

“शिक्षा मानव को बन्धनों से मुक्त करती है और आज के युग में तो यह लोकतंत्र की भावना का आधार भी है। जन्म तथा अन्य कारणों से उत्पन्न जाति एवं वर्गगत विषमताओं को दूर करते हुए मनुष्य को इन सबसे ऊपर उठाती है।”

— इन्दिरा गांधी

"Education is a liberating force, and in our age it is also a democratising force, cutting across the barriers of caste and class, smoothing out inequalities imposed by birth and other circumstances."

—Indira Gandhi



Indira Gandhi
National Open University
School of Law

MIP-106
**Plant Varieties Protection,
Biotechnology, and
Traditional Knowledge**

Block

4

PROTECTION OF TRADITIONAL KNOWLEDGE

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BLOCK 4 PROTECTION OF TRADITIONAL KNOWLEDGE

Traditional Knowledge refers to the long standing traditions and practices of certain indigenous, or local communities, 'Traditional' however does not mean that the knowledge is ancient. 'Traditional Knowledge' is being created every day, as it evolves as a response of individuals and communities to the challenges posed by their social environment, This Block consists of four units on traditional knowledge.

Unit 13 of this Course explains the significance of traditional knowledge and the objective for protecting traditional knowledge. In this context it deals with prevention of bio-piracy, conservation of environment and the protection of livelihood of traditional knowledge holders.

Unit 14 of this course explains the current international efforts taken for the protection of traditional knowledge. Under this pretext topics like WIPO, WTO/TRIPs, Doha Declaration, the Nagoaya Protocol, etc are discussed.

Unit 15 of this Course explains the contentious issues for the protection of TK. It also explains why TK should be defined. It explains the concept of prior informed consent, and the tools for protecting TK under the IP regime.

Unit 16 of this course explain the Indian efforts towards the protection of Traditional Knowledge. In this unit we will study the Indian position on the protection of TK and the national efforts made towards its protection. It also explains the significances of draft rules, 2009 on the protection, conservation and management of TK.

REPORT OF THE COMMISSION ON THE PROTECTION OF PERSONAL DATA

The Commission has been set up by the Council of the European Communities to study the implications of the proposed Directive on the protection of personal data. The Commission has held several public hearings and has received many suggestions from interested parties. It has also conducted extensive research into the current state of affairs in the member states and in other countries. The Commission's report is based on the findings of its work and on the views of the public.

The Commission believes that the proposed Directive is a necessary and timely measure to protect the fundamental right of every individual to the protection of his personal data. It is essential that the Commission should ensure that the Directive is implemented in a way which respects the principles of proportionality and subsidiarity. The Commission also wishes to draw attention to the need for a high level of protection of personal data in all member states.

The Commission has proposed a number of measures to be taken in order to ensure the effective implementation of the Directive. These include the need for a high level of protection of personal data in all member states, the need for a high level of protection of personal data in all member states, and the need for a high level of protection of personal data in all member states.

UNIT 13 SIGNIFICANCE OF AND REASONS FOR PROTECTING TRADITIONAL KNOWLEDGE

Structure

- 13.1 Introduction
- 13.2 Objectives
- 13.3 Significance of Traditional Knowledge (TK)
- 13.4 Aims for Protecting TK
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 - 13.4.4 Protection of Livelihood of TK Holders
- 13.5 Summary
- 13.6 Terminal Questions
- 13.7 Answers and Hints
- 13.8 References and Suggested Readings

13.1 INTRODUCTION

Traditional knowledge refers to the long-standing **traditions** and practices of certain **indigenous**, or local **communities**. A fundamentally important aspect of traditional knowledge is that it is “traditional” only to the extent that its creation and use are part of the cultural traditions of communities. “Traditional”, therefore, does not necessarily mean that the knowledge is ancient. “Traditional” knowledge is being created every day; it is evolving as a response of individuals and communities to the challenges posed by their social environment. In its use, traditional knowledge is also contemporary knowledge. This aspect is further justification for legal protection. It is not only desirable to develop a system that documents and preserves traditional knowledge created in the past, which may be on the brink of disappearance; it is also important to envisage a system that contributes to the promotion and dissemination of innovations which are based on continuing use of tradition. Thus, it is not only about freezing and preserving knowledge that exists now, but about preserving what exists as an indispensable and powerful tool for fostering continued innovation and creativity. In many cases, traditional knowledge has been **orally passed** for generations from person to person. It is inter-generational and evolves continuously.

Over the past two decades, traditional knowledge (TK) has received increasing attention on the international agenda and being discussed at the various intergovernmental bodies. There is heightened concern to protect the traditional knowledge of indigenous communities at the national, regional and international levels. 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 and global cultural diversity; concerns about unauthorized and inappropriate patenting and use of TK, with

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.

Intellectual property issues related to genetic resources, traditional knowledge and folklore have emerged in a wide range of policy areas, including food and agriculture, biological diversity and the environment, human rights, cultural policy, trade and economic development. For example, intellectual property rights have been granted for uses of plants which form part of traditional knowledge systems in the agricultural, health and environmental fields. Traditional designs, songs and dances have been used by the entertainment and fashion industries to create works which are protected by intellectual property. Discussions about such uses of genetic resources, traditional knowledge and folklore have linked the protection of intellectual property to policy objectives as diverse as the promotion of free trade, environmental conservation, food security, cultural diversity, etc. These linkages, established through discussions in several international fora, have significant technical, administrative and policy implications for the intellectual property system.

Many countries and communities worldwide are considering how to best address these issues at the national, regional and international levels. As is apparent from the wide range of interests and concerns, TK is a complex and multi-faceted issue. It is thus being discussed in a range of forums, each with its own perspective and its own area of competence and expertise. This is useful and necessary, but will lack a holistic approach, which is needed. For each of three broad categories of TK-related objectives – preservation, protection and promotion (harnessing TK for development) – there are a number of possible policy tools and measures, which requires a multi-stakeholder policy dialogues for holistic approach, which is needed.

The preservation, protection and promotion of the traditional knowledge, innovations and practices of local and indigenous communities (TK) are of key importance for developing countries. Their rich endowment of TK and biodiversity plays a critical role in their health care, food security, culture, religion, identity, environment, sustainable development and trade. It is particularly crucial for the most vulnerable segments of their societies, and for indigenous peoples worldwide. But there are concerns that this knowledge is being used and misappropriated/patented by third parties, with few or none of the benefits being shared with the original TK-holders, and without their prior informed consent. While such concerns have pushed TK to the forefront of the international agenda, the best ways of addressing the range of issues related to its preservation, protection, further development and sustainable use are not yet clear.

Self Assessment Question

(Spend 3 minutes)

- 1) Define the salient features of 'traditional knowledge'.

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13.2 OBJECTIVES

After reading this unit, you should be able to:

- know about the importance of TK for the over-all development of the society;
- know about the reasons and aims for its protection;
- find out how the protection of TK can help in preventing bio-piracy;
- find out how the protection of TK can benefit the national economy;
- appreciate the importance of TK protection in the conservation of environment and sustainable development; and
- know how the protection of TK can help in the protection of the livelihood of the TK holders and in their economic upliftment.

13.3 SIGNIFICANCE OF TRADITIONAL KNOWLEDGE (TK)

It is now a well-documented fact that TK plays an important role in the global economy and is valuable not only to those who depend on it in their daily lives but to modern industry and agriculture. Most of the traditional societies depend on this knowledge for their food and healthcare needs. In 2003, WHO reported that countries in Africa, Asia and Latin America use traditional medicine (TM) to help meet society's primary health care needs. In Africa, upto 80% of the population uses TM for health care. In India, this percentage goes up to 70%. There are no reliable estimates of the total contributions of TK associated with traditional crop varieties (landraces) to the global economy, but the contribution of TK in the development and growth of pharmaceuticals and biotechnology-based industries are widely reported. It is stated that natural product-derived pharmaceutical alone contributed an estimated \$ 120 billion, or 40% of global pharmaceutical sales in 1997, with global trade in raw botanical materials approximating \$ 8 billion in the same year. A recent OECD study in 2001 outlined the relative importance of biotechnology patent activity by concluding that the absolute number of USPTO and EPO biotechnology patents has grown substantially in comparison with the total number of patents.

TK associated with biological resource is an intangible component of the resource itself. TK has the potential of being translated into commercial benefits by providing valuable leads for the development of useful products and processes. The valuable leads provided by TK save time, money and investment of modern biotech into any research and product development. It is estimated that a hit-rate of 80 percent or more can be achieved in developing medical drugs where the screening of plants is limited to species used by indigenous communities.

Significance of traditional knowledge is much broad-based, impacting many aspects of national life. Its protection is important for communities in all countries, particularly in developing and least developed countries. Traditional knowledge plays an important role in the economic and social organisation of those countries, and placing value on such knowledge is a viable means of promoting a sense of national cohesion and identity. Traditional knowledge can be about medicines and healing practices or in the form of cultural expression

such as folk songs, dances, handicrafts, handlooms, agricultural practices, etc. The traditional communities, who are the holders of this knowledge and developed these knowledge bases are generally ignored while protecting IPRs based on this knowledge. While the big companies, particularly pharmaceuticals, make big money out of the use and commercialization of this knowledge and getting IP rights over that, the traditional communities do not get any reward for preserving it for centuries. According to Wendland, discussions on the uses of TK have linked the protection of IP to policy objectives as the promotion of free trade, human rights, health, food, environment and biodiversity conservation, and cultural diversity.¹

Self Assessment Question

(Spend 3 minutes)

- 2) Discuss the significance of 'traditional knowledge' for the countries in general.

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13.4 AIMS FOR PROTECTING TK

The issue of protection and preservation of TK at the international level has been brought to the fore at the instance of developing countries, because of different concerns and perspectives expressed by developing countries as owners of TK-related resources. The principal concerns expressed about the protection of TK and TCEs at the international level are:

- concern about the granting of patents or other IPRs covering TK to persons other than those indigenous communities/peoples who have originated and legitimately controlled the TK;
- concern that TK is being used without the authorization of the indigenous communities/peoples who are its holders without proper sharing of the benefits that accrue from such use.

Underlying these concerns were the issues of bio-piracy, conservation of environment and eco-system, economic upliftment of the holders of TK, and the national development, even though not all of these concerns and perspectives are addressable within IP terms. Intellectual property role, in the context of TK is limited, as it is aimed at excluding the use of protected knowledge by unauthorized parties, and is not concerned with its promotion or diffusion, the goals which are fundamental for the sustainability of TK. IPRs function on exclusivity and are limited in time, held by an identifiable natural or legal person. At the end of protection period, they become part of the public domain. On the other hand, TK is held collectively (ownership), inherently dynamic, which grows/alters in response to changing environmental and social circumstances,

¹ See, Wend B. Wendland, "Intellectual Property, Traditional Knowledge and Folklore: WIPO's Exploratory Program", 33 IIC 485 (2002).

while being in continuity with land and habitat, and mostly exists in an unfixed form (oral). It originates, preserved and transmitted in a traditional context and is not limited to any specific field of technology or arts. The enforcement of IPRs requires to identify and isolate the protected information while the challenging aspect of TK is its holistic character.

13.4.1 Prevention of Bio-piracy

The term "bio-piracy" encompasses a variety of situations, including:

- The acquisition of GRs or TK without permission of their holder;
- Cases where benefits arising from the commercial use of GRs or TK are not shared with the provider of these resources or knowledge;
- Cases where TK is protected by IPRs, mainly patents. The holders of these IPRs have not been innovative themselves, but have simply copied this knowledge.

There has been an increasing number of widely reported cases of misappropriation (bio-piracy) and commercial exploitation of TK under patents and other IPRs, viz., patents on natural products such as *Neem*, *Turmeric*, Basmati rice, Hoodia cactus, African Potato, Ayahuasca, May Apple, Australian Smokebush, Periwinkle. In many of these cases, claims in the patents on plants and their genetic resources are not fundamentally different from the practices applied by the traditional communities in the utilisation of these plants as food, cosmetics or traditional medicines. Some of these cases have been successfully challenged, such as *Neem* and *Turmeric* but others were not, like patent over *ayahuasca*. In this case, Plant Patent on *Ayahuasca* drink, known as the "vine of the soul" among the Amazon Quichua people, produced from the bark of the *Banisteriopsis cappi* plant used for many medicinal purposes, was granted to an American, Loren Miller, in 1986 (patent no. 5751). Upon a request from the Coordinating Body for the Indigenous Organisations of the Amazon Basin in 1994, the Centre for International Environment Law (CIEL) filed a case before the USPTO which revoked the patent in 1999 on the basis that the drink was not distinguishable from the prior art presented by the CIEL. On appeal the patent was reinstated as the patent was not covered by the new rules in the U.S. on *inter partes* re-examination, introduced in 1999, and was not the part of patent law in 1986 on the date of filing the patent. Challenging the misappropriation in foreign jurisdictions is, however, an expensive and time consuming proposition with uncertain outcome.

This raises an important issue of legal protection of TK at national and international levels. The last few years have seen the right of indigenous and traditional communities to their knowledge, practices, innovations and creations being increasingly recognized by law. The recognition and respect of TK constitute essential tools to fight bio-piracy. There is a need to recognize and preserve TK in both, the *in situ* and *ex situ* manners by taking legislative measures. *In situ* preservation is the preservation of TK as a living, evolving body of knowledge. Steps can also be taken to preserve TK in an *ex situ* manner, namely through TK documentation, registries or databases.

The aim of TK protection is not simply to recognise the positive rights in respect of TK but also to prevent unauthorized appropriation (bio-piracy) and

ensuring benefit sharing out of its use as mandated under the Convention on Biological Diversity (CBD). Granting of IPRs/patents covering TK may be prevented by improving the information available to patent offices with regard to the examination of novelty and inventiveness by preparing databases, as is being done by India through Traditional Knowledge Digital Library (TKDL). With TK registries, determining access rights is of key importance. There are some concerns that registries may, in effect, fuel further bio-piracy or TK piracy. For the moment, keeping the registries as the property of the communities and governing access in line with customary access rights to the knowledge may be advisable. This is particularly true for TK not commonly known outside the community. But for other TK, a national level measures need to be devised. The TK database of the Tulalip tribe in the United States is an interesting initiative, as it enables access to each information field to be limited to certain groups of users. For example, community youth may have access to one subset of knowledge, community traditional healers to another, and researchers from outside the community to still another. The database is actually distributed among the different communities of the tribe, thus giving full local control.

Even though many initiatives are underway with regard to creating databases, but the databases have inherent limitations in the context of TK. Firstly, while they may forestall the grant of inappropriate patents, they are unable to address the problem of the non-accrual to the holders of TK of economic benefits resulting from the use of that knowledge. Secondly, they will mainly contain the TK, which is already in the public domain, and in that case prior informed consent is presumed. Thirdly, while documentation may fulfil the important function in protecting the TK as a part of defensive protection of TK, its role in positive protection is very much limited. Moreover, databases codify TK as it is identified and described at a particular time, which does not take into account its dynamic nature and it continuously evolve through incremental innovation. As such they are static and rigid and they would be useful only if being systematically updated to keep up with the evolution of knowledge. Opinion has also been expressed that creating databases may clash with the interests of indigenous communities to keep their knowledge secret and it will only serve the government-induced strategy of preventing misappropriation, and would not be a solution to a holistic approach towards conservation of TK.

Another aim to prevent unauthorized or inappropriate use of TK by third parties includes unauthorized commercial use as well as applications for IPR that are based on TK but are made without the prior informed consent (PIC) of the TK holders and without benefit sharing. Intellectual property protection can be categorized as defensive (preventing others from seeking IPR to one's TK) or positive (establishing IPR to one's TK, with the resulting possibility of preventing others from using the TK without permission). For both types of protection, there have been cases where TK holders have been able to use conventional IPR instruments to protect their TK. However, since these instruments were not developed with TK in mind, but rather modern industrial intellectual property, they are not always perfect to fight bio-piracy. Biodiversity-related TK could be specifically included in national policies and institutional arrangements on access to genetic resources and benefit sharing. The Convention on Biological

Diversity stipulates that access to genetic resources should be based on PIC of the member

State and mutually agreed terms (MAT) with benefit sharing. For TK associated with such resources, the national access and benefit-sharing regime could also stipulate that PIC of the

TK-holding communities (where these can be clearly identified) should be sought in accordance with their customary laws and on MAT, including benefit sharing. Where TK holders cannot be clearly identified or the TK is more or less in the public domain, fees could be paid by the interested party into a community development fund, as in Peru. India's draft Rules on the protection, conservation and effective management of TK relating to biological diversity, 2009 have the similar provisions and provide a mechanism of benefit-sharing. Besides, as demanded by developing countries, the IP applications related to GRs and TK should (i) disclose the country and source of origin of biological material and TK; and (ii) must provide evidence that laws and practices of the country of origin on PIC and benefit-sharing have been fully complied with. The Nagoya Protocol on ABS, 2010 has the provision in this regard.

Many reasons for the protection of TK and to remedy this situation of biopiracy and misappropriation of TK have been given are based on equity considerations. It is said that, given the important economic value of TK, the holders of TK should be part of the economic benefit-sharing derived from this knowledge. It is also based on the rationale of *quid pro quo*, i.e. that if the TRIPs Agreement requires developing countries, with traditional and indigenous communities, to provide IPRs for a broad range of subject-matters, including biological material, it is equitable that TK should have legal recognition and the holders should be rewarded for their efforts in conserving and preserving that knowledge. A significant example of this is the GRs linked to TK. Traditional communities developed varieties of GRs through planting, seed production and selecting the best adapted varieties through traditional farming. These communities know the qualities of the products derived from GRs, which could be very useful in different fields, such as medicine and agriculture. However, this knowledge is collected by scientists and researchers and they get IPRs and benefit from its commercial use, without compensating the traditional communities. Similar arguments apply to other intangible components of TK.

