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WHO OWNS TRADITIONAL KNOWLEDGE ?

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Contents

Foreword

The protection of traditional knowledge is among the important intellectual property rights issues to be resolved in the TRIPS Council during the Doha round of WTO negotiations, as acknowledged in the Doha Ministerial Declaration. The question "Who owns Traditional Knowledge ?" assumes high significance because novelty thresholds for patentability vary from country to country, and, patentability under TRIPS does not require prior informed consent of countries or communities from where organic and informational resources are procured.

This study provides a multi-disciplinary analysis of the the complexity of legal, economic, social, political and moral problems concerning rights to own and use traditional knowledge, as part of a wider research study aimed at formulating *sui generis* systems for the protection of traditional knowledge, genetic resources and folklore. This study places into perspective the international debate on a number of controversial issues that arouse passions but are poorly understood. This is a welcome addition to policy research on questions of profound significance which would impact inter-generational equities through international transfers of resources between knowledge societies.

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WHO OWNS TRADITIONAL KNOWLEDGE ?[1]

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Abstract

About forty percent of drug patents in the pharmaceutical industry are due to expire by 2006. Biotech firms are engaged in building cross-border value chains on an unprecedented scale in a bid to discover and develop new active ingredients from traditional medicine. This provides strong incentives for bioinformatics and bioprospecting, but also for biopiracy. The holders of traditional knowledge may share in benefits if they can participate in benefit streams that arise from the global development and trade in the healthcare industry. The protection of traditional knowledge is one of the major issues to be addressed in the recently launched Doha round of WTO negotiations. This is acknowledged in Paragraph 19 of the Doha WTO Ministerial Declaration which calls for the TRIPS Council to examine the issue. The question assumes high significance because traditional knowledge consists of information in the public domain as well as trade secrets; novelty thresholds of patent laws of countries differ greatly and are notoriously low in countries where the pharmaceutical industry is strongest; and, patentability under TRIPS does not require prior informed consent of countries or communities from where organic and informational resources are procured.

Keywords

Biotechnology, Bioprospecting, Biopiracy, Healthcare, Intellectual Property Rights, Patents, Traditional Knowledge, Traditional Medicine, TRIPS, WHO, WIPO, WTO

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I. Introduction

The purpose of this paper is twofold. First, I intend to provide an overview of the ongoing international debate on the question of whether rights to use of traditional knowledge belong inside international intellectual property rights (IPR) regimes or outside them, with a view to bring conceptual clarity to a topic that arouses passions, but remains poorly understood. Secondly, I propose to present the complexities and contradictions inherent in underlying policy choices presently being analysed and being developed as part of a wider research study aimed at formulating *sui generis* systems to bridge the knowledge gap between holders of traditional knowledge and bioprospectors through appropriate forms of new institutionalities and enforceable contracts. This introductory section relates the problematique to its context so that conceptual elements in the analytical framework and the threads of the international debate in the succeeding sections are placed in perspective.

About forty percent of all patents in the pharmaceutical industry are due to expire by 2006. The advent of biotechnology, and pharmacogenomics which more than halve costs and time taken for drug discovery and development are widely regarded as the main hope to overcome this vulnerability. Consequently, bioprospecting has become a mega billion dollar global industry and biotech firms are engaged in building cross-border value chains on an unprecedented scale in a bid to discover and develop new active ingredients from traditional medicine. This has created strong incentives for bioinformatics and bioprospecting, but also for biopiracy. Communities and countries that are rich in bio-diversity and knowledge of traditional medicine may gain if they are able to share in trade and investment benefits provided their knowledge is used with `prior informed consent' and they participate in the design of benefit streams from trade and investments that arise from the global development of the healthcare industry.

The protection of Traditional Knowledge is one of the major issues that to be addressed in the recently launched Doha round of World Trade Organisation (WTO) negotiations is protection of traditional knowledge. This is acknowledged in Paragraph 19 of the Doha WTO Ministerial Declaration (Document WT/MIN(01)/DEC/1) which calls

for the Trade Related Intellectual Property Rights System (TRIPS) Council to examine the issue. The question assumes high significance because traditional knowledge consists of information in the public domain as well as trade secrets; novelty thresholds of patent laws of countries differ greatly and are notoriously low in countries where pharmaceutical industry is strongest; and, patentability under TRIPS does not require prior informed consent of countries or communities from where organic and informational resources are procured.

The status accorded to traditional knowledge, genetic resources, and folklore poses particularly profound moral, legal, social and political problems. Such knowledge is not limited to definable or articulable sets of knowable elements. Yet, inter-generational equities could be irreversibly impacted internationally depending on the way solutions to appropriate benefits are structured by vesting ownership or use rights in such knowledge because resource availability and resource use would both be impacted. To date, it has not been possible, to develop an international system to protect human knowledge in these forms, despite a number of international treaties that partially address some of the issues through enabling clauses. Doubts have been expressed whether it would ever be possible to develop an international system to protect traditional knowledge and also whether it is necessary or desirable to have an international system to do so [2].

In the contexts of (a) trade and (b) issues concerning the environmental commons, TRIPS and the Convention on Biodiversity (CBD), respectively, required the creation of new economic rights and obligations to complement the intellectual property rights (IPR) system under WIPO. Matters concerning traditional knowledge, hitherto pursued only in the form of cultural rights or heritage issues at the UN, UNESCO and WIPO are regarded relevant also for development rights for which UNCTAD was created and economic rights for which earlier UN-ECOSOC and more recently, WTO have been mandated. The debates at WIPO, UNCTAD, CBD Conferences, and WTO have focussed on understanding the complex set of issues rather than on developing international norms. Much of the recent

[2] The U.S. policy stated in para 138 of the Report of the Fourth Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (December 9-17, 2002) maintains that "the case for an international sui generis system has not yet been made" (WIPO, 2002)

discussion at WIPO in the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore has also been side-tracked away from substantive issues to procedural ones over who should participate in the discussions on these issues and how participation of indigenous communities could be financed. Countries opposed to internationally binding instruments on the protection of traditional knowledge maintain that international norms may be difficult to create with any degree of certainty before national systems and norms have been developed and there is some experience to draw upon. Yet, instruments like CBD, TRIPS and the Cartagena Protocol were developed internationally long before countries legislated on these issues and created national systems. If one solution cannot suit all countries, a range of policy choices harmonisable with international regimes may need to be envisaged.

