WIPO-UNEP STUDY ON THE ROLE OF INTELLECTUAL PROPERTY RIGHTS IN THE SHARING OF BENEFITS ARISING FROM THE USE OF BIOLOGICAL RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE

Jointly produced by
the World Intellectual Property Organization (WIPO)
and
the United Nations Environment Programme (UNEP)

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Study nº 4

This is one of a series of Studies dealing with intellectual property and genetic resources, traditional knowledge and traditional cultural expressions/folklore

UNEP

WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

WIPO is a specialized agency of the United Nations system of organizations and has its headquarters in Geneva, Switzerland. Its mandate is the promotion of the protection of intellectual property throughout the world through cooperation among its 180 Member States and, where appropriate, in collaboration with other international organizations. WIPO implements this mandate by, *inter alia*, administering various multilateral treaties dealing with the legal and administrative aspects of intellectual property. In 1998, WIPO established a program on global intellectual property issues to explore, *inter alia*, the intellectual property aspects of biodiversity and biotechnology, and the protection of traditional knowledge. This Study was commissioned as part of that program. Following the initial, exploratory work of the global intellectual property issues program, the WIPO General Assembly decided, in 2001, to establish an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the Committee). Currently, this Committee provides the main forum in WIPO for discussions on intellectual property aspects of access to genetic resources and benefit-sharing and the protection of traditional knowledge. The Committee has generated a significant amount of substantive material on intellectual property aspects of genetic resources and traditional knowledge. This Study should therefore be read in conjunction with that material.

UNEP is the overall coordinating environmental organization of the United Nations system. Its mission is to provide leadership and encourage partnerships in caring for the environment by inspiring, informing and enabling nations and people to improve their quality of life without compromising that of future generations. UNEP works to observe, monitor and assess the state of the global environment, and improve our scientific understanding of how environmental change occurs, and in turn, how such change can be managed by action-oriented national policies and international agreements. UNEP's work concentrates on helping countries strengthen environmental management in diverse areas, including the conservation and sustainable use of biodiversity, marine and coastal ecosystem management, freshwater and land resource management, and cleaner industrial production and eco-efficiency, among many others.

Foreword

This Study was produced by the World Intellectual Property Organization (WIPO) and the United Nations Environment Programme (UNEP). It reflects years of cooperation between these two specialized organs of the United Nations to ensure that environmental policy and intellectual property policy are developed in a coordinated and mutually supportive manner.

The objective of the Study is to identify and explore the role of intellectual property rights in the sharing of benefits arising from the use of biological resources and associated traditional knowledge. The Study was commissioned in response to Decision IV/9 of the Conference of the Parties to the Convention on Biological Diversity (CBD). The subject of the Study – intellectual property rights and benefit-sharing in respect of biological resources – became even more topical when the World Summit on Sustainable Development (WSSD) established a commitment to negotiate "an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources". (WSSD Plan of Implementation, paragraph 44(o)). In particular, it is hoped that the Study may provide lessons relevant to the role of intellectual property rights in the implementation of Articles 8, 10 and 15 to 19 of the CBD and in the implementation of various WSSD commitments.

A pre-publication version of the Study was made available by UNEP and WIPO to the Ministerial Meeting at the Seventh Meeting of the Conference of the Parties to the CBD, held in 2004 in Kuala Lumpur.

Access and benefit-sharing systems aim to promote scientific and technological breakthroughs from the use of microbial, plant and animal genetic resources, while at the same time recognizing the contributions and rights of those who cultivated and preserved these resources, or have come to understand their uses. The judicious and effective use of the intellectual property system has a vital role in achieving the goals of equitable access and benefit-sharing. The patent system, for example, recognizes innovations based on genetic resources and provides a framework for investment in the development of valuable new products and processes. It therefore offers the potential to yield the desired benefits from access to genetic resources. Making sure these benefits are shared equitably with the custodians of genetic resources and traditional knowledge is a key challenge.

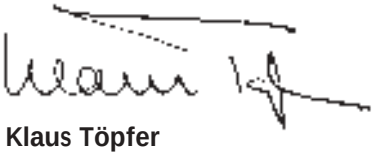
The Study highlights the need, when genetic resources are first accessed, for a clear understanding of intellectual property issues. Agreement on how intellectual property derived from access is used and how the benefits are shared is an important part of the exercise of prior informed consent, and an important, practical way of ensuring that access and benefit-sharing is fruitful, equitable and mutually agreeable, and becomes a true partnership between custodian and user of the genetic resource.