13.4.2 Benefits to National Economy

Protecting TK has the potential to improve the performance of many developing country economies by enabling greater commercial use of their biological wealth and increasing export of TK related products. TK and TCEs-based products as handicrafts, medicinal plants, traditional agricultural products, herbal medicines, cultural heritage tourism, and non-wood forest products (NWFPs) are traded in both domestic and international markets and already provide substantial benefits for exporter countries. For example, some 150 NWFPs, including rattan, cork, essential oils, forest nuts, and gum arabic, are traded internationally in significant quantities. TK is also used as an input into modern industries such as pharmaceuticals, cosmetics, agriculture, food additives, industrial enzymes, bio-pesticides, and personal care. In these cases, most of the value added is captured by firms based in developed countries whose advanced scientific technological and marketing capabilities make this possible through bio-prospecting and they capture much more than the added value to the TK. This situation needs serious attention so that developing countries could be rewarded from the added value to

their knowledge. There is a need to add value to TK at the local level in order to convert it into economically profitable enterprises for these communities.

TK can also provide valuable leads for third parties in the development of useful products and processes, which can save modern industry time and money. This makes it necessary that the benefits should be equitably shared with the countries providing the genetic resources and the communities providing the knowledge. Currently this is often not the case. Therefore, several experts emphasize the importance of implementing CBD articles, particularly Article 15, related to ABS. Suggestions for benefit sharing include direct contracts with communities, establishment of national or regional funds to collect revenue on behalf of the communities, a global bio-collecting society and access fees for TK databases. There is, however, a view that the financial returns on bio-prospecting have been overrated and that ABS regimes to date have often focused more on controlling access than on promoting it. This, combined with legal uncertainty has in some cases discouraged potential involvement by business.

To harness TK for development and trade, developing countries need assistance to build national capacities in terms of raising awareness on the importance and potential of TK for development and trade; developing institutional and consultative mechanisms on TK protection and TK-based innovation; and facilitating the identification and marketing of TK-based products and services. The aim is to promote the use and further development of TK systems and TK-based innovations; promote appropriate and sustainable commercialization; and ensure that a fair and equitable share of the benefits resulting from the use of TK is captured by the TK holders, and in this process, the country's economy should also benefit. But to harness TK for trade and development, several steps required to be taken by the governments at the national/regional levels:

i) To promote the use and further development of TK systems

It must first be recalled that TK has the greatest value to the TK-holding communities themselves. Many of them rely on TK for their very survival, particularly poor rural communities in developing countries. Thus, any measures that can strengthen and further develop this base of knowledge on which the communities depend will facilitate their movement along their own unique path of development. This can be done through documentation of TK. Also, steps must be taken to promote local exchanges and adaptation of TK, such as "community-to-community exchanges". The IPR implications of these may need to be worked out (for example, there might need to be an agreement that shared information is not then passed on to a third party). However, this has been shown to increase the knowledge bases of both communities involved and to lead to new ideas and solutions to common problems. The Honeybee Network in India is interesting initiative in this direction, promoting grassroots TK-based innovation through TK documentation and dissemination.

Measures aimed at enhancing the capacity of national and regional TK networks – for example, by facilitating communication between different countries of the region that are sharing common knowledge – could also be quite useful. Attempts should be made to integrate TK into national development strategies and development projects. Involving TK holders in the early stages of development projects will help ensure that the project is well suited to local realities and takes advantage of local TK resources, including knowledge of the environment, local

materials, appropriate technologies, etc. Often, local TK can be leveraged by global knowledge for increased project effectiveness and sustainability.

ii) Commercialization

It should be pointed out that commercialization of TK often refers to the commercialization of a TK-based or TK-derived product – a tangible good or service where TK is the “know-how” involved in its production. Commercialization is a sensitive subject for some TK holders. Many TK holders are not as interested in commercializing the TK themselves as in preventing the inappropriate commercial use of it by others. Generally, TK was not developed with commercial purposes in mind, but rather for local use within the community. Much TK is not an appropriate subject for commercialization, particularly that with special spiritual or cultural significance. For TK holders interested in exploring commercialization, the first step is to decide which parts of their TK are off limits and which are not. A next step is the identification, within the latter category, of TK that may have value in the marketplace. Commercialization can be done by third parties, with a share of benefits going to the communities; as a partnership between the communities and third parties; or by the communities themselves. In general, the more involved the community is in developing, producing and selling the product, the larger the share of the market value that will accrue to it. The more funds come into a community, the more likely it is that the community will be vibrant and that the TK held by that community will be preserved and further developed.

Thus, it is very important to promote community-based development. The tools for such development are not exclusive to the domain of TK. They cover a range of measures to promote small enterprise and informal sector development, such as access to finance; assistance in identifying market opportunities; scaling up operations, marketing, and export; and promoting the formation of producers' associations to create economies of scale and create more bargaining power in obtaining inputs at lower prices. Partnerships with larger entities in the country's formal sector or in foreign markets can play an important role. One area where commercialization has particularly significant potential is traditional medicine. Measures can be taken to promote the increased involvement of traditional communities in this industry – for example, through the cultivation and first-degree processing of medicinal plants.

Since the indigenous/local communities may not have the resources to undertake commercialization on their own, it will become the responsibility of the government to provide necessary assistance at the initial stages. In the case of traditional medicine industry, the government should create regulatory frameworks for ensuring the quality, safety and efficacy of these medicines; measures encouraging a sustainable supply of raw materials for industry (including prevention of over harvesting of wild resources and cultivation of medicinal plants); and measures relating to export promotion.

In some cases, conventional IPR instruments may increase the commercial value of TK-derived products or help protect successful products from unauthorized copying or use by third parties. This concerns, for example, the use of trademarks and geographical indications (GIs), such as the GI for “Darjeeling Tea”.

But the value of TK must not be measured in purely economic terms; however, there are other important reasons, such as environmental or cultural factors that emphasize the importance of its protection.

13.4.3 Conservation of Environment

The protection of TK is important for the conservation and sustainable development of environment as much of the world's crop diversity has been conserved and preserved by the indigenous/local peoples, which has helped in the protection and conservation of biodiversity. The TK of the indigenous communities/local peoples is central for their ability to operate in an environmentally sustainable way and to conserve genetic and other natural resources. Most of the indigenous communities live in areas where the vast majority of the world's plant genetic resources (PGRs) are found. Their knowledge is central to the conservation and preservation of GRs and other bio-resources. For centuries TK has enabled rural indigenous communities to survive in balance with their natural environment. By virtue of providing for this balanced relationship, TK is truly the "science" of sustainable development at the local level. The Rio Declaration, 1992 clearly recognizes this by stating that "Indigenous people and their communities, and other local communities, have a vital role in environmental management and development because of their knowledge and traditional practices".

Paragraph 26 (1) of the Agenda 21, adopted at the Earth Summit in 1992, accepts the link between indigenous peoples and the world's need for environmentally sensitive development, and states: "In view of the interrelationship between the natural environment and its sustainable development and the cultural, social, economic and physical well-being of indigenous people, national and international efforts to implement environmentally sound and sustainable development should recognize, accommodate, promote and strengthen the role of indigenous people and their communities." This principle is echoed in a number of other international environmental agreements, including but not limited to the Convention on Biological Diversity (CBD), the Convention to Combat Desertification, and the Statement of Principles for the Sustainable Management of Forests. It thus draws the attention to the important role traditional knowledge (TK) plays in promoting the sustainable management of natural and environmental resources, and to the urgent need to support capacity-building efforts aimed at promoting the use of TK to help ensure sustainable patterns of trade in goods and commodities deriving from natural resources.

Because TK is closely related to survival and subsistence, it provides a basis for efficient local decision making in agricultural farming and the exploitation of fisheries and forests, ensuring the long-term viability of natural ecosystems so that the resource needs of future generations can be met. In indigenous communities throughout the world, TK has prevented land and soil degradation, fisheries depletion, biodiversity erosion and deforestation. With the advent of globalization, however, TK and its environmental benefits are threatened. On the one hand, world trade has created increased demand from distant markets for locally sourced agricultural, fisheries and forest products, pushing producers to harvest resources beyond the sustainable limits that TK would normally advise.

There is also the danger that the biological resources, increasingly subjected to IPRs and patents are likely to be plucked to extinction, which raises concerns over their exhaustibility and loss of habitat, besides the loss of lifestyles and livelihoods to indigenous communities that have nurtured and used these resources for long. This may also ultimately affect the food security. International recognition and protection of TK would help in the protection/conservation of

the environment and to manage the biodiversity. Protection of TK is therefore closely linked to the protection of environment.

In the recent years, there has been increased mobilisation of traditional communities from their natural habitat and their increasing assimilation with the modern society. Global communications and mobility attract younger generations to a diverse set of non-traditional livelihoods, often in distant urban settings. This has affected transmission of TK to current and future generations. This has also become a cause of concern for TK protection. It is feared that this mobility may lead to the extinction of TK and affect prejudicially the biodiversity. Writing on biodiversity, Gray observes that: "the world biodiversity crisis is matched by a world 'cultural diversity' crisis. Indigenous peoples live predominantly in areas of high biodiversity while at the same time comprise 95 percent of the cultural diversity in the world"² The challenges of globalization therefore include identifying ways for local communities to fully participate in, and benefit from, globalization in an environmentally sustainable manner while ensuring that traditional livelihoods and TK are competitively compensated in financial terms to prevent their erosion.

It has, however, been pointed out that sales of TK-based products provide important sources of income for local communities and can give them incentives to preserve their TK and biodiversity resources. The Internet offers new opportunities for reaching global markets. However, extreme care is needed to avoid over-harvesting of natural resources, which can easily lead to species extinction. Sustainability has to be built in at several levels. Key elements of supporting sustainability include increasing awareness, training in sustainable harvesting, cultivating medicinal plants, increasing the value added at the community level, and increasing community control over local resource use.

Self Assessment Question

(Spend 3 minutes)

3) How the TK is vital in the conservation of environment?

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13.4.4 Protection of Livelihood of TK Holders

TK is often an undervalued and underutilized resource in the development process. Several experts point out that TK is in fact the key to sustainable development at the local level. TK is valuable first and foremost to TK-holding local communities who depend upon it for their livelihoods and well-being, as well as for enabling them to sustainably manage their local ecosystems. According to the World Health Organisation, up to 80 per cent of the world's population depends on traditional medicine for its primary health needs. In India, for example, there are 600,000 licensed medical practitioners of classical traditional health systems and over one million traditional community-based

² A. Gray, *Between the Spice of Life and the Melting Pot: Biodiversity Conservation and its Impact on Indigenous Peoples*, IWGIA Document 70 (1991, Copenhagen).

health workers. Over 90 per cent of food in sub-Saharan Africa is produced using customary farming practices. For those comprising the poorest segments of societies, particularly women, indigenous people and rural inhabitants of developing countries, traditional knowledge is indispensable for survival. This is especially true in many LDCs. TK is thus a vital element of the social capital of the poor and constitutes their main asset in their efforts to achieve control of their own lives.

There is a need to enable these communities to harness TK for their economic upliftment and growth. Consequently, the demand for an effective protection of TK has gained momentum, either through the application of the traditional IPR system or by means of a new *sui generis* system such as traditional community rights or community intellectual property rights, as also by recognising their cultural/land rights over their habitat. It should be strongly emphasized that intellectual property, however, is not only about property. It is also about recognition of and respect for the contributions of identifiable, human creators. From this perspective, intellectual property has a very important role to play in protecting the dignity of holders of traditional knowledge and, by conferring property rights in relation to such knowledge, giving those holders a degree of control of its use by others.

Indigenous peoples inhabit lands rich in natural resources and are at the same time among the poorest of the poor both because of their economical marginalisation and also because they are deprived basic social, cultural and political rights and fundamental freedoms, including rights to their lands, territories and resources. Consequently, they are strongly affected by the operations of national and transnational companies. It may be argued that biodiversity, and the traditional knowledge associated with using it in a sustainable manner, are a comparative advantage of those countries that are biodiversity-rich, enabling them to participate more effectively in global markets and thus rise above current levels of poverty and deprivation. This is an example of how protection of traditional knowledge at the national and the international levels may be seen as a potentially powerful tool for advancing the integration of least developed countries into the global economy. Involving indigenous peoples and traditional knowledge into natural resource management produces more equitable and successful outcomes.

A large number of countries – rich in genetic resources (GRs) and TK and folklore, believe that the traditional communities have been deprived of the benefits from the use of their knowledge, innovations and practices, which have been monopolised and used by others, mainly by major companies, without their authorization and without acknowledging or rewarding them for their knowledge, that is, there is a perceivable asymmetry between the benefits obtained by the companies that commercially exploit this knowledge and the lack of benefits for its true holders. Developed countries have a moral obligation to ensure that indigenous/local peoples receive a fair and equitable share of benefits arising out of the use of their TK and commercialization of GRs. Moreover, if the knowledge assets of developed countries are to be protected by means of an international agreement (viz. TRIPS) it is only fair and equitable that the knowledge assets of developing countries ought also to be similarly protected. It is indeed the responsibility of the international community to create an egalitarian system for the availability, acquisition, maintenance and enforcement of IPRs, which does not, *a priori*, exclude any section of the society. An international regime

would give control over the use of their knowledge assets and the capacity to ensure that they are not exploited commercially.

Industrialized countries have generally been supportive of the notion that indigenous peoples' rights are mainly about being permitted to practice their lifestyle and uphold their sense of identity through adhering to expressions of their folklore and culture. This, however, takes away attention from the essential questions of economic rights and the economic value of TK, some of which comes inextricably linked with their habitat and their title or lack of it to source livelihood from their habitat.

TK is currently being lost at an alarming rate. There are a number of possible measures for preserving TK. First, it is important to understand the root causes of the TK loss in each country. Often the process begins with destruction of the natural environment, which in turn disturbs and even destroys the indigenous and local communities embodying traditional lifestyles which are the main holders of the TK. Recognizing the rights of these communities to their traditional lands could help slow this detrimental trend. Often such communities start to decline owing to poverty, in which case strengthening their economic opportunities is an appropriate response. Lack of motivation in the younger generation to learn the traditions is another reason cited for its loss. They no longer feel proud of their heritage and way of life, considering it to be old-fashioned, and thus have little incentive to be recipients of the TK held by the elders. There is a fear that TK will extinct with the elders of the community. TK is generally viewed with disdain and inferior, as it does not conform to the accepted scientific methods of learning in the context of modern reductionist approach of science. In that case, raising awareness of the value of TK and of the cultural heritage may help, besides its becoming a tool in engaging them in a gainful employment at par with other vocations. Only by concerted efforts to protect it and accord it due respect, this trend can be stopped.

In addition to national systems, the protection of TK and equitable sharing of the benefits derived from the use of biodiversity resources and associated TK may also require measures by user countries and cooperation at the multilateral level. It must be ensured that the benefits of cumulative innovation associated with TK accrue to their holders while enhancing their socio-economic development. Frequently TK is used and appropriated without the prior informed consent of the holders. This situation needs a change.

13.5 SUMMARY

- Traditional knowledge refers to the long-standing **traditions** and practices of **indigenous/local communities**. It passes orally from generation to generation and evolves continuously.
- Because of its fast erosion due to misappropriation/biopiracy, concerns are aroused about its protection and efforts are underway to reward the **indigenous/local communities** for this knowledge out of its use and commercialisation.
- Number of tools and mechanisms, including the traditional IPRs and a *sui generis* approach, are being discussed to protect it.

Protection of Traditional Knowledge

- TK protection is vital to curb biopiracy, and to conserve and protect the eco-system.
- To curb bio-piracy, documentation of TK in the public domain can be a useful mechanism. Disclosure of the source of biological material and TK, and the evidence of compliance with the local laws on ABS in the IPR-related application can be very useful.
- TK can help in the growth of national economy, by trading in TK-based goods. TK plays a vital role in agricultural and medicinal industry, which is a thriving industry at present. This will also create employment opportunities for the **indigenous/local communities**.
- TK protection will significantly help in the upliftment of the **indigenous/local communities**. They live in lands rich in natural resources, but are deprived basic social, cultural and political rights and fundamental freedoms, including rights to their lands, territories and resources. By protecting their rights to land and helping them to use their TK in a gainful manner will improve their economic and social conditions.

13.6 TERMINAL QUESTIONS

- 1) What is 'traditional knowledge' and its significance for developing countries in particular.
- 2) What are the principal objectives of protecting TK and how they can be attained?
- 3) What are the vital steps discussed and suggested at the regional/international levels to curb bio-piracy and misappropriation of GRs and TK associated therewith?

13.7 ANSWERS AND HINTS

Self Assessment Questions

- 1) Traditional knowledge refers to the long-standing **traditions** and practices of certain **indigenous/local communities**. Its creation and use are part of the cultural traditions of communities; being created every day and continuously evolves as a response of individuals and communities to the challenges posed by their social environment. In many cases, traditional knowledge is passed **orally** for generations from person to person. It is inter-generational and continuously created and modified.
- 2) TK plays an important role in the global economy and is valuable not only to those who depend on it in their daily lives but to modern industry and agriculture. Most of the traditional societies depend on this knowledge for their food and healthcare needs. TK has the potential of being translated into commercial benefits by providing valuable leads for the development of useful products and processes. The valuable leads provided by TK save time, money and investment of modern biotech into any research and product development.