An important policy question in this context concerns whether the aims would be better fulfilled through systems that confer on people in general, and communities in particular certain rights over their traditional knowledge or whether creation of para-statal monopolies over such knowledge would be a better alternative to ensure inter-governmental co-ordination. This is not easily solved because non-contemporary traditional knowledge comprises unarticulated and unrecorded intangibles and there is an investment or cost necessary for its documentation into databases which can be privately owned. Also, exhaustible plant genetic resources have implications for biodiversity in certain categories of traditional knowledge like traditional medicine besides, subserving public health objectives under WHO's Traditional Medicine Strategy for 2002-2005. Moreover, traditional knowledge is valued not because of its antiquity (an argument that would limit its scope merely to protection of expressions of culture) but because more of it is transmitted orally, as part of knowledge necessary to sustain lives and livelihoods and it has an economic value which is variable. The Barton Commission (DFID, 2002) noted that a multiplicity of measures, only some of them related to intellectual property rights, would be necessary to protect, preserve and promote traditional knowledge

By its very nature, traditional knowledge requires participation of holders of such knowledge or on their behalf before such knowledge can be priced as a marketable

economic asset. This process can be accomplished in a number of ways but any path would involve several stages of resource and response development and the flows of costs and benefits can differ greatly depending on how rights in such knowledge are created, *pari passu*, with other existing intellectual property rights regimes. Further, moral rights, legal rights and property rights may overlap, but not necessarily. Traditional knowledge has historically been transmitted inter-generationally through customary practices that functionally differ for different kinds of traditional knowledge. The modalities of inter-generational transfers vary also with social and cultural traditions unique to communities that hold them. These differences in customary practices amounting to customary laws raise questions of policy about whether authority to appropriate benefits should regard such knowledge as excludable and rivalrous and whether all or part of such knowledge should be considered exhaustible if bundled as a marketable single good.

The search for ways to bridge gaps between responsibility for healthcare, the authority to design its value chains and the power and capacity to organise its delivery is not limited to allopathic medicine. There exist traditional medical systems like *kampo, unani, ayurveda, siddha, homeopathy, acupuncture, yoga,* to mention a few, capable of treating a wide range of diseases -not all- and are particularly effective for stress-related and lifestyle-related diseases, the fastest growing non-communicable diseases. The European Union's recent directive on herbal medicine (worldwide market value about $ 80 billion) is an indication of the growing interest in traditional medicine and the need to regulate. Also, India is getting ready to launch the world's first Traditional Knowledge Digital Library (TKDL) containing an ayurveda database translated into six languages sometime in 2003 [3]. Peru, Egypt, Thailand and Panama are among countries that have enacted new laws to protect traditional knowledge. Initiatives of these kinds, to be of use

[3] India's Traditional Knowledge Digital Library is a joint initiative of the Council of Scientific and Industrial Research and Indian Systems of Medicine & Homeopathy. The database has retrieval features enabling searches to commence from disease conditions to proven methods of preparations containing established active ingredients from botanical species identified by their Latin classification and in the original Sanskrit, besides French, German, Spanish, Japanese, English and Hindi and it is also possible to start from a botanical species and know what uses for it are already known. For each record in this database, the relevant International Patent Code has been listed alongside so that there is no excuse for a patent examiner anywhere in the world to miss this prior knowledge originally codified in Sanskrit in the Vedas, when dealing with patent claims.

beyond creating negative rights need to be linked to communities and enmeshed with other international regimes including but not limited to acceptance by other patent offices.

With its focussed and limited aims for the present, this paper is part of a wider international inquiry in progress with three main objectives:

Identifying and analysing the rationale underlying the complex set of policy choices to protect, preserve, and develop vast reservoirs of scattered traditional knowledge in its expressed and tacit forms including, but not limited to traditional medicine.

Evaluating policy options based on national and international experience to recommend an appropriate design for *sui generis* protection of different kinds of traditional knowledge, with a view to develop, preserve, use and trade in such resources.

Formulating a comprehensive *sui generis* system together with an assessment of the resources and linkages it would require to be effective.

As the above objectives get clarified and begin to be fulfilled, adoption nationally and/or internationally, *mutatis mutandis*, would reduce transactions costs of patent protection and also mitigate some degree of uncertainty and risks of procurement and modification of genetic resources and development of biotechnology in a whole range of life sciences applications in an efficient and equitable manner. This research is therefore of direct relevance to policy makers, and science parks that house internationally networked lifesciences projects because policies have to be made and decisions taken in anticipation of these developments. Firms, communities and governments need to be better prepared to adapt to the inevitable changes underway and take initiatives to have a role in designing and experimenting with alternative models.

II. What Is Traditional Knowledge Worth ?

Humans have always passed on knowledge about life, living, livelihoods, lifestyles, nutrition, healthcare and hygiene inter-generationally as part of kinship, cultural and social

traditions of bequeathing lived experiences of our habitat. If the intended beneficiaries are located within a limited space or limited sentience of a community, no institutions beyond the family or clan or tribe or community network are necessary to ensure continuity in such traditions. The sufficiency of substituting intermediating agencies such as learning institutions (schools or *gurukuls or* workshops) or administrative agencies deriving tax revenue (Olsonian stationary bandits or overlords) or those discharging judicial functions (arbiters and adjudicators) or acting as religious functionaries (priests, shamans) to function as information conduits may also be reasonably presumed.

Bio-information can be used globally through partnerships, trade and other forms of cross-border transfer-pricing arrangements, if tacit knowledge held communally can be converted to articulated information under a system of flexible property rights. This could raise the value of traditional knowledge by enabling it to be priced to correspond to its true international market value. This presents new opportunities to holders of traditional knowledge for cross-border partnerships in the international trading system. Forms of technology (such as information and communication technologies i.e. IT) and social organisation (regional, national and international economic governance) make it possible to share this knowledge widely and there is a global demand for such knowledge to be procured. However, institutions that would yield dispersed benefits do not emerge easily and there is a profit to be made if local knowledge has a use and commercial value beyond its local context. This problem can be narrowly postulated in the specific context of valuing traditional medical knowledge using a modified version of the Ruitenbeek Korup model (Ruitenbeek,1989) :

CPVi = a X EPVj where,
EPVj = Expected Production Value of a Patented End-product j
CPVi = Capturable Production Value of active ingredient, i
and, `a' is variable with value < 1

Typically, "a" tends to be very small in the beginning of the innovation cycle when biological resources are being researched and screened for further development or synthesis. For most part of the twentieth century, it was erroneously believed that plant genetic resources for drug uses are exhausted, and the value of "a" was so small that it was

close to zero. The discovery of Vinca alkaloids with anti-cancer properties and the recent interest in traditional plant resources that have a human medicinal-use history have caused people to rethink about the value of "a". However, the value of "a" is not easily fixed because biological resources are unquestionably of vast value which defies empirical or normative evaluation and humanity is very far from completing even a basic catalogue of all terrestrial and marine species (Wilson, 2002).

