the arrangement. A second issue was raised about the monetary benefits that the Kanis got from the arrangement. The Kerala Institute for Research, Training and Development of Scheduled Castes and Tribes (KIRTADS), a research institute set up by the Kerala Government for promoting integrated rural development by involving the scheduled castes and tribes in Kerala, maintained that the Kanis had not be adequately compensated for sharing their knowledge. Finally, the most important dimension of the Kani experiment was that it was a publicly funded organisation that took the initiative for sharing benefits with the local communities. Whether this model can be replicated in case a commercial enterprise was involved is really the moot point.

The use of contracts for sharing of benefits suffers from at least two limitations, which need to be taken into consideration. In the first place, they are voluntary agreements between the parties concerned. Given its nature, contracts cannot be relied upon as a way of realising the objectives of the CBD. The second, and the more important limitation of contracts, one that could prevent fair and equitable sharing of benefits, arises when the parties involved are of vastly unequal bargaining strengths. This is most likely to happen in the context of the present discussion, as the parties would be the commercial entities, usually the large companies, having significant market power and the traditional communities, most of which are at the fringes of the market system. Institutional structures would therefore have to be established to provide the traditional communities an opportunity to partake to the benefits arising out of biological diversity and/or associated knowledge.

The Way Forward

1. Action required on three broad fronts: (i) putting in place well considered legislations and/or complementary arrangements that would help address the needs of the holders of traditional knowledge, (ii) establishing the institutional structure needed for effectively implementing the legislations, and (iii) increasing coordination between the different actors who have an interest in traditional knowledge, including communities, commercial interests, civil society groups and the policy makers.
2. Making participation by local communities more effective during the implementation of the Biodiversity Act.
3. Establishing the institutional structure for ensuring fair and equitable sharing of benefits arising out of the commercial exploitation of biodiversity.
4. Consistent set of views needs to be developed with the utmost urgency as regards protection of traditional knowledge. Stakeholder dialogue needs to be initiated to ascertain whether or not conventional forms of intellectual property rights, in particular patents, would be the ideal way to approach the problem at hand.
5. Making Farmers Rights work effectively by setting out appropriate rules for the implementation of the Plant Breeders and Farmers Rights Act.
6. Reviewing various legislations, enacted both by the Central Government and different State Governments, with a view to amending those that may undermine the rights of the traditional communities over the resources they have been using.
7. Delineation of the rights and responsibilities of the different tiers of governance on the issue of biodiversity conservation.

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