- 3) TK is important for the conservation and sustainable development of environment as much of the world's crop diversity has been conserved and preserved by the indigenous/local peoples, which has helped in the protection and conservation of biodiversity. The TK is central for their ability to operate in an environmentally sustainable way and to conserve genetic and other natural resources. Most of these communities live in areas where the vast majority of the world's plant genetic resources (PGRs) are found. Their knowledge is central to the conservation and preservation of GRs and other bio-resources, which help in ensuring the food security of the nation as well.

Terminal Questions

- 1) Refer to Section 13.3
- 2) Refer to Section 13.4
- 3) Refer to Section 13.5

13.8 REFERENCES AND SUGGESTED READINGS

- 1) P. Principe, "Economics and Medicinal Plants", in T.R. Tomlinson and O. Olayiwola Akerela (eds), **Medicinal Plants : Their Role in Health and Biodiversity** (1998, University of Pennsylvania Press, Philadelphia).
- 2) Daniel Gervais, "TRIPS, Doha and Traditional Knowledge", 6 JWIP 403 (3: 2003).
- 3) Ajeet Mathur, *Who Owns Traditional Knowledge*, Working Paper No. 96, Indian Council for Research on International Economic Relations (ICRIER), Jan. 2003, p 12 et seq.
- 4) Thomas Cottier, "The Protection of Genetic Resources and Traditional Knowledge : Towards More Specific Rights and Obligations in World Trade Law", 4 JIEL 561 (1998).
- 5) S. K.Verma, "Protecting Traditional Knowledge – Is a *Sui Generis* System an Answer?" 7 JWIP 765 (Nov. 2004).

UNIT 14 CURRENT INTERNATIONAL EFFORTS FOR THE PROTECTION OF TK

Structure

- 14.1 Introduction
- 14.2 Objectives
- 14.3 International Efforts for the Protection of TK
 - 14.3.1 World Intellectual Property Organisation (WIPO)
 - 14.3.2 World Trade Organisation (WTO) TRIPS
 - 14.3.3 Convention on Biological Diversity (CBD)
 - 14.3.4 Food and Agriculture Organisation (FAO)
- 14.4 Need for a *sui generis* framework for TK Protection
- 14.5 Summary
- 14.6 Terminal Questions
- 14.7 Answers and Hints
- 14.8 References and Suggested Readings

14.1 INTRODUCTION

The protection of traditional knowledge, innovations and practices (hereinafter referred to as TK) of indigenous/local communities has received an increasing international attention since the adoption of the Convention on Biological Diversity (CBD) in 1992. The CBD, through its Article 8(j) has broadened the scope and mandate of protection with wider objectives. It led to heightened concern to protect the traditional knowledge (TK) of indigenous communities at the national, regional and international levels. Since then it is actively on the agenda of different inter-governmental bodies, including the human rights bodies, viz., WTO/TRIPS Council, WIPO, UNEP/CBD, FAO, UNCTAD, WHO, ILO, United Nations Human Rights Commission, UN Permanent Forum on Indigenous Issues. A number of countries and regional organisations are proposing or have already adopted measures to protect TK in their respective jurisdictions. At the level of inter-governmental bodies, the most extensive work/discussions have taken place in the WIPO, which had established an Inter-Governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (hereinafter referred to as IGC) in 2000 with the mandate to discuss intellectual property (IP) issues that arise in the context of (i) access to genetic resources and benefit-sharing; (ii) protection of TK, whether or not associated with those resources; and (iii) the protection of expressions of folklore. Its discussions since then have led to an understanding of the technical dimensions involved in the protection of TK and clarifying many concepts thereto. Even though no comprehensive document on the protection of TK has been adopted so far, but piece-meal progress in the form of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), adopted by the FAO in 2001, and the recently concluded Nagoya Protocol under CBD in October 2010 has been seen.

14.2 OBJECTIVES

After reading this unit, you should be able to:

- know the initiatives undertaken by different inter-governmental bodies for the protection of TK;
- know the progress achieved by different bodies in their endeavour to adopt a mechanism to protect TK;
- able to know the main demands of developing countries in this regard;
- scope and mandate of ITPGRFA and whether it really addresses the issue of protection of TK in a comprehensive manner;
- scope and main plank of the Nagoya Protocol;
- know the global issues in the protection of TK; and
- explain the need of a *sui generis* system for the protection of TK.

14.3 INTERNATIONAL EFFORTS FOR THE PROTECTION OF TK

The first effort to protect TK, specifically folklore, under the IP regime was a joint initiative taken by WIPO/UNESCO in 1978, which led to the adoption of the WIPO-UNESCO Model Provisions for National Laws on the Protection of Expressions of Folklore against Illicit Exploitation and Other Prejudicial Actions in 1982. It was in the nature of guidelines to WIPO members to protect folklore in their jurisdictions. Since then, numerous efforts have been initiated to protect TK by inter-governmental bodies, which are aimed at entrusting legal control to indigenous/local communities over the exploitation of their TK when such knowledge has special cultural significance. The human rights bodies also adopted important conventions in this regard, viz., the ILO Convention No 169 of 1989 and the draft UN Declaration on the Rights of Indigenous Peoples, 1994.

The ILO Convention obliges the States to “respect the special importance for the cultures and spiritual values of the peoples concerned of their relationship with the land or territories or both” (Art.13). States are to promote “the full realization of the social, economic and cultural rights of these peoples with respect for their social and cultural identity; their customs and traditions and their institutions” (Art.2 (2)). The Governments have the responsibility to develop, “with the participation of the people concerned, co-ordinated and systematic action to protect the rights of these peoples and to guarantee respect for their integrity.” (Art. 2 (1)) Their social, cultural, religious and spiritual values and practices are to be recognized and protected (Art. 5). The concept of cultural identity thus provides an important link between cultural rights and cultural heritage, implying the collective right of indigenous peoples to the protection of their own cultural heritage. The Convention, though does not define TK, or explicitly mention indigenous resources or folklore, nevertheless recognizes the rights of indigenous peoples over natural resources pertaining to their land, and to their traditional activities in order to maintain their cultures and economic self-reliance and development, which are to be safeguarded (Arts. 15 & 23). More importantly, they can “decide their own priorities for the process of development as it affects their lives, beliefs, institutions and spiritual well-being and the lands

they occupy or otherwise use, and to exercise control, to the extent possible, over their own economic, social and cultural development (Art. 7). The Convention clearly accepts the inter-relationship between cultural heritage law, land rights, and cultural rights of indigenous peoples in their own traditions, which includes TK as well. The Convention is important in providing a model definition of indigenous and tribal peoples (Art. 1.1).

The draft UN Declaration on the Rights of Indigenous Peoples accepts the right of self-determination of indigenous peoples (Art. 3). It recognizes their “collective right to live in freedom, peace and security as distinct peoples”, (Art. 6(1)); their right to the full recognition of their laws, traditions and customs (Art. 26); and full maintenance, protection and promotion of past, present and future manifestations of their cultures (Art. 12). The Declaration demands that States abstain from removing them from their lands or territories (Art. 10), respect their traditions and indigenous knowledge (Part III) and restore and protect the environment (Art. 28). Cultural and intellectual property rights are recognized in Article 29, by accepting their full ownership, control and protection over their cultural and intellectual property. The draft includes the right that States obtain their “free and informed consent” before any projects affecting their lands, territories or resources may be approved, “particularly in connection with the development, utilisation or exploitation of mineral, water or other resources” (Art. 30). However, there is no explicit mention of TK and traditional resources (like with the ILO Convention), but the term “other resources” in Article 30 could be broadly interpreted to cover them.

14.3.1 World Intellectual Property Organisation (WIPO)

The WIPO's direct and positive involvement in the foray of TK started in 1998. During 1998-1999, the WIPO embarked on nine fact-finding missions (FFMs) in various parts of the world on exploring the intellectual property aspects of TK protection, bearing in mind the needs and expectations of TK holders.¹ In its 26th session, the WIPO General Assembly established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). The IGC's actions (which has so far met in 20 sessions since its inception in 2000) have resulted in three separate texts- on TK, Traditional Cultural Expressions (TCEs) and Genetic Resources (GRs), which will be negotiated in a single negotiating text. The IGCs efforts have focussed on trying to understand the needs and expectations of traditional/local communities, ascertaining the adequacy of current methods for protecting TK, and surveying proposals to enhance such protection. It has produced an impressive number of documents, including the model clauses for genetic resources contracts, a toolkit for documentation of TK protection, and elements of a possible *sui generis* system. Latest texts contain the draft provisions for an international instrument to protect the TK and based on the final text of the draft treaty on TK, the WIPO may decide to convene a Diplomatic Conference for its adoption in 2012-2013. In the Draft Articles on the protection of traditional knowledge, prepared at IWG 2 in March 2011 (wipo/grtkf/ic/18/7), TK has been defined as “knowledge resulting from intellectual activity in a traditional context including the know-how, skills, innovations, practices and learning that form part of the

¹ See **Intellectual Property Needs and Expectations of Traditional Knowledge Holders**, WIPO Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge (1998-1999) Geneva 2001.

traditional knowledge systems of an [indigenous people or local community²]. The draft has also come out with the eligibility criteria for TK protection, scope of protection, sanctions, remedies and exercise of rights, and administration of rights. A contracting party may, in consultation with the holders of traditional knowledge, establish an appropriate national or regional competent authority or authorities for this purpose. It has provisions on exceptions and limitations to TK rights, and on term of protection, which may last as long as the traditional knowledge fulfills the criteria of eligibility for protection as outlined in the Draft.

Beyond the Committee's work, WIPO has also taken steps to enhance the coverage of documented TK in the minimum documentation of the Patent Cooperation Treaty (PCT) and to expand the International Patent Classification (IPC) to contain categories for TK subject matter to provide for more accurate and focussed searching for relevant TK during the patent examination process.

The WIPO's approach in the matter of TK protection is mainly IP-related. The documents produced acknowledge the general difficulties with protecting the TK under IP law. The IGC has centred its activities mainly on solutions that tend to minimize the rigours of IP criteria. The IP solution is sought for TK in the public domain, which is a small part of the vast arena of TK that has strong moorings in cultures and traditions/rituals etc. The notion of public domain as understood in the formal IP system dominated the identification of the definition as fixing the criteria for the protection of TK. That fundamentally questioned the customary right of the TK holders. TK was part of the communities and they owned it. The eligibility conditions were putting the burden on the holders of TK to prove that it belonged to them. That was against the basic understanding that TK belonged to the community. The policy objective was to prevent misappropriation and misuse of valuable TK. This approach would facilitate misappropriation and put the burden of establishing ownership on TK holders rather than enabling them to empower, preserve and protect their culture and tradition. But this approach is not adequate enough to protect and cover all forms of valuable TK. Once TK qualified, an eligibility condition should not put any further discrimination on the nature of protection based on further classification of TK because this might be unfair to the community. Regarding knowledge kept in secret, it was an accepted fact that knowledge kept in secret would receive higher protection through the basic principles of trade secrets. This can be taken care in a *sui generis* law, which is different from an IP instrument.

Developing countries desire to protect the holistic character of TK. The IGC's work has heightened the awareness among the developing countries to safeguard their valuable knowledge asset. WIPO had earlier proposed a bottom-up approach under which developing countries first assess how existing national mechanisms of IP could be more effectively used to protect TK before introducing protection at the international level.

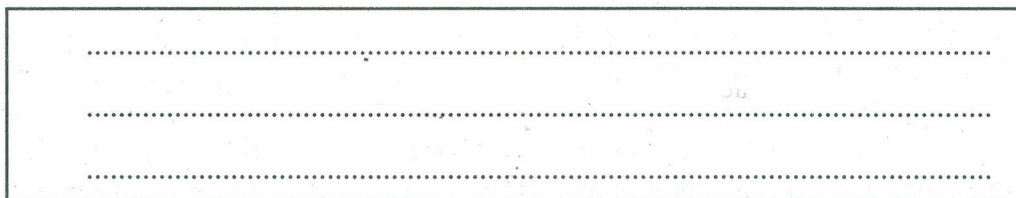
Self Assessment Question

(Spend 3 minutes)

- 1) Describe the latest position of negotiation in the IGC on TK protection.

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² The term "indigenous people and local community" is used as a place holder. This term will be addressed by the group considering beneficiaries of protection.



14.3.2 World Trade Organisation (WTO)/TRIPS

The TK has come-up on the agenda of the WTO under the TRIPS Agreement. The Agreement, as such deals with the traditional concepts of intellectual property and does not have any specific provision on the protection of TK, rather it is being excluded by virtue of Article 70(3), considering it as a part of public domain.³ The relevant provisions in this context could be Article 39 (protection of undisclosed information), if the TK is kept as secret knowledge, and Article 22 (protection of geographical indications). Obviously they are of limited application and are unable to meet the concerns of developing countries.

The issue of protection of TK being brought before the General Council of the WTO in the context of Article 27(3)(b) of the TRIPS in 1999, which was to be reviewed under its terms. Article 27(3)(b) requires Members to protect plant varieties, “ either by patents or by an effective *sui generis* system or by any combination thereto”. A country while constructing a *sui generis* regime may take into account the protection of TK as the plant genetic resources have a double nature: they are physical material and the carriers of hereditary information which is capable of self-replication and also a part of TK. This double nature gives rise to a conceptual tension between physical property in germplasm on the one hand and the IPRs in intangible elements of GRs (genotype) which constitute inventions, trade secrets or new plant varieties on the other. TK also became an issue in the context of patenting on biological inventions, which saw a tremendous surge after the adoption of TRIPS, and made microorganisms, microbiological and non-biological processes as patentable.

At the Third Ministerial Conference of the WTO at Seattle, developing countries from Latin America and Africa wanted that the TRIPS review , *inter alia*, should “establish on a mandatory basis within the TRIPS Agreement a system for the protection of intellectual property, with an ethical and economic content, applicable to the traditional knowledge of local and indigenous communities, together with the recognition of the need to define the rights of collective holders”, and it should lead ultimately to a multilateral legal framework. They also called for the harmonization of TRIPS and the CBD, relating to the protection of TK and use of GRs.

Developing countries arguments centred on clarifications about the exclusions under Article 27(3)(b). They wanted that the information relating to the origins of a biological invention become part of the patent application process and that the principle of prior informed consent under the CBD, should be incorporated into TRIPS. There was heightened concern about the grant of patents and/or other IPRs covering TK to persons other than the indigenous peoples/communities, who own and control them, and their TK is being used without their authorization and without sharing benefits with them that accrue from such use. The United

³ Article 70.3 of the TRIPS reads: “There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain”.

States and other industrialized countries, on the other hand, argued that the CBD's objectives on access to GRs and TK could best be achieved through national legislations and contractual arrangements, based on the national legislation, which could include commitments on disclosure. But this does not address the issue of consequences of non-compliance with the national legislation and the IPRs granted on GRs and TK.

a) Doha Declaration

The strong position taken by the developing countries on the protection of TK, nevertheless, led to its inclusion in Doha Ministerial Declaration in November 2001 in paragraphs 19 and 32.

Para 19

We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension

Para 32

We instruct the Committee on Trade and Environment, in pursuing work on all items on its agenda within its current terms of reference, to give particular attention to:

- i) the effect of environmental measures on market access, especially in relation to developing countries, in particular the least-developed among them, and those situations in which the elimination or reduction of trade restrictions and distortions would benefit trade, the environment and development;
- ii) the relevant provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights; and
- iii) labelling requirements for environmental purposes.

Paragraph 19 mandated the TRIPS Council that in pursuing its work programme including under Article 27.3(b), and the implementation of the TRIPS Agreement under Article 71.1, it should examine, *inter alia*, the relationship between the TRIPS Agreement and the CBD, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPS Council should take into account the objectives and principles of the TRIPS Agreement set out in Articles 7 and 8 and the development dimension.

Under Para 32, the Committee on Trade and Environment was instructed that, in pursuing its work on items on its agenda, to give particular attention to three issues, including the relevant provisions of the TRIPS Agreement (Para 32). It

is, however, to be noted that TRIPS Agreement does not make any reference of CBD in its provisions. Though adopted later in time after the CBD, it failed to take note of Article 16(5) of the CBD, which clearly states that patents and other IPRs may have an influence on the implementation of the CBD and the parties shall ensure that such rights do not run counter to its objectives.

Since the Doha Round, the discussions before the TRIPS Council are centred on the relationship between the provisions of the TRIPS Agreement and the CBD and the protection of TK under the mandated review of Article 27(3)(b). In order to assist the Council to discharge its mandate, different nations/national groups have made submissions, which have reiterated the contrasting approaches on the issue of protection of TK under the TRIPS Agreement between the industrialized and developing countries. Industrialized countries consider WIPO the most appropriate forum to tackle the issue of legal protection of TK, and WTO is, in fact, not the right place to negotiate a full-fledged system of protection for a complex subject matter like TK or folklore.