Hayek was among the first to suggest that such questions of knowledge economics should not be conceived in terms of how given resources can be best allocated but rather how to secure the best use of resources known to any of the members of society, for ends whose relative importance only these individuals know (Hayek, 1945, p.519). For securing the best use of traditional knowledge, the nature of traditional knowledge may be broadly distinguished by two useful criteria: antiquity (whether it is contemporary or non-contemporary) and embeddedness (whether it is tangible or intangible) in the form of the following taxonomy (See Table 1)

Table 1. Taxonomy of Traditional Knowledge

TRADITIONAL KNOWLEDGE	**CONTEMPORARY**	**NON-CONTEMPORARY**
TANGIBLE	(1) NEEM PACKAGED AS TOOTH PASTE	(2) NEEM TWIG FOR DENTAL CARE
INTANGIBLE	(3) NEEM FOR CALCIUM ABSORPTION IN MAMMALIAN BONE TISSUE	(4) NEEM AS ANTI-SEPTIC

NOTE: *The neem tree (Azadirachta indica or Free Tree) has been the subject of at least 153 patents worldwide. Inventions described in virtually all neem-related patents used public domain traditional knowledge as the starting point. Neem-related traditional knowledge is cited here to distinguish between different categories of traditional knowledge. In Figure 1, knowledge of neem in categories (3) and (4) could constitute a trade secret or be disclosed for taking a patent. Thus, (3) has been patented but not (4), being part of prior art in the public domain until someone succeeds in adding an inventive step or some other ingredient and claims a new use. Category (1) can only be protected by trade mark unless neem is synthesised which could make it patentable. Category (2) knowledge is in the public domain. In this example, the diffusion of traditional knowledge delimited this knowledge from being confined to a local indigenous group or community.*

All forms of contemporary knowledge [(1) and (3) above] -whether tangible or intangible are amenable to coverage under IPR regimes unless someone prefers to hold them as trade secrets and succeeds in doing so. Non-contemporary traditional knowledge to the extent that it is tangible [(2) above] as in case of *in situ* plant varieties that occur in nature or codified informational resources - regardless of whether the information is in print or in digitalised databases- can also be protected to the extent that organic resources can be brought within the protective scope of plant varieties protection under Convention on Biodiversity (CBD) and informational resources (such as publications about it) can be protected under Copyright or other forms of intellectual property rights (IPR). In all such cases, questions of resource valuation and sharing can generally be settled by statute, contract or custom or a combination of them and the rewards for innovation as a quid pro quo to disclosure can be regulated. Category (4) always presented special difficulties and Biotechnology has also made the determination of categories more complex and non-transparent due to the following problems:

(a) Tangible *ex-situ* collections can be privately owned and held in laboratories without any requirement to disclose the source of the biological resource in its organic and informational forms. Laboratory cultures (benevolent, malevolent and virulent) derived from them and modifications genetically introduced in such *ex-situ* collections, particularly to plant genetic resources and universally patentable micro-organisms are unknowable unless deposited as part of specimen disclosure in a recognised depository under the Budapest Treaty. If a party does not make such disclosures or if there be only one depository within a single country's control where disclosures of Type-4 plus viruses may be made, the positive externalities associated with disclosure of innovation may be delayed or even lost forever (Mathur, 2001). In this situation, public-private partnerships in a limited sectoral or national interest have an incentive to obstruct inspections under Biological Weapons Convention (BWC) on grounds that such inspections might cause industrial espionage and adversely impact competitiveness of the pharmaceutical industry. If a country chooses not to ratify the Convention on Biodiversity but insists that other countries comply with their obligations under TRIPS, the only recourse left to other countries would be to

renegotiate TRIPS or renounce it by notice in accordance with the Vienna Convention on the Law of Treaties. This situation has resulted from the failure of the international community to link the rights and obligations under TRIPS to rights and obligations under BWC and CBD on a take-it or leave-it package deal basis.

(b) Intangible non-contemporary knowledge [Category (4) in Figure 1] held in the form of trade secrets or in the public domain use of one or more local, regional or national community may have economic value beyond its proximate natural environment in securing healthier lifestyles or prevention or treatment of diseases. Yet its value is small if it is underused and its value, however large, would reduce to zero if it is overused and exhausted.

The market value of a biological resource held in a laboratory as envisaged in (a) above is higher than that of a comparable *in situ* specimen in nature because the ex situ specimen has already been selected on the basis of some information available to the holder such as (b) above. There are no enforceable means to verify the origin of privately held *ex-situ* collections and the reasons they exist are worth recalling. Biotechnology is a hit-or-trial business and the costs can be significantly reduced by pinpointing promising substances in advance of hit and trial.

The value of Category 4 traditional knowledge (TK) depends on:

(i) The extent to which such knowledge is known <u>outside</u> the close-knit bonding of a family, clan, tribe or community.

(ii) The degree to which such knowledge is replicable <u>within</u> the close-knit bonding of a family, clan, tribe or community.

(iii) The extent of measures taken to guard the secrecy of information.

(iv) The value of the information inside the community to the holders and to their competitors, if any.

(v) The amount of effort or expenditure in money required by the holders to care for and keep developing such knowledge.

(vi) The ease or difficulty with which the information could be acquired or duplicated by others.

As far as the informational value of Category 4 TK is concerned, unless (iv) or (v) be prohibitively high, such knowledge is hardly likely to remain a secret and is in the nature of a public good - in that it can be promoted non-rivalrously and on a non-excludable basis - with pro-active supportive policies. However, the experience of the plunder of Vavilov agro-climatic zones of principle crop varieties suggests that the moment such resources are geographically mapped out by bioprospectors, the price of the organic components would keep rising until they are synthesised in *ex-situ* collections. There is also the danger that biological resources so targeted are likely to be plucked to extinction which raises concerns over their exhaustibility and the loss of habitat and biodiversity, besides the loss of lifestyles and livelihoods to the indigenous communities that have nurtured and used these resources a long time. The tenfold rise in the past five years in the price of *neem* and *turmeric* (both plants have multiple uses and have not yet been synthesised !) which were the subject of successful lawsuits in the EU and U.S.A. respectively, challenging their patentability bears witness to this phenomenon. Thus, underuse of biological resources for discovering and developing healthcare products as well as their overuse are both problematic and valuation must strive for a balance that is anchored in sustainability of habitats, which include people.

The worth of traditional knowledge may also be estimated from arrangements pharmaceutical firms have made in different places and the amounts they are willing to pay for exclusive rights of bioprospecting. In the agreement between Costa Rica and Merck, Merck obtained a monopoly right to bioprospecting in Costa Rica for an annual fee of $ 568, 000 with a promise of 50 percent royalty share in any marketable product developed (Lerch, 1998). Another firm, Shaman Pharmaceuticals operates a parallel non-profit firm called "Healing Forest Conservancy" through which it ploughs back at its own discretion, a unilaterally determined part of the value extracted from indigenous people and shamans in Asia, Africa and Latin America. There is not much to choose between the risk of regulatory capture and private markets because either solution can exclude the holders of

traditional knowledge from being parties to a negotiated contract. The use of biological resources can also be linked to permits and know-how licences for medicinal knowledge where bioprospecting is authorised through people's biodiversity registers as in Peru and India (Glowka, 1998, p.7). In the case of the Arogyapachha fruit (*Trichopus Zeylanicus*) used by the Kani community in India for its anti-fatigue effects, the plant came to the attention of a scientific expedition in 1987 and was found to activate the body's natural defenses by acting on the cellular immune system with hepato-protective, anti-peptic ulcer and cholorectic effects. The drug "Jeevani" developed from this herb was patented by Kerala's Tropical Botanic Gardens Research Institute as contemporary knowledge and the Kani community rewarded with a 50 percent share in royalties through a trust fund together with remuneration for participation in its expanded cultivation and development (Wilder, 2000). This brought considerable prosperity to the Kani community and raised their income by an average of about Euro 200 per month for every household.