The developing countries, on the other hand, do not find the present IP regime adequate to address their concerns in relation to TK. They find the patent system faulty as it does not take into account TK as prior art, nor does it take care of the requirements of benefit-sharing and prior informed consent (PIC). They are insisting that the TRIPS Agreement should be suitably amended or provide mechanism requiring that an applicant for a patent on biological material or TK should, as a condition to acquire patent rights, (a) disclose the source and country of origin of the biological resources and of the traditional knowledge used in the invention; and (b) provide evidence of prior informed consent and fair and equitable benefit sharing under the relevant national regime. Developing countries, including India, in 2006 moved a draft Article 29*bis* as an amendment to the TRIPS Agreement, requiring disclosure of source, PIC and ABS for GR and TK based applications.

These requirements in patent applications on biological inventions, according to these countries, will ensure that national legal regimes for preventing bio-piracy and benefit sharing are effectively implemented when use or commercialization of TK takes place outside the country. This will also reduce the instances of bad patents and enhance ability of countries to track down and challenge bad patents. The disclosure requirement may also be justified on grounds that it would ensure effective enforcement at the international level, and thus complement provisions in national patent laws that permit revocation of patents for failure to disclose material information, or submission of false information with an intend to mislead. Other points made by developing countries can be viewed as necessary to improve national compliance with treaty obligations regarding PIC and benefit sharing found under the CBD (Art. 15). They further argue that such compliance will be consistent with the objectives of the CBD as well as with Article 7 of the TRIPS Agreement. A *sui generis* system will provide proprietary right to ensure that market forces will operate to generate fairness and equity.

These deliberations at the WTO/TRIPS Council clearly reveal that no perceptible achievement has been registered on the issue of protection of TK. Developing countries, which constitute the three-fourths of WTO membership, are the chief holders of TK have demanded the inclusion of TK in TRIPS Agreement to get a fair return on their resources. WTO may be considered to be the most appropriate forum with its dispute settlement mechanism.

14.3.3 Convention on Biological Diversity.

The CBD⁴ is the principal international instrument which explicitly acknowledges the role of traditional knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles in biodiversity conservation and its sustainable development. The scope of the TK, however, is confined to genetic materials (GRs). It is a framework convention that sets out general principles that the parties agree to be guided by and work towards them in a long-term process. According to Article 8(j) of the Convention, each contracting party, subject to its national legislation, is required to:

- i) respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological resources;
- ii) promote the wider application of such knowledge, innovations and practices with the approval and involvement of their holders; and
- iii) encourage the equitable sharing of benefits arising from the utilisation of such knowledge, innovations and practices.

Article 8

Each Contracting Party shall, as far as possible and as appropriate:

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices

Apart from Article 8(j), however, no other provision of the CBD requires the consent or involvement of the indigenous/local communities in granting access to genetic resources. It, in fact, does not specify that who are the stakeholders in issues related to genetic resources, but only places binding legal obligations on national governments, parties to the Convention. Article 15 recognizes the sovereign rights of States over their natural resources and their authority to determine access to genetic resources and that access, where granted, shall be on mutually agreed terms and subject to prior informed consent of the provider party (a contracting party). Article 15(5) provides that “access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources”, and does not talk about the indigenous communities. But in giving effect to other provisions of the Convention, the governments have the authority to determine the mechanism for the involvement of these communities and other stakeholders and specify their roles and responsibilities (Art. 15(7)). Article 18(4) states that Contracting Parties shall “encourage and develop methods of cooperation for the development and use of technologies, including indigenous and traditional technologies”. But the most controversial provision is Article 16(5) which requires Parties to cooperate to ensure that patents and other IPRs “are supportive of and do not run counter to its [CBD’s] objectives.”

⁴ The Convention came into force on 29 December 1993 and currently has 193 parties. The major non-party is the United States.

In furtherance to this framework, TK is on the agenda of the CBD since 1996 and an extensive and complex work programme has grown around the issue of IPRs and their role in the implementation of the CBD. The COP-IV in 1998 established an "ad hoc open-ended inter-sessional working group" to "provide advice on the application and development of legal and other appropriate forms of protection for the knowledge, innovations and practices of indigenous and local communities". The working group worked towards strategies to protect TK, based on a combination of approaches, and full respect for customary law and practices, including the use of existing IP mechanisms, the use of contractual arrangements, register of TK and guidelines and code of practices. It also considered the *sui generis* mode of protection of TK, by focusing on the specific needs and interests of indigenous and local communities in the protection, utilisation and equitable sharing of benefits when access to their genetic resources are sought.

In another significant development, in 2002, the COP-VI adopted the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilisation, which called upon the parties to use the Guidelines when drafting their laws and policies "on access and benefit-sharing, and contracts and other arrangements under mutually agreed terms for access and benefit sharing". The Guidelines are voluntary in nature, which the parties may take into account while giving effect to their obligations under the CBD. The Guidelines suggest that Material Transfer Agreements (MTAs) on GRs may include conditions under which the user on accessed GRs may seek IPRs, and monetary and non-monetary benefits may include "joint ownership of relevant intellectual property rights". Parties have been invited "to encourage the disclosure of the country of origin of genetic resources in applications for intellectual property rights, where the subject matter of the application concerns or makes use of genetic resources in its development, as a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resources was granted." They have further been invited "to encourage the disclosure of the origin of the relevant traditional knowledge, innovations and practices of indigenous and local communities."

As means to implement the CBD requirements for mutually agreed terms, the guiding parameters suggested for contractual agreements provide that the "provision for the use of intellectual property rights include joint research, obligation to implement rights on inventions obtained and to provide licenses by common consent" and "the possibility of joint ownership of intellectual property rights according to the degree of contribution." In order to seek compliance with the prior informed consent of the contracting party providing such resources and mutually agreed terms, the countries may take measures to encourage the disclosure of the country of origin of the genetic resources and the origin of TK in applications for IPRs.

On some of the more important topics, further information and work was requested, viz., impact of IPRs on access/use of GRs and scientific research; role of customary law; relationship between disclosure requirements and international legal obligations; efficacy of disclosure requirements; feasibility of an internationally recognized certificate of origin system; monitoring, compliance and enforcement; and role of oral evidence of prior art in granting IPRs. COP-VII has further elaborated on these issues and has invited parties to recognize TK,

whether written or oral, as prior art. Parties are to ensure under their domestic law compliance with the requirement of prior informed consent of the indigenous communities and put in place mechanisms to ensure fair and equitable benefit-sharing at the national level with relevant stakeholders and indigenous/local communities. It invites WIPO to take into account the CBD's work on these topics, and WIPO's work should be supportive of the CBD. These initiatives, though, to a great extent addressed the concern of developing countries, but did not create any binding legal obligation.

The importance of the Bonn Guidelines for developing countries is that it was a significant step towards the harmonization of the regime of access and benefit sharing. It is also important to note in the context of the CBD, particularly Article 15, that by emphasising on national sovereignty and the authority of governments to regulate access to GRs cannot rule out the bilateral negotiations between the biodiversity-rich but technologically- poor countries and those seeking access to these resources. In other words, CBD promotes bilateral agreements between the providers and users of resources for which a multilateral approach would be mutually beneficial by laying down the framework of fair terms, as in bilateral negotiations, the biodiversity rich countries quite often are not in a strong position to negotiate a fair deal.

Self Assessment Question

(Spend 3 minutes)

2) What are the salient features of the Bonn Guidelines?

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a) Nagoya Protocol

Based on the work of its Ad Hoc Open-ended Working Group on Access and Benefit-sharing, the COP-X on October 29, 2010, adopted the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (ABS) to the Convention on Biological Diversity. The Protocol is in the nature of a treaty and would create binding obligations for the parties. The Protocol is aimed at effectively implement Article 15 (Access to Genetic Resources) and 8(j) of the Convention and its three objectives. The Protocol significantly advances the Convention's third objective by providing a strong basis for greater legal certainty and transparency for both providers and users of genetic resources. It covers the TK associated with GRs and benefits arising from their utilisation and aims at creating greater legal certainty and transparency for both providers and users of genetic resources by establishing predictable conditions for access to GRs and ensuring benefit sharing after GRs leave the country providing GRs. Protocol imposes obligations on parties to take measures regarding access to GRs, benefit-sharing and compliance.

Its objective broadly is fair and equitable sharing of benefits arising from the utilisation of GRs, including by appropriate access to GRs and by appropriate

Protection of Traditional Knowledge

transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components. Towards this objective, it provides fair and non-arbitrary rules and procedures for prior informed consent and mutually agreed terms. Such terms to be in writing, including: a dispute settlement clause; terms on benefit sharing, including on IPRs; terms on subsequent 3rd party use, if any; and terms on changes of intent, where applicable. Benefits to be shared shall include those arising from the utilisation of GRs as well as subsequent applications and commercialization. Benefits shall be shared only with the Party providing such resources (that is the country of origin) and on the basis of mutually agreed terms (MAT). It also considers the importance of genetic resources for food and agriculture for food security.

Benefit-sharing obligations require benefit-sharing measures at domestic-level, which should, inter alia, provide for the fair and equitable sharing of benefits arising from the utilisation of GRs and TK associated therein with the contracting party providing GRs. Benefits may be monetary or non-monetary such as royalties and the sharing of research results or joint ownership of relevant IPRs. Parties required to take measures to provide access to GRs in accordance with prior informed consent (PIC), and mutually agreed terms (MATs) as required by another contracting party; cooperate in cases of alleged violations of these requirements; encourage contractual provisions on dispute resolution; take measures regarding access to justice; and take measures to monitor the utilisation of genetic resources after they leave the country.

For an effective implementation at the domestic level, the Protocol provides a range of tools/mechanisms for parties to resort which includes establishing national focal points (NFPs) and competent national authorities (CNAs) to serve as contact points for information; grant access or cooperate on issues of compliance; an Access and Benefit-sharing Clearing-House to share information; and capacity-building to support key aspects of implementation, which may include (i) Develop domestic ABS legislation to implement the Protocol, (ii) Negotiate MAT; (iii) Awareness-raising; (iv) Technology Transfer, (v) Targeted financial support for capacity-building. Financial mechanism envisaged under the Protocol for capacity building and development stress on the capacity building needs of developing/least developing countries, and priorities/needs of indigenous and local communities to be catered. Financial mechanism of the Protocol is the same as of the CBD. Developed countries shall provide financial and other resources for the implementation of the Protocol. CBD has now established the Global Environment Facility (GEF). The Fund is to help developing countries to implement the Protocol. World Bank will act as the trustee of the Fund.

The Protocol also envisages the need for a global multilateral benefit sharing mechanism to address the fair and equitable sharing of benefits derived from the utilisation of GRs and TK associated with genetic resources that occur in trans-boundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of GRs and TK associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally. But TK associated with ex situ GRs, GRs outside the national boundaries, ex situ collections prior to the entry into force of the Nagoya

Protocol are not covered under it. The Protocol also talks about the trans-boundary cooperation. The IGF's Draft Articles on TK in Art. 12 also insists on trans-boundary cooperation by stating that, "where traditional knowledge is located in territories of different contracting Parties, those contracting Parties shall co-operate by taking measures that are supportive of and do not run counter to the objectives of this instrument. This cooperation shall be done with the participation [and consent] of the traditional knowledge holders."

Specific obligations to support compliance with domestic legislation or regulatory requirements of the Party providing GRs and contractual obligations reflected in mutually agreed terms are a significant innovation of the Protocol. These compliance provisions as well as provisions establishing more predictable conditions for access to GRs will contribute to ensuring the sharing of benefits when GRs leave a Party providing GRs. In addition, the Protocol's provisions on access to TK held by indigenous and local communities when it is associated with GRs will strengthen the ability of these communities to benefit from the use of their knowledge, innovations and practices.

14.3.4 Food and Agriculture Organisation (FAO)

The FAO, in November 2001, adopted the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)⁵, which is based on FAO's International Undertaking, first adopted in 1983. The Treaty is limited to plant genetic resources (PGRs) for food and agriculture. It is much influenced by the CBD, but does not encourage the IPRs over PGRs and the TK related thereto. The use of PGRs for medical and healthcare purposes is outside its scope (and can be subjected to IPRs). It recognizes the rights of farmers (without defining who is a farmer) and local/indigenous communities, who have been in the centres of origin and diversity, in conserving, improving and making available these resources (Art. 9). The implementation of farmers' rights requires the "protection of traditional knowledge relevant to plant genetic resources for food and agriculture" (Art. 9. 2). It is the responsibility of the national governments to involve them equitably in benefit sharing from the utilisation of PGRs (Art. 9.2(b)). Involvement of local/indigenous communities in decision-making has not been talked about in the CBD. Article 13 details the provisions on benefit sharing. Access to PGRs shall be provided solely for purposes of utilisation and conservation for research, breeding and training for food and agriculture. The transfer/access to PGRs shall be subject to the multilateral system, according to the terms of standard Material Transfer Agreement (MTA, Art. 12). The Treaty, however, does not specifically refer to indigenous people, except in relation to States' responsibility to "promote *in situ* conservation by supporting *inter alia*, the efforts of indigenous and local communities" (Art. 5.1(d)). The Treaty is limited in its scope and principally aimed at preventing the loss of agrobiodiversity rather than biodiversity in general, and establishes the farmers' rights, and not of local/indigenous communities.

Self Assessment Question

(Spend 3 minutes)

- 3) What is the significance of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) towards the protection of PGRs and TK?

⁵ The Treaty has entered into force on 29 June 2004.

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14.4 NEED FOR A *SUI GENERIS* FRAMEWORK FOR TK PROTECTION

As is evident from the above discussions, the focus at the international foras are centered around numerous legal, economic, policy and scientific issues in TK protection under the intellectual property regime and they do not take the holistic character of TK. There is no legally binding instrument to protect TK comprehensively as yet apart the FAO's ITPGRFA and the CBD's Bonn Guidelines and now the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation. The Nagoya Protocol, a treaty, has a limited scope related to ABS, but does not talk about the protection of TK as such. It is limited, to the access to GRs and benefit-sharing and thus relate to physical rather than intellectual or intangible aspects of these resources, which is mainly related to TK and is the subject matter of intellectual property protection. Moreover, these measures are not comprehensive enough to address the concerns and needs of developing countries, which desire an international mechanism, acknowledging the holistic nature of TK and collective rights of indigenous/local communities over it. According to developing countries a *sui generis* mode would be most appropriate to protect the holistic character of the TK and tackle the problem of illegal acquisition of GRs. It should reaffirm the principle of national sovereignty over genetic resources; recognize the role of the State in the preservation and protection of TK and expressions of folklore; recognize the economic rights of TK holders and custodians as well as their moral rights against the culturally offensive use of their knowledge; recognize the role of customary law and protocols in the protection of TK and expressions of folklore; and recognize the complementary nature of defensive and positive measures relating to the protection of GRs, TK and expressions of folklore. This is a long and all-encompassive agenda for a regime. The views, however, have been expressed against a single, all-encompassing *sui generis* regime of protection for TK which may be too specific and not flexible enough to accommodate local needs. These views notwithstanding, the demand for a *sui generis* system is strong enough to be dismissed, and the latest working draft of the IGC on TK has delineated the nature and scope of such a regime, and will be adopted ultimately in the form of a treaty – a long-standing demand of developing countries.

The discussions at the TRIPS Council/WTO have revealed two important demands of the developing countries distinctly, directed mainly to misappropriation of TK:

- First, the call for recognition of the rights of TK holders relating to their TK, and,

- Second, concerns about the unauthorized acquisition by third parties of IPRs over TK.

In this regard, two forms of protection have been developed and applied. These two approaches should be undertaken in a complementary manner –

- Positive protection: giving TK holders the right to take action or seek remedies against certain forms of misuse of TK; and
- Defensive protection: safeguarding against illegitimate IPRs being taken by others over TK subject matters.

In order to give effect to these demands, an international agreement is required and national mechanism needs to be put in place.

- i) patent applicants must disclose the country and source of origin of the biological material and the traditional knowledge; and
- ii) must provide evidence that the prevalent laws and practices of country of origin on prior informed consent and benefit-sharing have been fully respected.

These demands have been accommodated in the IGC draft in Article 3, which in one of the alternatives states:

- 3.1 The beneficiaries of protected traditional knowledge, shall/should have adequate and effective legal means/measures to exercise control and exploit their traditional knowledge, to authorize the access and use of their traditional knowledge, to have a fair and equitable share of benefit arising out of the use of their traditional knowledge and to prevent any unauthorized disclosure, use, or other exploitation and in particular any acquisitions, appropriation, or use that fails to meet the prior and informed consent of the traditional knowledge holders or infringes the mutually agreed terms.
- 3.2 In respect of traditional knowledge there should/shall be measures to require that those using traditional knowledge beyond its traditional context:
 - a) acknowledge the source of traditional knowledge and attribute the traditional knowledge holder where known, unless the traditional knowledge holders decide otherwise; and
 - b) use traditional knowledge in manner that respect the cultural norms and practices of its holders.

It is for the country concerned to take measures to see that these obligations are properly met.

14.5 SUMMARY

- Different inter-governmental bodies are seized with the task of adopting a viable mechanism to protect the TK, viz., WIPO, WTO/TRIPS, CBD, FAO and human rights bodies of the United Nations.
- WIPO is actively involved in this matter since 1998. In 2000, it established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), which has since

then held 20 sessions, and hope to be ready with a draft text of treaty on TK during 2012.