(c) Tangible forms of knowledge are protected by laws governing real or physical property whereas only personal or intangible property can be protected by intellectual property rights. For indigenous people, the distinction between tangible and intangible aspects of traditional knowledge (in terms of Table 1 above) may not be relevant because material or organic resources and commercial profits founded on the distinction between goods and services do not play an important part in their lives until they are brought into frequent and intensive contact with economic forces operating beyond the community. The transformative nature of non-contemporary traditional knowledge as it gets passed on through contemporary experiences does not lend itself easily to a static evaluation of its elements, none of which may be assignable as a property right to any living individuals. From the pattern of decided Australian land title cases, it seems that claims on behalf of the global environment or the global good of industry have been accepted by Australian courts as a justification for denying any rights or titles to interests of indigenous people by ruling that there is no personal property question involved in cases of real property concerning lands or forests. In cases where knowledge is not separable from the natural habitat, the introduction of the notion of excludability to real property changes the status of Type

3 TK and Type 4 TK from being non-rivalrous and non-excludable to becoming rivalrous, excludable and more importantly, *exhaustible* - thus affecting the valuation of its economic worth significantly. In some cases, the value may be bid up to the notion of a market price and in others, the value may be eroded in the absence of a suitable pricing mechanism.

May apple (*Podophyllum peltatum*) used by native Americans for centuries as an ameliorate for skin warts, ulcers and cancerous growths is the source of *Etoposide* used for the treatment of cancerous growths with a US $ 500 million world market value; Vinca alkaloids originating from the traditional medicinal use of periwinkle have led to blockbuster drugs Vincristine and Vinblastine with estimated global sales of $ 300 million; oil of evening primrose *(Oenthera*) used by indigenous populations in the Americas for skin problems is currently marketed for eczema and pre-menstrual problems with an estimated market of over $400 million; and, Australian smokebush (*Conospermum*) given by aborigines to their old folk was found to contain Conocurvone, a substance that treats rheumatism and lumbago and destroys HIV virus in low concentrations with the predictable outcome that a private Victorian firm Amrad financed by an American Institute now pays Australian $100 million a year to the Western Australian Government for the exclusive privilege to develop the discovery. In all these cases, while captive commercial cultivations exist, the plants can no longer be found in nature by the indigenous communities that historically found their properties and used them. This has also happened with *Rauwolfia Serpentina,* once common in the forests of India and Nepal as the source of reserpine which is now on the endangered list. It is not known what benefit, if any, was shared by the drug developers with the communities concerned in these cases.

III. Access to Plant Genetic Resources

Commercial bioprospecting of plant genetic resources is informed by traditional knowledge of indigenous peoples and value is created when tangible organic elements and intangible informational resources come together. 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 as medicine by indigenous communities (Sheldon, Balick and Laird, 1997). The access to a country's plant genetic resources is governed by an evolving mosaic of national laws, international conventions, multilateral agreements concerning biodiversity and intellectual property rights and plurilateral codes of practice developed in the context of *sui generis* modalities created in the work of the Food and Agricultural Organisation (FAO). The ownership status of seed banks, gene banks and germplasm banks [established by the Consulting Group of International Agricultural Research Institutes (CGIAR) as a means of facilitating what became known as the `green revolution'] has remained unclear since they are neither private nor under the control of any State or national authority and they were also not created by any international instrument or organisation.

The UN Commission on Environment and Development which produced the Brundtland Report (Brundtland, 1987) created a stir about the sharp rise in species extinction rate long before the Rio Earth Summit convened in June 1992. The Convention on Biological Diversity (CBD) opened for signature at the Rio Summit was an attempt at conservation and utilisation of the world's biological resources. The principle of "fair and equitable sharing" in the CBD is based on recognition of the sovereign right of countries to exploit their own genetic resources pursuant to their own environmental policies. Contracting parties were required to create conditions to facilitate access to genetic resources on mutually agreed terms and conditions with "prior informed consent" and "equitable remuneration" as the basis of policy (McConnell, 1996). Article 8 (j) of CBD which envisages "*equitable sharing*" of benefits arising out of the use of traditional knowledge, innovations and practices of indigenous and local communities with such communities needs to be read together with Article 15 (7) of CBD. The latter requires each contracting party to take legislative, administrative or policy measures, as appropriate "*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".*

Certain provisions of CBD are particularly relevant to the question of sovereign rights over *in situ* biological resources within ecosystems and natural habitats and *ex situ*

collections, as in gene banks covered under Section 9 of the CBD. Access and benefit-sharing provisions of CBD do not apply to the genetic resources of a country collected prior to the entry of the CBD into force in that country. This means that a country with a pre-existing collection of genetic material may control access to that collection but has no legal right to insist upon a share of any benefits derived from the use of that collection. Biochemical extracts which do not contain DNA or RNA are also outside the scope of CBD. Governments were required also to establish a process to empower indigenous peoples and their communities [Chapter 26 of Agenda 21 at paragraph 26.3 (a)]. These measures had not been implemented when TRIPS came into force. Some scholars have denied the interdependent nature of TRIPS and CBD by arguing that these agreements are independent of each other since neither treaty makes reference to the other failing to note that CBD predates TRIPS and so TRIPS could not possibly have been referred in CBD. On the contrary, the error of omission of any reference to CBD in TRIPS is a clear error of commission considering that Article 16(5) of the CBD had presciently observed that patents and other intellectual property rights may have an influence on the implementation of this Convention and parties *"shall co-operate in this regard subject to international law in order to ensure that such rights are supportive of and do not run counter to its objectives"*

A national policy on international bioprospecting contracts may provide for grant of permits against a guarantee of full disclosure by a bioprospector similar to what is required within the context of the FAO International Undertaking on Plant Genetic Resources. However, such a policy to grant permits to bioprospectors needs national legislation based either on the CBD or on the International Convention for the Protection of New Varieties of Plants (UPOV), as amended to date. This is required also for the sake of consistency with Article 27.3 of the TRIPS agreement which requires that "*Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof*" (underlining mine). Article 14 of the UPOV Convention specifies the scope of registration and grant of intellectual property rights in relation to new, distinct, stable and uniform plant varieties. However, the novelty threshold in the UPOV convention had been kept deliberately very low and lower than the

most liberal patent regimes of that time when the UPOV convention was made in 1961. This was done to facilitate the acquisition of plant variety rights in germplasm considered a common heritage of mankind. There was no patentability of life forms anywhere in the world at that time.

When the FAO established the Permanent Commission on Plant Genetic Resources in 1983, biodiversity was not within its mandate and was neither listed as an issue nor regarded as an objective. The broadened mandate in 1995 includes biodiversity in relation to food and agriculture, but not healthcare. Since the Global System for the Conservation and Utilisation of Plant Genetic Resources for Food and Agriculture is limited to food and agriculture it is necessary to evaluate its elements and distinguish it from questions of access to plant genetic resources and traditional knowledge in development of intellectual property rights in healthcare and biotechnology for the pharmaceutical industry under TRIPS.

The Global System for food and agriculture was developed on the basis of voluntary codes of conduct for the collection and transfer of biotechnology and plant germplasm as a freely exchangeable heritage of mankind. Positive externalities of treating knowledge as a global public good were harvested without worrying about IPR issues until the 1990s [4]. The creation of plant breeders' rights in November 1989 superseded the notion of plant germplasm as a freely exchangeable heritage of mankind. This benefit to industrialised countries with firms active in seed production was obtained in exchange for promises on "farmers' rights" proposed by developing countries. However, "farmers' rights" were recognised only as a moral commitment to reward the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources particularly those in centres of origin/diversity. The derogation of plant genetic resources from being a common heritage of mankind to becoming subordinated under the sovereignty of States fragmented the world's knowledge resources and limited them to national domains with certain deleterious effects:

[4] During the 1990s there have been instances of litigation over the unsettled question of who owns CGIAR gene banks, since the time Australian agricultural research institutes sought patent protection for germplasm stored in ICARDA, Syria and IDRC, Canada (Blakeney, 1998, pp 3-11) .

(i) No comprehensive inventory of internationally contributed *ex situ* collections is available anymore even in relation to food and agriculture.

(ii) The right of access to *ex situ* collections by scientists in developing countries has become limited to reciprocal treaty obligations and subject to technical pre-conditions which many developing countries cannot meet.

(iii) National governments have become responsible for protecting *in situ* collections but developing countries are poorly equipped to do so and the International Fund for Plant Genetic Resources as the means to implement farmers' rights proposed in 1991 was never set up.

(iv) Indigenous and local communities have an incentive to bypass national governments by linking with firms and non-governmental organisations fronting for or aligned to bioprospectors holding out the prospect of foreign direct investment for community initiatives as a *quid pro quo* to harvesting traditional knowledge

Developing countries compensated the loss of economic rights through cosmetic gains in cultural rights under the International Covenant on Civil and Political Rights, 1966 and the ILO Convention No. 169 concerning Indigenous and Tribal Peoples in Independent Countries which came into force on 5.9.1991[5]. Within such contexts, countries do not have right to disclosure about any investigation or use of their knowledge or resources. The notion of "retrospective equity" or "restorative justice" is impossible to enforce as a moral obligation unless it can be structured into forms of use rights or economic incentives such as profit-sharing or a seed tax from which revenues may be channelled into a community fund (Brush, 1998; Swaminathan and Hoon, 1994).

[5] Developed countries have generally been supportive of the notion that indigenous peoples' rights are mainly about being permitted to practise their lifestyle and uphold their sense of identity through adhering to expressions of their folklore and culture. This takes away attention from essential questions of economic rights and the economic value of traditional knowledge, some of which comes inextricably parcelled with their habitat and their title or lack of it to source livlihoods from that habitat.

There have been several notable attempts to propose traditional resource rights (TRRs) to resolve problems of access to plant genetic resources (Posey, 1996; Posey and Dutfield, 1996; Glowka, 1998). TRRs would fit well with the conceptual framework in Table 1 of this paper and could promote an integrated rights concept that recognises the inextricable links between cultural and biological diversity. Due to the inability of statutory and contractual law to recognise communal property, the problem of vesting authority to contract by structuring roles and responsibilities into custodianship concepts of customary traditions remains unsolved. For this reason, it is difficult for marginalised indigenous local communities to influence policy planning and implementation on these issues of vital significance to them unless they can participate.

This has led to the suggestion that a *sui generis* system which places a higher value on respect for life, biological diversity, developmental rights, human rights, community rights and cultural heritage than on individual property rights may be required. Priority could be given to holders of knowledge over technical aspects of ownership such as who holds title to forest land on which a holder of knowledge may be located and claims to ownership of source materials by nationally mandated custodians of prior art[6].

The classification of biological knowledge into "life sciences" and "ethnobiological knowledge" is itself questionable. A hierarchy has been created as if biological knowledge within its own habitat is also "ethnobiological" simply because the ethnicity of the local population differs from the mainstream ethnicity of researchers of the so-called "life sciences" who are located principally in Western developed countries. Even if I stay with the term "ethnobiological knowledge" (which includes knowledge of ecosystems) for no other reason than that it would be recognised more easily by some readers, "ethnobotanical knowledge" is a subset limited to plants and micro-organisms as described by researchers

[6] A focus on ownership could alienate members of indigenous cultures or cause bickering over competing claims where "prior informed consent" and "equitable benefit-sharing " must reward the knowledge holders embedded in a community whose group relations are determined from within their membership rather than by conferred recognition on selected individuals by outsiders. Gadgil and Devasia's proposal (Gadgil and Devasia, 1995) does not cater to the contingency that ownership of natural resources and the knowledge held may be in different hands and the relevant indigenous group could be easily marginalised. .

on the basis of their interpretation of the contact they had with indigenous knowledge. The time and energy required and elapsed before some part of folklore is adopted as a finding of fact distances the indigenous communities from whom organic and informational resources are procured and this characteristic is not limited to traditional knowledge of developing countries [7].

At present, most indigenous people live in transition countries or developing countries which possess the largest part of rainforests and wetlands. The areas of greatest biodiversity are also areas of the greatest linguistic and ethnic plurality. Tropical rainforests accounting for only seven percent of the planet's surface are home to at least 1400 distinct indigenous and traditional peoples whose ecosystems contain between 50 percent and 90 percent of the world's known species (Harmon, 2002). Considering the abundance of known and unknown life forms in nature, the expenses and time saved by using ethnobotanical knowledge are obvious. However, even when indigenous people understand the opportunities available from their possession of ethnobiological knowledge, "*the overwhelming power, expertise and skills of pharmaceutical companies and Governments (overseas and host countries) is generally sufficient to convince indigenous people to co-operate on their terms"* (De Koning, 1999, p.33). Thus, the hidden nature of bioprospecting places practical hurdles for the contribution of indigenous people to be proved.

Highly organised bioprospectors maintain written records in contrast to the dominance of oral traditions among indigenous people which further disadvantages the indigenous people in their quest to receive a share in the benefits as joint inventors under patent regimes or be remunerated as contemplated by the CBD, Agenda 21 or the original UPOV. If the preservation of traditional knowledge is believed to encourage innovation, the incentives to indigenous peoples to increase its availability to industry for the benefit of all humankind should be organised similar to the universal justifications for intellectual property laws. Customary laws, communal concepts and normative principles could be

[7] Finnish fish biologists recently "discovered" that salmon can use extremely small rivulets leading to River Tenojoki as spawning ground which was earlier thought impossible. Saamis have always known this. The traditional Saami names of several of these rivulets includes the Saami word for "salmon spawning bed" (Skutnab-Kangas, 2002, quoting Pekka Aikio, President of the Saami Parliament in Down to Earth, Volume 11, No.15, December 31, 2002, p.34)

recognised in a *sui generis* system. Such a system could make the validity of patents dependent upon proper disclosure and could factor in costs of finite environmental resources which are renewable and regenerable as well as recognise costs of endogenous growth with exhaustible natural resources (Dasgupta and Heal, 1979; Sagoff, 1988).

IV. The Economics of Bioprospecting

Biological resources are, *inter alia*, economic goods and include valuable traditional knowledge. Prospectable Biological Resources comprise two categories: organic resources and informational resources. The availability of organic resources depends on maintaining biodiversity of the biosphere in three important respects: genetic diversity within a species, species diversity within an ecosystem, and ecosystem diversity within a habitat. Biotechnology, genetic engineering techniques and the commodification of biological resources have increased the potential value of bioprospecting because scientific advances enable us to isolate, identify and synthesise lifeforms which can provide a rich source of new building blocks not only for medicines but also for dyes, colourants, perfumes, chemicals, pesticides, biosensors, bioelectronics and biochips.