- TRIPS Council has focused on the protection of TK under the IP regime. Developing countries demands are centred around the disclosure requirement about the source of biological material and evidence on compliance with the ABS requirements in the patent applications.
- Doha Declaration adopted in 2001 require the TRIPS Council to examine the relationship between the TRIPS Agreement and the Convention on Biological Diversity, and the protection of traditional knowledge and folklore.
- CBD efforts are related to giving effect to Articles 8(j) and 15 of the CBD, particularly on access and benefit sharing out of the use and commercialization of GRs, which has now led to the adoption of Nagoya Protocol.
- Nagoya Protocol lays down the mechanism of access and benefit-sharing arising out of the use of GRs and TK related to that out of their commercialization. Benefit-sharing can be in monetary and non-monetary terms.
- The FAO's International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) requires the protection of farmers rights and protection of traditional knowledge relevant to plant genetic resources for food and agriculture.
- These efforts are not comprehensive and does not cover TK in a comprehensive manner, which requires a *sui generis* framework for its protection. The IGC is currently preparing the final draft of a *sui generis* framework.

14.6 TERMINAL QUESTIONS

- 1) Describe the major features of the ILO Convention and the draft UN Declaration on the Rights of Indigenous Peoples relating to TK.
- 2) What are the principal demands of developing countries on IP protection of TK in the TRIPS deliberations? Describe the mandate of Doha Round on TK.
- 3) What are the essential features of the Nagoya Protocol?
- 4) Why there is a need for *sui generis* framework for the protection of TK?

14.7 ANSWERS AND HINTS

Self Assessment Questions

- 1) The IGC deliberations have resulted in three separate texts- on TK, Traditional Cultural Expressions (TCEs) and Genetic Resources (GRs), which will be negotiated in a single negotiating text. Latest texts contain the draft provisions for an international instrument to protect the TK. Based on the final text of the draft treaty on TK, the WIPO may decide to convene a Diplomatic Conference for its adoption in 2012-2013. The text contains provision of definition, eligibility for protection, scope and duration, beneficiaries, exceptions and limitations, and remedies.

- 2) The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilisation, provide guidelines to parties in drafting their laws and policies on access and benefit-sharing, and contracts and other arrangements under mutually agreed terms in this regard. The Guidelines are voluntary in nature, which the parties may take into account while giving effect to their obligations under the CBD. The Guidelines suggest that Material Transfer Agreements (MTAs) on GRs may include conditions under which the user on accessed GRs may seek IPRs. It emphasizes on the disclosure of the country of origin of GRs in applications for IPRs, and compliance with prior informed consent and the mutually agreed terms on which access to those resources was granted.
- 3) The ITPGRFA is the first international treaty on the protection of farmers' rights and protection of traditional knowledge relevant to plant genetic resources for food and agriculture. It is limited to plant genetic resources (PGRs) for food and agriculture. It does not encourage the IPRs over PGRs and the TK related thereto. It recognizes the rights of farmers and local/indigenous communities, who have been in the centres of origin and diversity, in conserving, improving and making available these resources (Art. 9). It is the responsibility of the national governments to involve them equitably in benefit sharing from the utilisation of PGRs (Art. 9.2(b)), and details the provisions on benefit sharing. The transfer/access to PGRs shall be subject to the multilateral system, according to the terms of standard Material Transfer Agreement (MTA).

Terminal Questions

- 1) Refer to Section 14.3
- 2) Refer to Sub-section 14.3.2
- 3) Refer to Sub-section 14.3.3
- 3) Refer to Section 14.4

14.8 REFERENCES AND SUGGESTED READINGS

- 1) UNCTAD- ICTSD, *Resource Book on TRIPS and Development*, Cambridge University Press, 2005, ch. 21.
- 2) Burton Ong (ed.) *Intellectual Property and Biological Resources*, Marshall Cavendish Academic, 2004, ch. 6.
- 3) Christoph Antons (ed.) *Traditional Knowledge, Traditional Cultural Expressions and Intellectual Property Law in the Asia-Pacific Region*, Wolters Kluwer, 2009.
- 4) S. K. Verma, "Protecting Traditional Knowledge – Is a *Sui Generis* System an Answer?" 7 JWIP 765 (Nov. 2004).

UNIT 15 GLOBAL ISSUES IN THE PROTECTION OF TK

Structure

- 15.1 Introduction
- 15.2 Objectives
- 15.3 Global Issues in the Protection of TK
 - 15.3.1 Definition of TK
 - 15.3.2 Prior Informed Consent (PIC)
 - 15.3.3 Access and Benefit Sharing (ABS)
- 15.4 Tools for Protecting TK
 - 15.4.1 Application of Existing IPRs
 - 15.4.1.1 Copyright
 - 15.4.1.2 Patents
 - 15.4.1.3 Geographical Indications (GIs)
 - 15.4.1.4 Trade Secrets
 - 15.4.1.5 Trademarks/Trade Names
 - 15.4.2 Adaptation of *Sui generis* Regime
- 15.5 Summary
- 15.6 Terminal Questions
- 15.7 Answers and Hints
- 15.8 References and Suggested Readings

15.1 INTRODUCTION

Ever since the Convention on Biological Diversity (CBD) was adopted in 1992 (it currently has 193 parties and it came into force in December, 1993), the protection of TK has become a major issue at the international level. Article 8(j) of the Convention states: "Each Contracting Party shall, as far as possible and as appropriate: subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices." Thus, each contracting party is required to:

- i) respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological resources;
- ii) promote the wider application of such knowledge, innovations and practices with the approval and involvement of their holders; and
- iii) encourage the equitable sharing of benefits arising from the utilisation of such knowledge, innovations and practices.

Increasing instances of bio-piracy made protection of TK an international issue. As the developing countries are the principal holders of TK and the indigenous communities were denied any benefit arising out of the use and commercialization of plant genetic resources (PGRs) and TK associated by the multinational biotechnological firms, developing countries strongly championed for TK's protection at international level. As a result of pressure from developing countries, a number of inter-governmental bodies have been working since the adoption of the CBD to evolve a viable international instrument to protect the TK. The WIPO embarked on adopting a *sui generis* through its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), established in 2000. The subject is also actively on the agenda of the CBD, WTO, FAO, UNCTAD since then. Because of differences among the parties on different vital issues, that have emerged in these negotiations, viz., definition, scope, beneficiaries, mechanism of access and benefit sharing relating to the use and commercialization of GRs¹ and TK associated therewith, the deliberations have not led to any binding international instrument so far, except the Nagoya Protocol, with its limited ambit related to access and benefit sharing arising from the utilisation of GRs. Currently, the IGC is working on the final negotiating text for a *sui generis* regime, which the WIPO General Assembly may take up for adoption in 2013, addressing the contentious issues, which include the definition of TK, prior informed consent (PIC), access and benefit-sharing, and tools for its protection.

15.2 OBJECTIVES

After reading this unit, you should be able to:

- know the contentious issues in according protection to TK in a comprehensive manner;
- why it is necessary to define TK;
- what is the significance of prior informed consent (PIC) and whose consent matters;
- how to ensure access and benefit sharing related to GRs;
- know about the tools of protection under the existing IP regime; and
- how the *sui generis* mode will be more effective in protecting TK.

15.3 GLOBAL ISSUES IN THE PROTECTION OF TK

The deliberations on at different inter-governmental fora have brought to the fore certain contentious issues for adopting an agreed framework on TK. These issues, among others, relate to the definition of TK, a mechanism of access and benefit sharing on TK and an appropriate tool to protect the TK, which may not necessarily be under the existing IPRs.

¹ The CBD defines 'genetic resources' as 'genetic material of actual or potential value', and 'genetic material' as 'any material of plant, animal, microbial or other origin containing functional units of heredity' (Art. 2).

15.3.1 Definition of TK

TK is a very broad term referring to various knowledge systems, encompassing several components, held by traditional communities or to knowledge acquired in a non-systematic way. What characterizes traditional knowledge is the fact that, generally, it is not produced systematically, but in accordance with the individual or collective creators' responses to and interaction with their cultural environment. They embrace different aspects and forms of information's expressions, making it difficult to agree on a legally and scientifically acceptable definition. In addition, traditional knowledge, as representative of cultural values, is generally held collectively. This results from the fact that what can be sometimes perceived as an isolated piece of literature (like a story or a song) or an isolated technical invention (the use of a plant resource to heal wounds, for instance) is actually an element that integrates a vast and mostly coherent complex of beliefs and knowledge, control of which is not in the hands of individuals who use isolated pieces of knowledge, but is vested in the community collectively. Furthermore, most traditional knowledge is transmitted orally from generation to generation and is thus inter-generational, and remains largely undocumented. For these reasons, there is no formally agreed definition of 'traditional knowledge', but the commonly accepted view is that the traditional knowledge comprises the 'knowledge, innovations, and practices of indigenous and local communities accumulated over generations of living in a particular environment., developed from experience gained over centuries and adapted to the local culture and environment, which is transmitted orally from generation to generation. It tends to be collectively owned and takes the form of stories, songs, folklore, proverbs, cultural values, beliefs, rituals, and agricultural practices, including the development of plant species and animal breeds among others'.

This definition encompasses all forms of knowledge – technologies, know-how skills, practices and beliefs – that enable the community to achieve stable livelihoods in their environment. A number of terms are used interchangeably to refer to the concept of TIK, including Indigenous Knowledge (IK), Indigenous Technical Knowledge (ITK), Local Knowledge (LK) and Indigenous Knowledge System (IKS). TK is unique to every culture and society and it is embedded in community practices, institutions, relationships and rituals. IK is considered a part of the local knowledge in the sense that it is rooted in a particular community and situated within broader cultural traditions. It is a set of experiences generated by people living in those communities. TK is based on, and is deeply embedded in local experience and historic reality, and is therefore unique to that specific culture; it also plays an important role in defining the identity of the community. It has developed over the centuries of experimentation on how to adapt to local conditions. It therefore represents all the skills and innovations of a people and embodies the collective wisdom and resourcefulness of the community.

Precisely how the term TK is defined has important implications for the kind and scope of a possible protection regime of TK. It is important for the purposes of establishing the criteria for protection, scope of protection and the beneficiaries. There are several characteristics which are:

- TK consists in innovations, creations and practices originated and used by indigenous and local communities;
- It is inter-generational, transmitted from generation to generation;

- It is transmitted in oral form;
- It is usually held by the community in general;
- It is not static and constantly being evolved, improved and adapted to the changing needs of the users.

Categories of TK could include – agricultural knowledge; scientific knowledge; technical knowledge; ecological knowledge; medical knowledge, including related medicines and remedies; biodiversity related knowledge, expressions of folklore in the form of music, dance, songs, handicrafts, designs, stories and artwork; elements of languages, such as names, geographical indications and symbols; and movable cultural properties. Thus, there are three main items which encompass the general term TK, including TK, genetic resources and traditional cultural expressions/folklore. The attributes listed above are common to all of them, but they have their clear area of thrust, TK is understood as the group of practices acquired by a community through the observation and coexistence with the ecosystem in which it lives. GRs are the existing biological material in a certain ecosystem, that are used, for example, in agriculture and medicine. It may have close connection and co-exist with TK. TCEs are understood as the accumulation of fixed and unfixed cultural expressions of a community, such as artistic works, handicrafts, designs, dances and musical and dramatic performances.

WIPO's IGC had created three working groups on the three substantive themes on the protection of TK, GRs and TCEs, which have come out with draft texts. WIPO's Draft Articles on the Protection of Traditional Knowledge prepared at IWG 2 (WIPO Doc. WIPO/GRTKF/IC/18/7, 17 March 2011) provides a draft definition and the eligibility criteria of protection of TK. A formal definition is yet to be adopted, but broadly it means knowledge resulting from intellectual activity in a traditional context including the know-how, skills, innovations, practices and learning that form part of the traditional knowledge systems of an [indigenous people or local community]. It is dynamic and evolving. It is the result of the intellectual activities in diverse traditional contexts, including knowledge, skills, innovations, practices and teachings in a collective framework of [indigenous peoples and local communities]. It is transmitted from generation to generation in diverse forms and is inalienable, indivisible and imprescriptible; and is intrinsically linked to biodiversity and sustains cultural, social and human diversity embodied in traditional lifestyles.

WIPO Doc. WIPO/GRTKF/IC/18/7

Article 1

Definition of Traditional knowledge

Option 1

1.1 Traditional knowledge means knowledge resulting from intellectual activity in a traditional context including the know-how, skills, innovations, practices and learning that form part of the traditional knowledge systems of an [indigenous people or local community²].

² The term "indigenous people and local community" is used as a place holder. This term will be addressed by the group considering beneficiaries of protection.

Option 2

- 1.1 (a) Traditional knowledge is dynamic and evolving. It is the result of the intellectual activities in diverse traditional contexts, including knowledge, skills, innovations, practices and teachings in a collective framework of [indigenous peoples and local communities];
- (b) Traditional knowledge is part of a collective, ancestral, territorial, spiritual, cultural, intellectual and material heritage;
- (c) Traditional knowledge is transmitted from generation to generation in diverse forms and is inalienable, indivisible and imprescriptible;
- (d) Traditional knowledge is intrinsically linked to biodiversity and sustains cultural, social and human diversity embodied in traditional lifestyles.

Criteria for eligibility for protection of TK is that: it is the unique product of or is distinctively associated with an indigenous people or local communities; collectively generated, preserved and transmitted from generation to generation; is integral to the cultural identity of an indigenous people or local community, that is recognized as the owner through a form of custodian or collective and cultural ownership responsibility. Such a relationship may be established formally or informally by customary practices, laws or protocols. Beneficiaries of protection are holders of traditional knowledge who generate, preserve and transmit knowledge in a traditional or intergenerational context [in accordance with Article 1]. Holders of traditional knowledge include, but are not limited to, indigenous peoples, local communities [and nations]. In sum, it is possible to characterize TK as information which has been developed in ancestral times among indigenous people from generation to generation, and actually is subject to improvement and adaptation, without necessarily being codified, and is primarily collective in nature. It may possess commercial value depending on its potential or actual use.

15.3.2 Prior Informed Consent (PIC)

One of the principal demands of developing countries against unauthorized acquisition of GRs and TK by third parties of intellectual property rights is that their applications for IPRs (patents) must provide evidence on compliance with the country of origin's laws on PIC and benefit sharing. Article 15 of the CBD while recognizes the sovereign rights of States over their natural resources and the authority to determine access to genetic resources rests with the national governments and is subject to national legislation, but Art. 15.3 states, "Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party." Para 7 of Art. 15 states: "Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 ... with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms." Thus, what is at stake is the possibility of detecting commercial gains from the use of genetic resources (GRs), so that countries supplying those resources can demand their

share in the benefits. But Article 15 talks about the prior informed consent of the contracting party providing access to such resources and not of traditional/indigenous communities, the holders of TK. However, the country providing such resources may put a system in place, which may require the involvement and the PIC of the holder/s of the TK. The FAO's International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) recognizes the rights of farmers (without defining who is a farmer) and local/indigenous communities, and imposes responsibility on the national governments to involve them equitably in benefit sharing from the utilisation of PGRs (Art. 9.2(b)). The transfer/access to PGRs shall be subject to the multilateral system, according to the terms of standard Material Transfer Agreement (MTA, Art. 12).

In order to have an international framework on PIC and ABS, the recently adopted Nagoya Protocol, 2010, in Article 6 provides:

Access to Genetic Resources

- 1) In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilisation shall be **subject to the prior informed consent of the Party providing such resources** that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.
- 2) In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.
- 3) Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:
 - a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;
 - b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;
 - c) Provide information on how to apply for prior informed consent;
 - d) Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;
 - e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly;
 - f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and

- g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, *inter alia*:
 - i) A dispute settlement clause;
 - ii) Terms on benefit-sharing, including in relation to intellectual property rights;
 - iii) Terms on subsequent third-party use, if any; and
 - iv) Terms on changes of intent, where applicable.

Article 7 of the protocol specifically talks about the PIC of the indigenous people.

Article 7. Access to Traditional Knowledge Associated with Genetic Resources

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

Thus, even though Article 15.3 of the CBD talks about the PIC of the contracting parties, the Nagoya Protocol requires the PIC or approval and involvement of the indigenous and local communities. In this regard, the governments have to put in place the legislative and administrative machinery in place. For the involvement of the local or indigenous communities, their empowerment is necessary, so that they can meaningfully participate in the negotiation and provide an informed consent. Article 21 of the Protocol talks about the awareness raising in this regard. It provides that "Each Party shall take measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues. Such measures may include, *inter alia*: ... (g) Education and training of users and providers of genetic resources and traditional knowledge associated with genetic resources about their access and benefit-sharing obligations; (h) Involvement of indigenous and local communities and relevant stakeholders in the implementation of this Protocol; and (i) Awareness-raising of community protocols and procedures of indigenous and local communities." Article 22 talks about the capacity-building and capacity development. In support of the implementation of this Protocol, capacity-building and development may address, *inter alia*, the following key areas:

- a) Capacity to implement, and to comply with the obligations of the Protocol;
- b) Capacity to negotiate mutually agreed terms;
- c) Capacity to develop, implement and enforce domestic legislative, administrative or policy measures on access and benefit-sharing; and
- d) Capacity of countries to develop their endogenous research capabilities to add value to their own genetic resources.

Thus, for an effective participation of indigenous communities to giving their informed consent for an access to GRs and TK, their empowered a pre-requisite.

Self Assessment Question

(Spend 3 minutes)

- 1) What is the mandate of CBD on PIC and how it is given effect under the Nagoya Protocol?