Bioprospecting may be viewed as being only partly concerned with harvesting tangible organic material for genetic manipulation or for extracting and exploiting the information provided by the organic material. A second source of informational resources are compilations of information in the form of publications, databases, gene banks on the basis of which bioprospectors can learn about phenotypes (observable characteristics of life forms) and genotypes (genetic composition of life forms) and use or maintenance of organic resources. A third source is ethnobiological knowledge, an important conveyor of experience based on direct experience of natural systems because the chemical arsenals of plants represent more than 300 million years of evolution of ecologically active compounds and industries need information which could convert organic resources into a usable form in a market economy (Suthersanen, 1999, p.54).

A key function of cost-benefit analysis is to predict patterns of economic activity and resource use through comparisons of inter-temporal net present values. If eco-systems

are treated analogous to markets, sustainable development must imply limits on the exploitation of resources linked to feasible investments that would at least maintain the quality and quantity of resource flows over time. Suthersanen (1999) raises an important question in this context by asking aloud whether biological resources should be treated as private goods or public goods ? This question is not easily answerable because free goods also have social costs. Some form of licenses/permits, taxes, cess or fees to be paid by bioprospectors are widely regarded as necessary to compensate for the social costs of bioprospecting. This is something that national authorities can statutorily institute and would merely be a new form of Pigouvian price correction[8].

The prospect of estimating a value by assuming a ceiling on the amount of available knowledge from within a given territorial area or pricing each unit of knowledge in such a situation tantamounts to creating a new currency if such knowledge could be a store of value as well as a medium of exchange, besides being a unit of reckoning for accounting purposes[9]. This aspect also arises in the context of works of art, music, cinema where schemes are based on property rights, which is a well-established Coasian way of removing externalities and dealing with the problem of social costs (Coase, 1960; Demsetz, 1967). In several areas of commons pricing concerning the environment, property interests have been successfully created in pollution rights which are priced and traded in auction markets and through brokers. This interaction of demand and supply that sets prices (positive prices and negative prices) in a market is not easily reproduced in a community of holders of traditional knowledge unable to show an opportunity cost for the labour of communication between transmitters and recipients of information because an activity would not normally be regarded as production without the foregoing of some priced resource. The implicit quasi-proprietary rights in knowledge in the form of trade secrets may be impossible to realise as a rent premium component of wages as is

[8] Pigou (1932) had postulated that externalities can be removed through corrective taxes noting presciently for his time that in complex private transactions overarching authority of territorial jurisdiction would be desirable.

[9] This thought first came up during a discussion with Arvind Virmani when he wondered aloud whether the functions of a system would be better understood by evaluating the roles of institutions responsible for its functioning such as in the case of a monetary system which led us into examining how these three functions of a currency get fulfilled is more revealing about the state of the monetary system and therefore also more relevant when new currencies or quasi-currencies are being postulated.

commonly the case in recognised professions where skills are systematically invested in for years before a professional practice commences. In such situations, the knowledge resources may be imputed onto the tangible organic resources themselves as was done in the case Franklin v. Giddins (1978 Qd. R.72) where the defendant was deemed to have obtained the trade secret of propagating nectarines when he stole budwood from the plaintiff's orchard.

Whether the better policy choice would be that professional services be loaded onto goods in bundles of traditional resource rights in local communities or whether the notion of intellectual property should somehow be expanded to recognise professional services of traditional ethno-biological communal knowledge holders remains to be settled. Even if a perpetual non-extinguishable communal right could be created by a *sui generis* system, the solution found would need to cater to another contingency viz. that ethno-botanical informational resource rights might not be naturally demarcable into single regions and some knowledge may already be held in use by more than one community in more than one country. Is the right to be compensated for professional services to be conferred on the first group to claim the property right or on all groups? If the requirements vary between two or more groups, bioprospectors would tend to strike a deal with the more lenient group which would simply lead to a competitive race to the bottom for everyone.

Suthersanen (1999, pp72-73) points out that a deal struck between an indigenous group and a bioprospecting firm "valued at the price of training the people of the group, providing technical support, a trust fund, a scholarship program and a grant back or royalty-free licences for patented products developed and fees for collection of resources" taken together may cover short term cost advantages gained by a bioprospector but still be insufficient to develop that country's own research and biotechnological industry." Implementation of the CBD provisions would solve this but the CBD has not yet been ratified by many countries, which also include U.S.A. While nothing prevents countries from adopting the CBD provisions into national legislation, cross-border aspects would be governed by WTO, not CBD.

The main problem to be solved in the economics of bioprospecting is that while it is certain that certain kinds of knowledge produced through bioprospecting will eventually increase the productivity of resources used, the use of the resource can be classified neither as a cost nor as an investment without knowing whether the end-result is going to be some viable product or a saleable parcel of knowledge.

V. The Care and Feeding of Ideas

In the biotechnology (BT) industry, resources acquires value when ideas are cared for and cross-fertilised through an incubation process where several parties work together in a climate of relative trust or under cross-licensing contracts. The tacit knowledge of therapeutic processes and the incubation such knowledge requires are fundamentally different from the linking of disembodied skills in the IT industry. If indigenous communities are the nurseries for the care and feeding of traditional knowledge, science parks are the nurseries where discoveries are confirmed and inventions made with more advanced tools.

There is no reason to provide incentives only to science park communities and not to indigenous communities but recognised forms of incorporated collective identities represented in science parks have no equivalent in forms of collective and communal expression[10]. Indigenous communities could be helped to undertake or collaborate in biological research utilising traditional knowledge and practices and they could also be helped to learn contemporary methods and techniques that would develop their knowledge base and economic livelihood possibilities. Yet to relate to them on their terms would require at least the understanding that knowing a song or a herb cure or a piece of folklore may also have some other significance for indigenous communities in whose understanding such knowledge carries responsibilities to show respect to and maintain a

[10] The failure of communal interests to be recognised in intellectual property rights cases in Australia such as Yumbulul v Reserve Bank of Australia (1991 2 IPR 481) and Milpurrurru v Indofurn Pty Ltd (1995) 91-116 CCH AIPC 39,051) is in sharp contrast to judgements of the Constitutional Court in South Africa in State versus

Makwanyane (SA CB 6th June1995) which upheld the notion of "ubuntu" (people's relatedness) as a more important value than personal property, in the context of the right to life) and judgements of the Supreme Court of India which upheld the precedednce of Directive Principles of State Policy over property as a fundamental right and further equated economic death with death itself.

reciprocal relationship with plants, places, humans, animals with which the song, the herb cure or that piece of folklore are connected.

The CBD's failure to institute any global system by which to value organic and informational resources, particularly the lack of any provision for trans-border assessments or dispute resolution has resulted in a situation where the competitive advantage capturable through economic rents by resource-rich countries can be nullified through indirect subsidies to bioprospecting as in the case of the Australian smokebush. In this case, Australia's Conservation and Land Management Act, as amended to introduce conservation as a feature, enables denial of the use of smokebush to the aboriginal people who first discovered its therapeutic application. The constitutional guarantee to native land title rights is thus interpreted narrowly to imply "everyman's rights" of hunting, gathering and fishing in areas where the native title has not been extinguished but the right to exclude commercial prospectors from hunting, gathering and fishing is not available to the indigenous communities. A commodified global commons with commercial enclosure and privatisation of all ecosystems and all the knowledge that makes up earth's living space, physically and intellectually is a frightening prospect (Wiener, 1950; Suthersanen, 1999, p.81).

Numerous groups of indigenous peoples from all across the world have made countervailing moves to assert their right to discover and make what they consider appropriate use of new knowledge derived from their habitat. Three main planks of new laws to promote biological resource innovations which could equitably balance indigenous community interests can be identified:

1. Heritage legislation which would recognise biological and cultural heritage as inextricably linked and provide authorities and incentives for community self-management initiatives.

2. Biodiversity conservation and national biodiversity registers linkable at some stage to global registers together with a transparent system of transfer of

biotechnology and organic and informational resources under different kinds of permissible arrangements with prior informed consent and participation of indigenous communities enabling them to choose from different kinds of structurable economic incentives.

3. Institution of plant varieties' protection and farmers' rights under a *sui generis* system after reviewing the accessibility of *ex-situ* collections in genebanks and germplasm banks for food and agriculture and then extending the model, *mutatis mutandis*, to healthcare based on community control of *in situ* and *ex situ* collections, including decisions of what is allowed to be preserved *ex situ* and under what conditions.

Traditional knowledge evolves in communities as a living tradition but storing it in *ex situ* collections fixes it temporarily as information, and its value as information depreciates rapidly unless it is updated. Secondly, knowledge holders and their communities divorced from their heritage would perish just as knowledge without holders to practise it can be lost. Thirdly, documenting traditional knowledge is unauthorised without prior informed consent of the holders of such knowledge who are generally treated as "informants" by "experts" who make retrievable databases. Fourthly, it is irresponsible to engage in an action that may reduce the world's flow of knowledge even if it temporarily increases digitalised information stored as zeros and ones (Mathur, 2000). It is noteworthy that representatives of indigenous peoples attending the Workshop on Traditional Knowledge and Biodiversity organised by the Secretariat of the Convention on Biodiversity in November 1997 demanded a moratorium on the registering of traditional knowledge.

A pertinent question that therefore deserves to be researched is why indigenous groups are opposed to recording or registering traditional knowledge and how recording or registering traditional knowledge affects the market for innovation and particular rights to income or property.

VI. Rights of Traditional Knowledge Holders

Three well known cases of biopiracy in the 1990s are worth recapitulating**.**

The European Patent Office granted Patent No. 436 257 B1 to W.R. Grace and Company for their "discovery" of fungicidal effects of neem oil. The patent was challenged by the Government of India through its Council of Scientific and Industrial Research on grounds of it being part of India's traditional knowledge. The patent could not be maintained for lack of novelty and inventive step and the European Patent Office annulled the patent through a judgement in September 1997. In this case, the challenge to the patent on behalf of the traditional knowledge holders succeeded because there was a record of the traditional knowledge being known and used in India. Had the European Patent Office been required by European Law to take into cognisance only that prior art which is published within its own jurisdiction, the outcome of this case could have been different.

For this reason, the second case is more insightful. An American patent was granted to the University of Mississippi Medical Center for the use of turmeric in wound healing. Had this happened due to the ignorance or negligence of the patent examiner, there might be a lesson to draw that traditional knowledge should be packaged to be brought within the scope of codes perused by patent examiners who cannot possibly be expected to know everything from everywhere. In the instant case, the application itself admitted that turmeric had been used as a traditional medicine in India. The challenge to the patent was mounted on the basis of an ancient Sanskrit text that attested to the non-contemporary nature of the knowledge held in the public domain for a long time. A paper published in 1953 in the Journal of the Indian Medical Association was further cited as proof of "prior art". However, patent examiners in the U.S.A are not required to accept evidence of traditional knowledge held outside U.S.A as prior art. This patent could not have been struck down by claiming "prior art", had the patent application been made more cleverly. The patent was cancelled only because of the failure to demonstrate novelty in the patent application itself.

In another case, such novelty was written into the patent application when an American patent was granted to Sarah Ward and Pat Mooney of Colorado State University for a highly nutritious drought-resistant Andean food crop species Quinoa (*Chenopodium quinoa*) indigenous to Apelawa, Bolivia and Peru based on a claim that a reliable system of cytoplasmic male sterile plants had been derived from the Apelawa variety of quinoa that would make the labour intensive removal of anthers from plants unnecessary in the breeding of hybrids. An international campaign by Bolivia's National Association of Quinoa Producers on behalf of Andean farmers who held this traditional knowledge and had been exporting such quinoa to the United States for decades led to the abandonment of the patent (Dutfield, 1999). Had the claim of the patent been narrower, it could have been sustained.

In each of these cases, the rights of traditional knowledge holders were affected and it is difficult to be satisfied with the remedies which were costly and uncertain. If someone improves a piece of traditional knowledge and establishes novelty within a narrow range, novelty would be satisfied and the owner of the patented property be under no legal obligation to share any part of the profit gained with the original holders of that traditional knowledge. This is the main reason why *sui generis* systems are needed to reward the caring and feeding of ideas at source.

Many developing countries did not benefit when biological resources were the common heritage of mankind. Therefore, new Biodiversity laws in developing countries make `prior informed consent' of the government a pre-condition to the export of biological resources. For the risk of regulatory capture to be reduced, such schemes should require prior informed consent of local self-governance institutions too. The experience gained from the People's Biodiversity Registers (PBR) Programme administered by the World Wildlife Fund could enable elected local community councils to serve as repositories who may charge fees for access to the PBRs. This way, elected local community councils, their village constituents, constituted trusts and individuals would all be eligible for seeking different kinds of claims to their knowledge. The

requirement to disclose the source of genetic origin would be verifiable under the PBR system. The PBR system is presently under experimentation in parts of India.

Local innovations databases can also be held communally. An example of this is SRISTI's honey bee database in Ahmedabad which has registered more than twelve thousand grass-root innovations to date. Another policy choice worth examining is whether designed digitalised databases of traditional knowledge can be shared among patent offices without the requirement of disclosure so that negative rights to international non-patentability are quickly established and time gained to institute a system of positive rights for holders of traditional knowledge. The database solution appeals strongly where the traditional knowledge is already diffused beyond indigenous communities or published, especially when there are no particular owners alive except the State, by default as the proprietor of all unclaimed heritage. This could also help towards the creation of some kind of a global registration system on a multilateral or plurilateral basis. There are significant risks in keeping database information "undisclosed" because that would not deter patentability which depends more on how different patent offices deal with admissibility of foreign prior art and raise or lower barriers for interpretation of what constitutes novelty.