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15.3.3 Access and Benefit Sharing (ABS)

Access and benefit-sharing is a thorny issue in the protection of TK. Developing countries, holders of TK, are asking for fair and equitable benefit sharing in return for access to GRs and TK associated therewith. They want that access to *in situ* and *ex situ* genetic resources (GRs) held at CGIAR (Consultative Group on International Agricultural Research) Centres, should be on terms that recognize the contribution made by indigenous communities in developing countries in conserving, improving and making available these resources. Article 15(7) of the CBD, while impressing upon the regulatory framework for the access to GRS, states that access will be accorded with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon **mutually agreed terms (MAT)**. The CBD in 2002, at COP-VI adopted Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilisation, which the parties may use in drafting their laws and policies “on access and benefit-sharing, and contracts and other arrangements under mutually agreed terms for access and benefit sharing”. The Guidelines are voluntary in nature and legally not binding, which the parties may take into account while giving effect to their obligations under the CBD on ABS. They provide some background to the discussion on the practical interaction between the IP system and the CBD. The Guidelines suggest that Material Transfer Agreements (MTAs) on GRs may include conditions under which the user in accessed GRs may seek IPRs, and monetary and non-monetary benefits may include “joint ownership of relevant intellectual property rights according to the degree of contribution”. Parties have been invited “to encourage the disclosure of the country of origin of genetic resources in applications for intellectual property rights, where the subject matter of the application concerns or makes use of genetic resources in its development, as a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resources was granted.” They have further been invited “to encourage the disclosure of the origin of the relevant traditional knowledge, innovations and practices of indigenous and local communities in applications for IPRs.” The guidelines to a great extent address the concerns of developing countries, which have not been rewarded for their contribution. But in contrast to ITPGRFA, which envisages a multilateral system of benefit

sharing, the CBD/Bonn Guidelines are premised on bilateral approach, which may not be fair enough when the parties to an agreement would be unequal.

The recently concluded Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation, 2010 at the COP-X has elaborate provisions on ABS. Article 5 of the Nagoya Protocol also talks about it and the Protocol lays down the framework in this regard.

Article 5. Fair and Equitable Benefit-sharing

- 1) In accordance with Article 15, paragraphs 3 and 7 of the Convention (CBD), benefits arising from the utilisation of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.
- 2) Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilisation of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.
- 3) To implement paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate.
- 4) Benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex.
- 5) Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilisation of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

Annexure to the Protocol enlists the monetary and non-monetary benefits. Monetary benefits may include: access fees; up-front payments; milestone payments; payment of royalties; licence fees in case of commercialization; special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity; salaries and preferential terms where mutually agreed; research funding; joint ventures; joint ownership of relevant intellectual property rights. Non-monetary benefits may include, among others: sharing of research and development results; strengthening capacities for technology transfer; institutional capacity-building; access to scientific information relevant to conservation and sustainable use of biological diversity, food and livelihood security benefits; social recognition; (q) joint ownership of relevant intellectual property rights.

However, question of benefit sharing arises only after the GRs and the TK associated with that have been commercially utilised. Art. 3 of the Protocol

provides, "This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilisation of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilisation of such knowledge." If the TK does not lead to any benefit, there will be no benefit sharing.

The protocol is in the nature of a treaty and once it is ratified by 50 States, it will be binding on the parties.

Self Assessment Question

(Spend 3 minutes)

2) What is the mandate of Nagoya Protocol on ABS?

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15.4 TOOLS FOR PROTECTING TK

In choosing the tools for the protection of TK, two approaches are looked into by the proponents of the TK protection – positive protection and defensive protection. Positive protection requires legal recognition of rights over TK, either under existing IPR regime or *sui generis* regime. Defensive protection is aimed at safeguarding against illegitimate IPRs, particularly patents, being taken by others over TK subject matter. Systems for protecting TK include customary law, IPRs such as patents, plant variety rights, copyrights, etc. and concepts existing in civil and common law systems and contracts such as licensing and material transfer agreements. Protection to TK is also being provided through *sui generis* systems such as through bio-diversity related regulations such as access and benefit sharing regimes or a conservation framework legislation or a combination of all the above systems. None of them is comprehensive enough and have its own limitations.

15.4.1 Application of Existing IPRs

15.4.1.1 Copyright

Copyright has its relevance in the realm of TCEs/folklores, such as artistic works, handicrafts, designs, dances, and musical and dramatic performances. Its protection is on the agenda of the IGC. A group of countries from Latin America and the Caribbean considers that copyright can be used to protect the artistic manifestations of TK holders, especially artists who belong to indigenous and native communities, against unauthorized reproduction and exploitation. However, copyright has some fundamental limitations in the folklore context, since it excludes some expressions from eligibility for copyright protection, such as

- copyright requires an identifiable author, which is a problematic concept in case of TCEs;

Protection of Traditional Knowledge

- copyright gives protection for a limited period of time and some communities do not want their knowledge to be released in public domain which may be appropriated by others;
- copyright normally requires works to be fixed, whereas most TCEs are not fixed and passed on orally from generation to generation.

15.4.1.2 Patents

The patent system could be used for the protection of technical solutions that are industrially applicable, new and involve an inventive step. For example, patents may be granted for products isolated, synthesized or developed from genetic structure, micro-organisms and organisms existing in nature. Patents may be granted to protect some elements of traditional medicine. However, there are some major difficulties in affording patent protection to an invention based on TK, viz.:

- TK is collectively held and generated while patent law treats invention as an achievement of individuals. In the context of TK, it is difficult to identify unequivocally the inventor;
- Patent specification must be written in a technical language that examiners can understand, and it is difficult to do so with the TK;
- Applying for patents, maintaining and enforcing them once they have been granted is an expensive affair. This may not be possible for traditional communities to do so on their own.

15.4.1.3 Geographical Indications (GIs)

GIs may, in some cases, be a suitable means to enhance the value of agricultural products, handicrafts and other TK based products. GIs do not protect a specific technology or knowledge as such, but only prevent the false use of the GI and thus its scope in protection TK is very limited. They may be used to enhance the commercial value of natural, traditional and craft products, if their particular characteristics can be attributed to their geographical origin, resulting from the traditional processes and knowledge of certain communities in the given region. GIs, if exploited effectively, may afford better protection of the economic interests of the communities and regions from where such products originate.

15.4.1.4 Trade Secrets

Trade secrets are used to protect un-disclosed TK, including secret and sacred TK. Under this modality, all information is protected against unauthorized acquisition or use by third parties. In many traditional societies, it is common for some healers or shamans to protect their knowledge through secrecy they do not want to share. The protection of the trade secret is the responsibility of the holder of the secret, and knowledge should be confidential. As the knowledge of the community is diffused among the various members of a community, it is difficult to gain protection of TK through this method, unless it is kept secret by one person, as is the case of healers, then the system can work to protect TK.

15.4.1.5 Trademarks/Trade Names

Trademarks may be used to protect signs or symbols of commercial interest for local and indigenous communities. They may protect all goods manufactured and services offered by manufacturers, craftsmen, professional and traders in local and indigenous communities. Similarly, trade names may protect any manufacturer, craftsman, professional person or trader in a native or indigenous community, and may also be used to identify the bodies that represent such persons or in which they are grouped.

In conclusion, taking into account the reality of these communities, whether IPRs exist or not, indigenous communities are likely to face serious challenges in the process of acquiring, maintaining, and enforcing these rights, while protecting their TK. These may discourage them to take advantage of these rights.

Self Assessment Question

(Spend 3 minutes)

3) Why patents are not a satisfactory mode of protection of TK?

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15.4.2 Adaptation of *Sui generis* Regime

As is evident that the existing IPR regime is not sufficient to protect the holistic character of TK and it merely provides piecemeal positive protection. Intellectual property role, in the context of TK is limited, as it is aimed at excluding the use of protected knowledge by unauthorised parties, and is not concerned with its promotion or diffusion, the goals which are fundamental for the sustainability of TK. IPRs function on exclusivity and are limited in time, held by an identifiable natural or legal person. At the end of protection period, they become part of the public domain. On the other hand, TK is held collectively (ownership), inherently dynamic, which grows/alters in response to changing environmental and social circumstances, while being in continuity with land and habitat, and mostly exists in an unfixd form (oral). It originates, preserved and transmitted in a traditional context and is not limited to any specific field of technology or arts. The enforcement of IPRs requires to identify and isolate the protected information while the challenging aspect of TK is its holistic character. Hence, it is necessary to clarify the identifiable subject matter of TK in any international regime.

The WIPO's approach in the matter of TK protection is mainly IP-related. The documents produced acknowledge the general difficulties with protecting the TK under IP law. The IGC has centred its activities mainly on solutions that tend to minimize the rigours of IP criteria. The IP solution is sought for TK in the public domain, which is a small part of the vast arena of TK that has strong moorings in cultures and traditions/rituals etc. The issues of access and benefit-sharing, prior informed consent, bio-piracy and misappropriation of TK, need to harness TK for the economic upliftment and growth of indigenous communities and

their empowerment are significant aspects to be considered in any mechanism to protect TK. This can be possible only through a *sui generis* regime.

A number of countries like Brazil, Costa Rica, India, Peru, Philippines, Andean Community (Bolivia, Colombia, Ecuador, Peru and Venezuela), some African initiatives (based on model OAU Law) are either providing or propose to provide protection to TK through a combination of various systems, including *sui generis* systems. These legislation contain provisions for prior informed consent, benefit sharing, some restrictions on applying for IPRs based on biological resources and associated TK without PIC and protection through various other means like registration of TK, systems of contract, recognition of customary laws, etc. However, the actual measures provided or proposed are different in each country. There is no uniformity in the provisions and each country's legislation is developed based on the specific requirements of individual country and its communities, their lifestyles and types of traditional knowledge and the way it is being protected or held by the traditional communities and the way it is being accessed for modern scientific purposes. It is very clear that a uniform international system for protection of TK would not be able to cater to the requirements of individual country. Rather, the need is for a system which recognizes such diversity, while at the same time lays down common norms for the protection of TK for all countries. At the national level also, to have a *sui generis* system, the first step is to assess the current TK-related situation in the country, including, for example, determining the main types of TK, who the TK-holders are, how the TK is being used, what are the current policies and institutional frameworks, and who are the main stakeholders and interested parties. The next step could be to have a national multi-stakeholder policy dialogue (with full participation by TK holders) in order to share the assessment findings and discuss the objectives that a national *sui generis* system should address. For each of three broad categories of TK-related objectives – preservation, protection and promotion (harnessing TK for development) – there are a number of possible policy tools and measures. Possible instruments for the protection of TK include traditional/customary law, modern intellectual property rights instruments, *sui generis* systems, documentation of TK, and instruments directly linked to benefit-sharing. This non-exhaustive menu of options is intended to serve as a starting point for further exploration and discussion. A holistic approach to the problem is essential.

Any regime to be effective must have a viable enforcement mechanism without which it will not meet with the desired objectives. There should be a monitoring system to see its implementation in the form as laid down. The enforcement of TK is closely related to the issues of identifying the stakeholders, how the right will accrue and who will be competent to enforce the right. In the case of IPRs, the protected information is also to be identified. The national legislations need to address these aspects to make the system exact. This will require the determination of the objectives to be achieved through the protection of TK for which a proper definition of TK would have to be attempted. All these aspects together will require a human- right- centric approach.

The concerns of local/traditional communities on this matter can be addressed under a *sui generis* regime on plant varieties in an appropriate manner, while according access to genetic resources, as mandated by the CBD. It has been observed that access regimes created by some developing countries have proved to be very restrictive, at the cost of genuine research, which may prove to be

detrimental to national interests.² The national regime must provide a distinct approach to facilitate the access to genetic resources for purely commercial purposes and that for scientific purposes for further research and development in this field. The procedure needs to be transparent and less cumbersome for genuine parties. A distinct authority be designated to grant permission to researchers to access and remove biological specimens. The involvement of local/traditional communities must be ensured in decision-making in the matter of access and sharing of benefits arising out of the use of their TK in genetic resources.

The IGC's current deliberations/texts are confined to a *sui generis* regime on TK and have the negotiated text on the definition, eligibility, scope, term and beneficiaries of TK protection. It has the provisions related to sanctions, remedies and administration of TK, but it relates to TK in the public domain.

15.5 SUMMARY

- Since the adoption of CBD, the protection of TK has become an international issue and different inter-governmental bodies are working towards this end, including the WTO/TRIPs, CBD and WIPO. The deliberations at these bodies have highlighted certain contentious issues on which developed and developing countries hold different approach.
- These issues mainly centred on the definition, prior informed consent and mechanism for access and benefit sharing.
- Definition is crucial to identify the subject matter of protection, eligibility and scope of protection, beneficiaries of the protection and their capability to enforce their rights related to protected TK.
- Developing countries demand that any application for IPR related to TK subject matter should provide evidence of PIC and ABS as mandated under national law of the provider country.
- The IGC's latest negotiating draft on TK has provision in this regard.
- So far the approach of inter-governmental bodies in the protection of TK is lop-sided and is confined to positive protection in the context of IPRs, such as copyright, patents, trade secrets, geographical indications, and trade marks
- Existing IPR regime is of limited utility in the protection of TK and is not very useful for indigenous community, who do not have means to acquire, maintain and enforce those rights. IPR regime also does not cover TK in a holistic manner, which has cultural, environmental and national food security aspects.
- A *sui generis* regime, which should take into account the specific features of TK, viz., collectively owned, inter-generational, continuous improvement, infinite duration etc., will be best suited
- Under a *sui generis* regime, countries shall be able to cater the specific needs of their indigenous communities.

² See Heath and Weidlich, *op. cit.* 61, at 83; Jose Maria A. Ochoa, *The Anticommons in Bioprospecting: Regulation of Access to Genetic and Biological Materials in the Philippines*, *The World Bulletin*, Vol. 15, Nos. 1-6, Jan. -Dec. 1999, 150, at 157; C. Fowler, "Sharing Agriculture's Genetic Bounty", *Science* 297 (2002: 157).

15.6 TERMINAL QUESTIONS

- 1) Describe the contentious issues in the protection of TK. What is the significance of definition for the protection?
- 2) What are the principal tools of protection for TK? Describe the shortcomings of existing IPR regime in the protection of TK.
- 3) Why a *sui generis* regime will be better suited for the protection of TK and what should be its salient features?

15.7 ANSWERS AND HINTS

Self Assessment Questions

- 1) Article 15 of the CBD recognizes the sovereign rights of States over their natural resources and the authority to determine access to genetic resources rests under their national law. But the access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party (Art. 15.3). The Nagoya protocol reiterates this and provides that each Party shall take measures in accordance with domestic law for access to GRs and TK with the prior and informed consent or approval and involvement of their indigenous and local communities.
- 2) Article 3 of the Nagoya Protocol provides that in accordance with Article 15, paragraphs 3 and 7 of the Convention (CBD), benefits arising from the utilisation of GRs as well as their subsequent applications and commercialization shall be shared in a fair and equitable way with the Party that is the country of origin of such resources and providing such resources or a Party that has acquired the GRs in accordance with the Convention. Such sharing shall be upon mutually agreed terms. If the TK does not lead to any benefit, there will be no benefit sharing. Benefits may be in the form of monetary and non-monetary terms.
- 3) Patents are granted for any technical invention industrially applicable, new and involve an inventive step. For example, patents may be granted for products isolated, synthesized or developed from genetic structure, micro-organisms and organisms existing in nature. Patents may be granted to protect some elements of traditional medicine. But, in the case of TK, patent protection may not be affordable, because TK is collectively held and generated while patent law treats invention as an achievement of individuals. For TK, it is difficult to identify unequivocally the inventor; it is difficult to write patent specification for TK in technical language; and applying, maintaining and enforcing a patent is an expensive proposition, which these indigenous communities may not be able to do.

Terminal Questions

- 1) Refer to Section 15.3
- 2) Refer to Section 15.4
- 3) Refer to Sub-section 15.4.2

15.8 REFERENCES AND SUGGESTED READINGS

- 1) UNCTAD- ICTSD, *Resource Book on TRIPS and Development*, Cambridge University Press, 2005, ch. 21
- 2) Burton Ong (ed.) *Intellectual Property and Biological Resources*, Marshall Cavendish Academic, 2004, ch. 6
- 3) Christoph Antons (ed.) *Traditional Knowledge, Traditional Cultural Expressions and Intellectual Property Law, in the Asia-Pacific Region*, Wolters Kluwer, 2009
- 4) S. K. Verma, "Protecting Traditional Knowledge – Is a *Sui Generis* System an Answer?" 7 JWIP 765 (Nov. 2004).
- 5) Marcelin M. Tonye, "Sui Generis Systems for the Legal Protection of Traditional Knowledge and Biogenetic Resources in Cameroon and South Africa", 6 JWIP 763 (Sept:2003).