VII. SUI GENERIS SYSTEMS ?

The TRIPS agreement is the most important development in international intellectual property law because it was made as an Annex to the WTO Agreement bringing intellectual property under the rubric of trade for the first time. TRIPS has subsumed the international intellectual property regime created in the 1880s based on the Berne and Paris Conventions by providing for administrative and judicial enforcement of IPRs and border control of trade in infringements. This development was regarded necessary because of the perceived toothlessness of the Paris and Berne Conventions and the inability of WIPO to modify the Paris Convention. The resistance of developing countries led by Brazil and India based on the contention that intellectual property rights were the sole province of WIPO becauset GATT could be concerned only with trade in tangible goods wore thin when the General Agreement on Trade in Services (GATS) was

negotiated under sustained U.S. pressure of unilateral action under Section 301 of the U.S. Trade Act. against India, Brazil, Thailand, China, EU and Australia that were placed on the "priority watch list". Tariff exemptions for Indian pharmaceutical products under the Generalised System of Preferences were revoked in 1992. The U.S also criticised the Dunkel Draft for providing too long a transitional period to developing countries with regard to pharmaceutical patents. The Preamble to TRIPS heralded the demise of WIPO as the leading intellectual property agency by stating the desire of WTO Members "*to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade*"

The appellation "trade related" limits the application of TRIPS to copyright protected works and industrial property produced in commercial quantities but the concept of industry covers agriculture, fishing and extractive activities. Although IPRs are generally distinguishable from rights under know-how agreements, there is no system for registration of know-how despite the fact that IPRs cannot be effectively utilised without substantial quantities of know-how. Breeding techniques are patentable, if the technique is repeatable [since the Rote Taube (Red Dove) Supreme Court Decision in Germany in 1969 [1970 I IIC 136] and in U.S.A. since the Supreme Court Decision in Diamond v Chakrabarty case [(1980) 206 U.S.P.Q 193; 447 U.S. 303] when the court ruled that genetically engineered bacteria were patentable] because the criteria of patentability is not whether an invention involves living matter or inanimate matter but only whether it involves a human-made invention. This logic is now enshrined in the patentability of life forms in TRIPS.

UNESCO is left with no role in intellectual property matters after U.S.A. left UNESCO to join the Berne Convention [11]. Therefore, the Model Conventions UNESCO developed and the academic discussion on these within its portals has left no working

[11] UNESCO had a say in copyright matters only because U.S.A was not a signatory to the Berne Convention and had sponsored an alternative Universal Copyright Convention to be administered by UNESCO

legacy. Moreover, Article 9 of TRIPS refers to the Berne Convention administered by WIPO and redefined it by excluding moral rights under Article 6 bis of the Berne Convention from TRIPS. Further, under Article 10.2 of TRIPS, copyright protection accorded to databases as compilations of data does not extend to the data or material itself. This registration and recording of traditional knowledge in databases is worthless from the perspective of being rewarded for drawing attention to prior art unless it be a disclosure as part of a registerable claim. The silence of the TRIPS agreement on any specific scheme of protection for appellations of origin, after considerable discussion on whether to incorporate the scheme provided for in the Lisbon Agreement suggests that the TRIPS regime has also superseded the protection contained in these earlier instruments.

UNCTAD, founded as an organ of the UN General Assembly in 1964, remained focussed on transfer of technology issues and developed a voting pattern based on blocs: Group A comprising developing countries of the Afro-Asian Region and Yugoslavia, Group B of Western Industrialised Countries, Group C of Latin American Countries and Group D of Socialist Countries. This bloc pattern of working spilled over to WIPO but of these groupings, only Group B retains its coherence. The creation of WTO as a specialised agency of the UN armed with adjudicating authority has marginalised the role of UNCTAD although the establishment of such an organisation as WTO formed no part of the Ministerial Declaration at Punta del Este that launched the Uruguay Round of Trade Negotiations in 1986[12]. TRIPS endorses the catalogue of prohibitions of restrictive trade practices identified by UNCTAD in its Transfer of Technology Code. It remains to be seen how Articles 7 and 8 of TRIPS will be interpreted by dispute panels when it comes to questions of compulsory licensing, parallel imports and national or international exhaustion of IPRs.

[12] The formation of a multilateral trade organisation (MTO) was proposed by the EC in 1990 after the EU had been mooted and at a time when Group D countries were in disarray. The Dunkel Draft of 1991 was the first formal circulation of such a proposal and caught many Group A developing countries unawares. Some developing countries remained under the erroneous impression that the veto they possessed in GATT was sufficient clout to block an MTO or TRIPS if it were to weigh against their interests and failed to note that GATT was being unsubscribed from and would have no members left when WTO was opened for signature with TRIPS as an Annex.

TRIPS is a done deal. A search for improvements can be pursued only through a review of TRIPS as provided for in Articles 27.3 (c). and Article 71 of TRIPS or by interpreting the minimum standards of intellectual property protection that TRIPS obliges member countries to observe as the maximum national standards required since members are not required to grant more extensive protection than that and are free to determine the appropriate method of implementing the TRIPS provisions within their own legal system and practice. A particularly prickly problem arises from Article 70.8 of TRIPS which requires that the means that must be made available for processing of pharmaceutical product patents must adopt the criteria for patentability laid down in TRIPS notwithstanding the transitional provisions which allow developing countries time to introduce their TRIPS obligations. If Article 27.3 (b) is read carefully, it is also obvious that if and when plants and animals could be produced by non-biological and microbiological processes, they would not be excludable under the permitted exclusions from patentability. The enabling proviso of Article 27.3.(c) permitting members "to provide for the protection of plant varieties either by patents or by an effective sui generis system" is therefore not easily implementable. However, the possibility that patented products may be put on the market through non-sale transactions and countries are free to create *sui generis* systems for rewarding the caring and feeding of ideas opens some new doors.

Conclusions

Traditional knowledge does not lend itself easily to concepts of property in any form of known IPRs. To hail it as *sui generis* is inadequate without a system of use rights and obligations that can be created and operated at least at a national level. It is doubtful that an international *sui generis* system can be instituted without first constructing national *sui generis* systems although it would be useful that international guidelines be agreed upon so that at some stage the national systems created may be harmonised. With China having opted to bring traditional knowledge under IPR ownership, the main initiatives for *sui generis* systems appear to emanate from Peru, Egypt, Brazil and India. The question of who are entitled to seek protection of which forms of traditional knowledge and who may confer recognition and status on the holders of traditional knowledge in a *sui generis*

modality raises a number of policy questions about the role of communities and functions of communally held knowledge in traditions that are part of heritage and culture as well as living traditions of habitat preservation and human interactions. Policy questions also arise about the structuring of economic incentives, about rights and obligations that are anchored in responses and behaviour rather than in resources. Questions of valuation are vital to the sharing in value-added and the role of private and public investors organised as nationally networked or globally networked bioconservors and bio-collectors needs to be examined. Mere digitalisation of published or codified information to ease the work of patent examiners cannot resolve the question of how holders of traditional knowledge should be rewarded for their care and feeding of ideas. The attention accorded to traditional medicine could be a way of identifying characteristics also for other kinds of traditional knowledge and folklore that concern living communities at risk of being dislocated from their past traditions, their present habitats and their future of inter-generational continuity of life itself.

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