UNIT 16 INDIAN EFFORTS TOWARDS TK PROTECTION

Structure

- 16.1 Introduction
- 16.2 Objectives
- 16.3 India's Efforts for the Protection of TK
 - 16.3.1 Patents Act
 - 16.3.2 Protection of Plant Varieties and Farmers' Rights Act
 - 16.3.3 Biological Diversity Act
 - 16.3.3.1 Draft Rules on TK, 2009
- 16.4 Traditional Knowledge Digital Library (TKDL)
- 16.5 Summary
- 16.6 Terminal Questions
- 16.7 Answers and Hints
- 16.8 References and Suggested Readings

16.1 INTRODUCTION

India is one of the 12 mega-biodiversity countries of the world and rich in traditional and indigenous knowledge, both coded and informal. It has not brought out any TK-specific regime so far. It is a party to the TRIPS Agreement, CBD and Plant Genetic Resources for Food and Agriculture (PGRFA 2001) Treaty. The laws adopted to give effect to its obligations under the TRIPS, CBD and ITPGRFA have reiterated India's stand in different intergovernmental bodies working on the protection of TK. Issue of bio-piracy is central to all the legislative efforts of the Government of India. It has adopted three statutes relevant to the issue of TK and biological resources, which are in force and are as follows:

- Patents (Amendment) Act, 2005;
- The Protection of Plant Varieties and Farmers' Rights Act, 2001; and
- The Biological Diversity Act, 2002.

There are strong linkages between these three pieces of legislation and some over-lapping. Whereas the Patents Act grants patents on biotechnology, the Plant Variety Protection law provides a *sui generis* regime on plant breeder's rights (PBRs) and the Biological Diversity Act provides a mechanism to protect and share plant genetic resources (PGRs). In December 2009, the Government of India framed 'The Protection, Conservation and Effective Management of Traditional Knowledge relating to Biological Diversity Rules, 2009' and sought the comments of the public, primarily to evolve a *sui generis* system for the protection of TK in India. The draft Rules are still being deliberated.

16.2 OBJECTIVES

After reading this unit, you should be able to:

- know India's position on the protection of TK and the national efforts made in this direction;
- identify the principal provisions of the Patents Act related to protection of TK;
- know the role of Protection of Plant Varieties and Farmers' Rights Act (PPVFRA) and the extent of involvement of indigenous communities in the protection of TK;
- find out the extent and scope of Biological Diversity Act in the protection of TK related to GRs originating in India and the compliance with the provisions of CBD on TK;
- significance of the draft Rules, 2009 on the protection, conservation and management of TK; and
- explain the position of India after the adoption of Nagoya Protocol to which India is a signatory (not yet ratified).

16.3 INDIA'S EFFORTS FOR THE PROTECTION OF TK

16.3.1 Patents Act

The Patents (Amendment) Act, 2005 has made biotechnological processes as patentable. The amended Act had changed the earlier position, wherein under Section 5 of the 1970 Patents Act only methods or processes of manufacture were patentable. In the 2005 amendment to the Patents Act of 1970, this provision has been dropped in compliance with India's obligation under Article 65(4) of the TRIPS Agreement. It makes biological processes as patentable, including biochemical, biotechnological and microbiological processes. Plants and animals in whole or any part thereof are not patentable, including seeds, varieties and species and essentially biological processes for the propagation of plants and animals, but micro-organisms are made patentable (Section 3(j)). An invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component/s is also non-patentable (Section 3 (p)). The traditional Indian forms of medicines are thus out of its purview.

The Act makes it mandatory for patent applicants to disclose in the patent application the source of origin of the biological material and associated knowledge used in the invention (Section 10.4(d)(D)). It also allows opposition to a patent application for a patent due to the failure of an applicant to disclose or wrongly mention in the specification the source of origin of the biological material for the invention. Section 25(1)(h), (j) and (k) further provide that failure to disclose to the Controller any information required under the Act as provided in Section 8 (which deals in information and undertaking regarding foreign applications) or the complete specifications, or to provide the wrong

source of the geographical origin of the biological material used for the invention, or knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere, can be grounds for opposition to a grant of patent.

The Act also incorporates provisions for the protection of biodiversity and traditional knowledge by refusing to grant patent or revoke a patent if the application wrongfully mentions the source of geographical origin of biological material, or the invention claimed was related to TK oral or otherwise, of any local or indigenous community in India or otherwise (Section 64(p) & (q)). This measure is taken to protect folklore or knowledge belonging to local or indigenous community of any country. This provision is in line with the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation (adopted by the Conference of Parties to the Convention on Biodiversity, 2002), Para. 16(d)(ii), suggesting Parties to adopt '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'.

16.3.2 Protection of Plant Varieties and Farmers' Rights Act (PPVFR Act), 2001

The PPVFR Act though not directly related to protection of TK, has important provisions on benefit sharing and farmers' rights. The plant varieties, which are not patentable under the Patents (Amendment) Act, are specifically dealt with under the PPVFR Act. The main focus of the Act is on defining plant breeder's rights (PBRs). The Act is extended to all categories of plants, excluding micro-organisms (which are patentable). The Act is primarily based on the UPOV Convention, providing a *sui generis* regime for PBRs, but it includes a number of provisions, not present in the UPOV Convention. For instance, it recognizes the role of farmers as cultivators and conservers, and the contribution of traditional, rural and tribal communities in the country's agro-biodiversity by making provision for benefit sharing and compensation, and also protecting the traditional rights of the farmers (Section 39 and 41).

The Act creates a regulating body – the Protection of Plant Varieties and Farmers' Rights Protection Authority (the Authority), which is empowered to (among other things) determine the applicable benefit sharing (Section 3 and 26). Benefit sharing is meant to provide individuals or groups with the possibility of receiving financial compensation when a protected variety is developed. The Authority, while determining the amount of financial compensation, will take into account whether the variety is extant and nature of the use of the genetic material of the claimant in the development of the variety; and the commercial utility of and demand in the market for the variety so developed (Section 26). The Act also provides for a National Gene Fund (the Fund), to which the amount accruing from the benefit sharing will be credited. The amount collected in the Fund shall be utilised for the payment of benefits to the claimant, compensation to the village community for exploitation of their variety, for conservation and sustainable use of genetic resources, and purposes as defined in the Act (Section 45). To give effect to the rights of village or local communities and for benefit sharing, the Central Government may devise one or more schemes as provided in the Act (Section 46).

Chapter VI of the Act is devoted to farmers' rights, which protect the traditional rights of farmers to save, use, exchange, share or sell their farm produce of a protected variety, which is in line with Article 15(2) of the 1991 Act of the UPOV Convention. However, the farmer is not entitled to sell branded seed. It also acknowledges the rights of a farmer to register a new variety, bred or developed by him/her, and accords him/her (the farmer) protection like any other breeder under the Act (Section 39). A farmer who is engaged in the conservation of GR of land races and wild relatives of economic plants and their improvement through selection and preservation is entitled to recognition and reward from the Fund. The Act also recognizes the rights of the communities, and, once their contribution is quantified, they will be entitled to compensation from the Fund. The Act only talks about the compensation to the community if their contribution in the evolution of a variety is verified and accepted, but it falls short of granting them any proprietary right. It allows communities to file claims for their contribution to the development of a protected variety (Section 41).

The registration of a variety is not allowed in cases where prevention of commercial exploitation of such variety is necessary to protect public order or public morality or human, animal or plant life and health or to avoid serious prejudice to the environment (Section 29). The Central Government can exclude any genera or species from the purview of protection in public interest. The Act makes provisions for compulsory license of protected varieties in the public interest if the right-holder does not arrange for the production and sale of seeds. This ensures that the protected seeds are available to the farmers (chapter VII). In line with the patent law, the PPVFR Act provides that the Authority shall determine the duration of the license (which may vary from case to case), terms and conditions of the license, viz. royalty and other remuneration to the breeder of the variety, and ensure that the compulsory licensee of such variety possesses the adequate means to provide to the farmers the seeds or its propagating material at reasonable market price (Sections 48-51). The provisions on benefit sharing and compensation will be subject to the rules, guidelines and schemes framed by the Central Government and the Authority.

Self Assessment Question

(Spend 3 minutes)

- 1) Discuss the role of the Protection of Plant Varieties and Farmers' Rights Protection Authority in the protection of benefit sharing.

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16.3.3 Biological Diversity Act

The Biological Diversity Act, 2002, gives effect to the mandate of CBD and, to some extent, to the Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA). It addresses the issues which are relevant to biodiversity management in general and PGRs management in specific. The Act is more explicit in its approach towards TK. It contains elaborate provisions on benefit sharing but is weak in relation to PIC and the involvement of communities in decision-making.

The main focus of the Act is to regulate access to GRs and associated traditional knowledge by foreign individuals, institutions or companies with the purpose of securing equitable sharing of benefits arising out of the use of these resources with the local people, who are conservers of biological resources and holders of knowledge and information relating to the use of these resources, and to protect knowledge of local communities related to biodiversity. On benefit sharing, the Act takes into account the Bonn Guidelines (Section 21). The different provisions of the Act address the problem of bio-piracy. However no definition of 'TK' or 'community' has been attempted.

The main focus of the Act is to regulate access to GR and associated knowledge by foreign individuals, institutions or companies with the purpose of securing equitable sharing of benefits arising out of the use of these resources with the local people (who are the conservers of biological resources and holders of knowledge and information relating to the use of these resources), and to protect knowledge of local communities related to biodiversity. For this purpose, the Act has created the National Biodiversity Authority (NBA) at the national level, and the State Biodiversity Boards and Biodiversity Management Committees at the state and local levels respectively (Section 8, 22 and 41). The NBA is the apex body to oversee the implementation of the Act, and issue guidelines for access to and equitable benefit sharing from GRs (Section 18). The Act also proposes to set-up Biodiversity Funds at central, state and local levels – known as the National Biodiversity Fund, the State Biodiversity Fund, and Local Biodiversity Fund respectively. The proceeds from the National Biodiversity Fund will be used to channel benefits to benefit claimers, and for conservation and promotion of biological resources and for the socio-economic development of areas from where the resources have been accessed; such socio-economic development to be done in consultation with the local bodies concerned (Section 27).

Traditional knowledge of people related to biodiversity shall be respected and protected by the Government, through such measures as recommended by the NBA. These may include registration of such knowledge at the local, state or national levels, and other measures of protection, including a *sui generis* system for possible IP protection (Section 36(5)). The state governments will notify National Heritage Sites (which are important from the biodiversity standpoint), in consultation with institutions of local self-government, in order to identify and monitor areas rich in biological resources, and for *in-situ* and *ex-situ* conservation of biological resources (Section 37).

To address the problem of bio-piracy, the Act has elaborate provisions to grant access to biological resources by non-resident Indians, foreign individuals, companies or associations, or local companies or associations with non-Indian shareholders or management who cannot obtain any biological resources occurring in India or knowledge associated thereto for research or for commercial utilisation or for bio-survey and bio-utilisation without the prior approval of the NBA (Section 3). Similarly the research results relating to biological resources occurring in or obtained from India cannot be transferred for monetary consideration without the approval of the NBA. However, publication of research papers or dissemination of knowledge through seminars or workshops is exempted provided such publications conform to the policy guidelines of the Central Government (Section 84). Similarly, collaborative research projects involving transfer or exchange of biological resources or related information

between institutions, including government sponsored institutions, are exempted from these obligations, if such transfer or exchange conforms to these guidelines.

A foreign or other party referred to in the Act under Section 3(2), if intending to obtain any biological resources occurring in India or knowledge associated thereto for research or for commercial utilisation or for bio-survey and bio-utilisation or transfer of results of any research relating to biological resources occurring in or obtained from India, is required to obtain prior approval from the NBA after making an application and on payment of a prescribed fee (Section 19). A person, who has been granted approval, cannot transfer any biological resources or knowledge associated thereto without the permission of the NBA (Section 20).

The Act creates a system of benefit sharing for TK holders. In this regard, the NBA is empowered (among other responsibilities) to frame guidelines on ABS (Section 18). The NBA, while granting approval, shall ensure equitable sharing of benefits on mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit-claimers (Section 21(1)). The NBA will consult the local bodies to ensure the equitable sharing of benefits. Forms/modes of benefit sharing are elaborated under Section 21. Such benefit sharing can be in monetary and non-monetary terms, such as a royalty, joint ventures, technology transfer, product development, education and awareness raising activities, institutional capacity building and venture capital funds, and the Act also envisages joint ownership of IPRs with the NBA or with identified claimers (Rule 20, 2004 Rules). Five per cent of the assessed monetary benefits will be earmarked for the NBA or the local Board towards administrative and service charges (Rule 20, para. 9). In the matter of IPR, the Act is very stringent. It requires that an inventor seeking any kind of IPR in or outside India for any invention based on any biological research or information on a biological resource obtained from India, obtain prior permission of the NBA. In case a person applies for a patent, prior permission of the NBA is required after the acceptance of the patent but before the sealing of the patent by the concerned patent authority. Further, the NBA, while granting the approval, may impose benefit-sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising from the commercial utilisation of such rights. But this provision will not be applicable to a person making an application for any rights under the plant variety protection legislation (Section 6). The NBA is also empowered to take necessary measures to oppose the grant in any country outside India of IPRs on any biological resource or associated knowledge derived/obtained from India (Section 18(4)). But this scheme has an interface with the Patents Act if the patent is sought in India. It is doubtful whether the Act will have extra-territorial jurisdiction in this regard.

State Biodiversity Boards will deal with matters relating to access by Indians to GR for commercial purposes and restrict any activity that is contrary to the objectives of conservation, sustainable use and equitable sharing of benefits. However, the local people and communities of the area, including those who have been practising indigenous medicine, will not be subjected to the rigours of the Act (Section 7). Any contravention of these provisions is an offence which is punishable with fine or imprisonment or both (Section 55, para. 2). The functions of the Biodiversity Management Committees are related to conservation, sustainable use and documentation of biodiversity at the local level, in order to

monitor and protect bio-resources to curb biopiracy and effectively challenge the IPRs granted wrongfully in foreign jurisdictions (Section 41). Though the State Biodiversity Boards and the Biodiversity Management Committees will monitor and protect the bio-resources at their levels and will be consulted in facilitating access to those resources, the final decision in this regard lies with the NBA.

It is, however, noticeable that on benefit sharing, separate bodies have been constituted under the PPVFR Act and under the Biological Diversity Act. These have similar functions, related to similar activities that are access to GR and traditional knowledge. But the Biodiversity Act focuses mainly on biopiracy and benefit sharing and does not provide any mechanism to check the impact of monoculture on biodiversity, generated by the introduction of IPRs in biotechnology, nor does the PPVFR Act address this issue. In benefit sharing, fine tuning needs to be done. The amount of royalty, based on some agreed formula, transfer of technology tools – with or without patent or *sui generis* system protection, training of the local scientists community, the other monetary benefits and so forth, require a clear understanding. It is, however, doubtful whether the provision on joint ownership of IPRs, incorporated in Section 21, will be acceptable to private multinational companies in the business of biotechnology unless there are clearly perceptible advantages to the technology-holder or the IPR pertains to orphan and neglected crop, which does not hold much value for the technology-holder. Furthermore, no machinery has been provided for dispute resolution on ABS.

The idea of a Fund under the Act in fact makes it evident that creators and holders of knowledge do not have proprietary rights to their knowledge. Their only reward is a potential financial contribution from this Fund to be decided by higher authorities. However, it is not clear whether the reward will be in the form of only monetary benefits or also be in kind. There are also a few other pertinent questions, such as whether the benefit (monetary/non-monetary) is to be a 'one-time' payment or a continuous process, for their contributions towards the future activities of conservation and cultivation of GRs? As most of the TK holders are resource-poor, often landless farm labourers, the reward in the form of land would help improve their condition as well as assist the protection of the environment and the conservation and cultivation of GRs, along with the protection of TK, which normally has close connection with the land. The Act also does not recognize the biodiversity related community IPRs. The provision for such a right could have been made under a *sui generis* system like that of the PPVFR Act, as a patent system is inherently incapable of doing so. The grant of specific IPR to the community, which is monopolistic in nature, will also be fraught with certain administrative and legal problems, particularly in its ambit and enforceability. Moreover, in the case of patents, it is doubtful whether the local communities will be able to withstand the challenges from formal breeders, who are well-equipped to defend their rights.

The issues of the mode of benefit sharing and the probable stakeholders, on the other hand, are fraught with many problems as is evident in the case of *Arogyapaacha (trichopus zeylanicus travancoricus)* experiment which resulted into an immune-enhancing, anti-stress and anti-fatigue drug Jeevani on the knowledge provided by Kani tribe of Kerala related to the plant. The scientists working with the Government of Kerala's Tropical Botanical Garden and Research Institute (TBGRI) helped to develop the drug from the active

ingredients of the plant. The rights to manufacture Jeevani was transferred to a private manufacturer, the Arya Vaidya Pharmacy (Coimbatore) Ltd. for a license fee of Rupees ten lakhs for 7 years and a 2% royalty on sales. The TBGRI decided to give 50% of the fee and royalty to the Kanis. Involving numerous stakeholders (including the Kerala's Forest Department as the plant was grown only in protected area), the benefit-sharing deal became very controversial. Once the product became commercially viable, the problem of over-extraction of the plant also came to light, raising concerns for its sustainable extraction from its natural habitat. Scientists also realized that without IP protection, the drug would not generate enough revenue by mere licensing.

This case, however, has highlighted the potential of GRs and associated TK as well as the role of indigenous and local communities in their beneficial use, which has also helped in the improvement and development of the indigenous communities. Effective protection through IPR is, nevertheless, a necessary condition for generating funds, which will be subject to benefit sharing. But other measures are also required to supplement the IPRs in order to ensure equitable benefit sharing, such as identifying the stakeholders and defining their role, ensuring the sustainable extraction of the bio-resources, acknowledging the local informants in the patent applications, modes of benefit sharing and so forth.

The Biological Diversity Act outlines the framework of benefit sharing, mainly when the foreign party is involved (whether seeking or granted access to genetic resources), but does not deal adequately with a case similar to *Arogyapaacha*, where the stakeholders are entirely local or Indian citizens.

16.3.3.1 Draft Rules on TK, 2009

Under the Biological Diversity Act (Sections 36(5) and 62), the Government of India is required to frame guidelines/rules on the protection of TK relating to biological diversity and benefit sharing. In December 2009, on the recommendation of the NBA, the government brought out 'The Protection, Conservation and Effective Management of Traditional Knowledge relating to Biological Diversity Rules, 2009'. The Rules are aimed to establish an access and benefit sharing regime which will be based on the principles of prior-informed consent of the community holding the traditional knowledge in question. The Rules define TK and Traditional Community. TK is defined as "*the collective knowledge of a traditional community including of a group of families, on a particular subject or a skill and passed down from generation to generation, either orally or in written form, relating to properties, uses and characteristics of plant and animal genetic resources; agricultural and healthcare practices, food preservation and processing techniques and devices developed from traditional materials; cultural expressions, products and practices such as weaving patterns, colors, dyes, pottery, painting, poetry, folklore, dance and music; and all other products or processes discovered through a community process including by a member of the community individually but for the common use of the community*". The definition is very broad which goes beyond the mandate of the Biological Diversity Act, confined to biological resources only. "Traditional Community" means a community holding the TK. Similarly, "prior informed consent" is defined as a written authorisation given by the traditional community to an applicant in the prescribed manner. NBA to oversee the rights of the traditional communities (TCs), allowing them to exercise their rights.

In the absence of any representing body of the community, NBA, through State Biodiversity Boards (SBBs) and Biodiversity Management Committee (BMC) will help communities to set up representative body. NBA has the ultimate authority to prevent abuse/misuse/misappropriation of TK, and shall institute legal proceedings. NBA is to maintain a TK Register for registration of TK. All details about the TK – name, location, description of TK, revealed by the traditional community, will be entered in the Register, or by *suo motu* efforts of the NBA, SBB, BMC with the permission of the traditional community. The permission of the traditional community is not needed if the TK is already in the public domain. TK has to be marked 'PUBLIC' or 'CONFIDENTIAL'. Details about the accessor of TK shall also be entered into the register. All existing/future databases shall be part of the register. If TK is not registered, no application for access will be allowed; if already accessed, then the accessor must approach appropriate bodies. For seeking permission for access, an application, in prescribed form is to be made to the NBA.

Before access is granted, provision has been made for National/State Standing Committees (SSCs) to advise on the viability of the application to advise NBA/SBB. The SBB to obtain the informed consent from the community in whose name TK is registered through the BMC. If communities are from three or more state, then the NBA has to obtain informed consent. Upon receiving the willingness of the traditional communities to participate in negotiation, the matter is to be referred to the SSC, which will assess the sustainability of the resources and other implications. Based on the report, the SBB has to facilitate consultations among the applicant, traditional community and BMC. Once the consensus emerges, then the SBB will set the terms and conditions for access, use and benefit sharing of TK, on which applicant and traditional community will sign. Based on this agreement, NBA will issue the "License of Use", incorporating PIC and terms and conditions. The term of the License will be of three years, renewable for another three years.

If TK is in the public domain or spread over in more than three states, National Standing Committee (NSC) will issue the PIC and negotiate benefit sharing. The agreement will be signed by the applicant and NBA, which will issue the "License of Use". NBA will allow access to PUBLIC TK, after assessing its sustainability, value of TK and other implications. Access to CONFIDENTIAL TK will be allowed after identifying the traditional communities and their consent. In case the TK is registered as CONFIDENTIAL, then the SSB to obtain PIC and access and benefit sharing agreement. Any third party or civil rights groups can approach the NBA in case of misuse/misappropriation/abuse on unregistered TK. License of Use is non-assignable and non-transferable. Any interested person may within 6 months of publication, apply for its opposition or revocation. NSC will examine such claim after hearing both the parties and submit its report to NBA. In case of misuse, license can be revoked. Benefit share as negotiated be paid directly by the applicant to TC and report about it annually to NBA. Under the Agreement concluded with the NBA, benefits will go to the **Traditional Knowledge Fund**, created under the Rules.

Licensee has to pay 'Milestone payments' of not less than 10% of the gross revenue in the Fund. Access fee charged by the NBA will also go to the Fund. The Fund has to be used for the protection, conservation and development of TK and TCs (Rule 11(2)). NBA has to develop plans/programmes/strategies for

the sustainable use of TK. It shall make plans in consultation with the TCs for the protection of TK or resources on the verge of extinction. It shall also notify TK heritage zones of areas of importance. National/State Standing Committees shall also be constituted. Any contravention/attempt to contravene/ abetting the contravention of the Rules shall be punishable with imprisonment up to 5 years or fine up to ten lakh rupees or both. Court will entertain complaints only if made by the government or any authority so authorized; or made by the benefit claimer. An appeal against any order of the NBA can be made only to the Supreme Court.

The Draft Rules, to a great extent, are in consonance with the Nagoya Protocol, 2010 on access and benefit-sharing and provides for the designated Authority for these purposes. But the Draft Rules, which were to be adopted in 2010, are still being under deliberation.

Self Assessment Question	(Spend 3 minutes)
2) Who is a traditional community under the draft Rules, 2009 and how the NBA will protect their interest?	
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These legislative measures of the government to protect TK together, however, fail to address the participation of farmers or local communities in decision making or in the protection of TK. The main focus of the legislation is confined to checking biopiracy and providing positive protection through IPRs. The actual operation and impact of the relevant legislation on TK protection, however, is yet to be seen. Furthermore, fine tuning on benefit sharing is yet to be done.

16.4 TRADITIONAL KNOWLEDGE DIGITAL LIBRARY (TKDL)

In the recent past, there have been several cases of bio-piracy of TK from India. First it was the patent on wound healing properties of haldi (turmeric) by the United States Patent and Trademark Office (USPTO), then patents were obtained in other countries on hypoglycemic properties of karela (bitter gourd), brinjal etc. There is also the view that the TRIPS Agreement is aiding the exploitation of biodiversity by privatizing biodiversity expressed in life forms and knowledge. Similarly, a patent granted on the neem as a fungicide was revoked by the European Patent Office in May 2000. But the time, effort and money involved in getting individual patents examined and revoked in foreign patent offices is prohibitive. Hence, an internationally accepted solution to such bio-piracy is necessary, beside legislation by individual countries.

However, it is often difficult to check unscrupulous patenting of TK because of lack of documentation and validation. It is sometimes believed that proper documentation of associated TK could help in checking bio-piracy. It is assumed

that if the materials/knowledge is documented, it can be made available to patent examiners the world over so that prior art in the case of inventions based on such biological materials/traditional knowledge is readily available to them. It is also hoped that such documentation would facilitate tracing of indigenous communities with whom benefits of commercialization of such materials/knowledge has to be shared. On the other hand, others believe that documentation may facilitate bio-piracy. Nevertheless, documentation has one clear benefit. It would check patents based on TK in public domain that is today difficult to prevent due to lack of availability of information with patent examiners. After the CBD came into force, in India, preparation of village-wise Community Biodiversity Registers (CBRs) for documenting all knowledge, innovations and practices has been undertaken in a few States. The objectives of these registries range from TK and biodiversity preservation at the local community level, to establishing rights to produce and sell indigenous products/handicrafts at the national level, to providing evidence of prior art to prevent inappropriate patents at the international level.

To prevent bio-piracy, there is a need for developing digital databases of prior art related to herbs which is already under public domain, and which can be accessed by the patent offices while processing patent applications related to GRs/TK. Section 36(iv) of the BD Act provides for protection of knowledge of local people relating to biodiversity through measures such as registration of such knowledge, and development of a *sui generis* system. In India an exercise has been initiated to prepare easily navigable computerized database of documented TK relating to use of medicinal and other plants (which is already under public domain) known as Traditional Knowledge Digital Library (TKDL). Such digital database would enable patent offices all over the world to search and examine any prevalent use/prior art, and thereby prevent grant of such patents, such as on *haldi* and *neem*, and bio-piracy.

The Biological Diversity Act, in Section 41, talks about the documentation of the biodiversity at the local level by the Biodiversity Management Committees, in order to check probable bio-piracy and also to effectively challenge the IPRs granted in foreign jurisdictions. There are some private initiatives on TK documentation, such as Sristi (the Society for Research and Initiatives for Sustainable Technologies and Institutions) and the Honey Bee Network. There are also varied experiments on documentation undertaken by the village communities, particularly in Kerala, which is one of the richest biodiversity states in India. In the Pattuvam (village in Kerala) experiment, the village undertook to register all its natural resources and knowledge pertaining to these resources. The Register was accompanied by the People's Biodiversity Declaration asserting that no monopoly claims on life forms will be accepted by people living in that area. Other provisions detailed the conditions under which experiments on life forms collected in the territory of Pattuvam can be undertaken. The Register was kept secret and information sharing was allowed only in exceptional cases. The Register is thus not aimed at containing the commercial exploitation of local resources by others but mainly to prevent their asserting rights over prior local knowledge. But there are problems with documentation, and it is evident that registers have limited utility.

First, while registers can be very effective to counter patent claims by others on knowledge held locally, they cannot stop the utilisation of genes from plants

produced in a given village by outsiders who will then be able to patent novel products and processes after prospecting those genes: Secondly, a register does not help anyone claiming rights to knowledge. On the contrary, the register is meant to show that it is in public domain and, therefore, is not patentable. Thirdly, open registers could be accessed at a charge by anyone. Closed registers, as in Puttuvam experiment, would be confined to local communities. They are useful for the limited purpose of profiling the TK of a region. They also have very narrow utility because merely acknowledging the knowledge of local people has no bearing on the fact that the conservers of biological resources, creators and holders of knowledge and information relating to the use of biological resources are also the owners of these resources and should thus have the right to determine their sale and access. The ultimate decision-making body under the Act is the NBA, which may over-ride the interests of the knowledge holders. To avoid bio-piracy, it thus sacrifices farmers and local communities' rights and denies them any right over their knowledge and inventions.

India has also created digital databases of prior art related to medicinal plants used in Indian systems of medicines, *Ayurveda*, *Unani* and *Sidda*. In 2001, **Government of India**, set up the **Traditional Knowledge Digital Library (TKDL)** as repository of 1200 formulations of various systems of Indian medicine, such as *Ayurveda*, *Unani* and *Siddha* and 1500 Yoga postures (*asanas*), translated into five international languages — English, German, French, Spanish and Japanese, which converts Indian TK (*Ayurveda*, *Unani*, *Sidda*, Yoga, among others) from existing prior art TK formulations or knowledge available in Hindi, Sanskrit, Arabic, Persian and Urdu. TKDL thus provides information on traditional knowledge existing in the country, in languages and format understandable by patent examiners at International Patent Offices (IPOs), so as to prevent the grant of wrong patents. TKDL thus, acts as a bridge between the traditional knowledge information existing in local languages and the patent examiners at IPOs.

TKDL is a collaborative project between Council of Scientific and Industrial Research (CSIR), Ministry of Science and Technology and Department of AYUSH, Ministry of Health and Family Welfare, and is being implemented by CSIR. An inter-disciplinary team of Traditional Medicine (*Ayurveda*, *Unani*, *Siddha* and Yoga) experts, patent examiners, IT experts, scientists and technical officers are involved in creation of TKDL for Indian Systems of Medicine. The project TKDL involves documentation of the TK available in public domain in the form of existing literature related to *Ayurveda*, *Unani*, *Siddha* and Yoga, in digitized format in five international languages. Traditional Knowledge Resource Classification (TKRC), an innovative structured classification system for the purpose of systematic arrangement, dissemination and retrieval has been evolved for about 25,000 subgroups against few subgroups that was available in earlier version of the International Patent Classification (IPC), related to medicinal plants, minerals, animal resources, effects and diseases, methods of preparations, mode of administration, etc.

Presentation on Traditional Knowledge Resource Classification (TKRC) at IPC Union led to the creation of WIPO-TK Task Force consisting of USPTO, EPO, JPO, China and India by IPC Union for enhancing the sub-groups in IPC for classifying the TK related subject matter and considering the linking of TKRC with IPC. In February 2002, a Committee of Experts recommended the inclusion

of approximately 200 subgroups on TK against the few existing sub-groups on medicinal plants, and linking of TKRC to IPC and thus, a new main group and its subgroups were included in IPC covering different categories of plants.

Till August 2011, 2,44,860 medicinal formulations have been transcribed. In 2009, Access Agreements related to TKDL were concluded by the CSIR with major patent offices in the world, viz., USPTO, EPO, Japan Patent Office, German Patent and Trade Mark Office. As a result, more than 100 patent applications based on TK have been rejected by these offices.

Documentation of traditional knowledge (TK) is one means of giving recognition to knowledge holders. But mere documentation may not enable sharing of benefits arising out of the use of such knowledge, unless it is backed by some kind of mechanism for protecting the knowledge. Documentation of traditional knowledge may only serve a defensive purpose, namely that of preventing the patenting of this knowledge in the form in which it exists.

Self Assessment Question

(Spend 3 minutes)

3) Discuss the significance of documentation in TK protection.

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16.5 SUMMARY

- India is rich in traditional knowledge associated with biological resources. The traditional knowledge is both coded, as in the texts of Indian systems of medicine; or is non-coded, which is oral and undocumented.
- India is a party to the CBD, but there is no TK-specific legislation in this regard, but the Government has enacted three significant statutes related to TK and access and benefit sharing.
- The Patent (Amendment) Act, 2005, provides for: exclusion of plants and animals from the purview of patentability); exclusion of an invention which in effect is traditional knowledge from patentability; mandatory disclosure of the source and geographical origin of the biological material in the specification when used in an invention ; and provision for opposition to grant of patent or revocation of patent in case of non-disclosure or wrongful disclosure of the source of biological material and any associated knowledge.
- The Plant Varieties Protection and Farmers' Rights Act (PVPFRA) 2001 deals primarily with the protection of plant breeder's rights over the new varieties developed by them and the entitlement of farmers to register new varieties and also to save, breed, use, exchange, share or sell the plant varieties, which the latter have developed, improved and maintained over many generations. It also provide for benefit sharing with the indigenous communities for their share in this regard.

- The Biological Diversity Act, 2002 primarily aims at regulating access to biological resources and associated traditional knowledge so as to ensure equitable sharing of benefits arising out of their use, in accordance with the provision of Article 15 of the CBD.
- The draft Rules, 2009, drafted under the Biological Diversity Act, provides a more refined mechanism on ABS.
- India has also signed the Nagoya Protocol, not yet ratified, which will put binding obligations on India on ABS.
- There have been attempts for creating databases on TK at the village and state levels. The Government of India, with the involvement of CSIR, has developed the TKDL, which is a value added digital database for (i) preservation of traditional knowledge; (ii) prevention of misappropriation of traditional knowledge; and (iii) creation of linkages with modern science to initiate active research projects for new drug discovery and development. It helps in checking the bio-piracy and misappropriation of the TK, by preventing bad patents by foreign patent offices over knowledge which is in the public domain.

16.6 TERMINAL QUESTIONS

- 1) Discuss the main provisions of the Patents (Amendment) Act that have the relevance in protecting the Traditional Knowledge. Do they reflect India's position on TK protection at the TRIPs deliberations?
- 2) What is the role of the National Biodiversity Body (NBA) under the BD Act in giving effect to ABS and checking the bio-piracy?
- 3) Describe the significance of TKDL in the protection of TK and providing defensive protection to TK-holders.

16.7 ANSWERS AND HINTS

Self Assessment Questions

- 1) Benefit sharing under the Act is meant to provide individuals or groups with the possibility of receiving financial compensation when a protected variety is developed. The PVFRP Authority is empowered to determine the applicable benefit sharing, and while determining the amount of financial compensation, the Authority will take into account whether the variety is extant and nature of the use of the genetic material of the claimant in the development of the variety; and the commercial utility of and demand in the market for the variety so developed. The Act also provides for a National Gene Fund (the Fund), to which the amount accruing from the benefit-sharing will be credited, which will be utilised, among others, for the payment of benefits to the claimant.
- 2) "Traditional Community" (TC) under the draft Rules means a community holding the TK. The NBA has to ensure that the prior informed consent of the TC is obtained before granting access to the TK, through the SBB/BMC and based on the report of the SSC assessing the sustainability of the

resources and other implications. The SBB will set the terms and conditions for access, use and benefit sharing of TK, on which applicant and traditional community will sign. Based on this agreement, NBA will issue the "License of Use", incorporating PIC and terms and conditions.

- 3) Documentation helps in checking unscrupulous patenting of TK. It is sometimes believed that proper documentation of associated TK could help in checking bio-piracy. It is assumed that if the materials/knowledge is documented, it can be made available to patent examiners the world over so that prior art in the case of inventions based on such biological materials/traditional knowledge is readily available to them. It is also hoped that such documentation would facilitate tracing of indigenous communities with whom benefits of commercialization of such materials/knowledge has to be shared. Documentation of traditional knowledge (TK) is one means of giving recognition to knowledge holders.

Terminal Questions

- 1) Refer to Sub-section 16.3.1
- 2) Refer to Sub-section 16.3.1
- 3) Refer to Sub-section 16.3.1

16.8 REFERENCES AND SUGGESTED READINGS

- 1) UNCTAD- ICTSD, *Resource Book on TRIPS and Development*, Cambridge University Press, 2005, ch. 21
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Notes

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