This is well illustrated by the three case studies which form the core of the present work. For example, the case study relating to a wild rice gene from Mali which was found to be resistant to bacterial rice blight, one of the most damaging rice diseases, shows how voluntary benefit-sharing agreements need to be improved to ensure that the custodians of genetic resources and traditional knowledge are better rewarded. The genetic code from the wild rice was sequenced, cloned and patented in 1995. Between the original access to the Malian genetic resource and the patent application a chain of innovation and value-addition took place which literally spans the globe: A rice specimen was originally accessed in Mali and transferred to a rice research program in India, where its resistance to bacterial rice blight was identified. The blight-resistant specimen was transferred to the International Rice Research Institute (IRRI) in the Philippines, which determined that the resistance was coded by a single locus called Xa21. The Filipino experts bred the resistance into cultivated rice varieties by

conventional plant breeding methods. One such variety was then acquired by the University of California at Davis, where gene Xa21 was mapped, sequenced and cloned. After a patent application was filed and granted for the cloned gene, a Genetic Resource Recognition Fund (GRRF) was established at UC Davis to share with the stakeholders in Mali and other developing countries the benefits arising from the commercial utilization of the patented gene. The plant, in which the disease-resistance gene was found, is considered a weed by many Malian farmers, but for the displaced peoples of the Bela community it is one of their staple foods and its stalks are used for many purposes. The case highlighted the fact that the Bela people received no formal recognition with the benefit-sharing arrangement as holders of detailed traditional knowledge and as primary conservators of this disease-resistant variety of wild rice.

It is hoped that such practical examples and the lessons that can be learned from them will make this Study a useful tool for policymakers and a wide range of stakeholders as to how the effective protection of intellectual property rights can support the conservation and sustainable use of biodiversity, as well as the equitable sharing of benefits arising from the use of biological and genetic resources.

Kamil Idris
Director General
World Intellectual Property
Organization (WIPO)



Klaus Töpfer
Executive Director
United Nations Environment
Programme (UNEP)

Acknowledgements

I have earned the gratitude of several institutions and individuals while pursuing this study. The enormous patience by colleagues at WIPO has to be appreciated at the outset. It is true that the goals of this study did get transformed during this period and that required some extra effort. However, the incorporation of many more issues and perspectives may have added to the relevance of this study. Readers will have to judge whether justice has been done to various viewpoints and perspectives adequately.

The objectivity in social sciences is suspect. The only thing that a researcher can honestly do is to make one's biases explicit. Readers would find that I am quite biased in favor of defending the intellectual property rights of creative individuals and communities. The only resource in which poor people are rich is their knowledge. Fourteen years ago when Honey Bee Network started, it became obvious to us that the IPRs of the peasants had to be protected. This sentiment has been expressed for the last thirteen years on every page of Honey Bee newsletter. And this was much before TRIPS or CBD had created popular consciousness on this subject. I am aware of lot of critics who believe that IPRs are instruments of control and domination by large corporations. That might have been the case. However, I am convinced that with suitable improvements and substantial changes, IPR system can serve the interests of creative people all around the world. I also believe that the Linux philosophy does provide a fruitful way ahead. If people use a particular knowledge for their own livelihood or survival, the inventor should not object. But if somebody tries to commercialize an innovation, then licensing must be obligatory. Just as we have researchers exemption in Plant Variety Acts, we may have to have survival exemption in the patent laws.

Dr. Shakeel Bhatti, Mr. Richard Owens, Mrs. Faith Odibo, Mrs. Phyllida Middlemiss, and Dr. G. Jaiya, at WIPO deserve particular thanks for considerable support during this study. Comments and suggestions from Shakeel were most valuable and in many cases have added enormous value to the quality of the study. There is no doubt that without his constant prodding and helpful chidings, this study would not have been completed.

I must thank large number of creative people and professionals, community members and elders I met in Mali, Nigeria and India. The senior researchers at University of California, Davis were also very helpful.

I plan to send a copy of this study to all the individuals who collaborated in this research and request that a summary in local language be sent to the committee members. I hope when they read this study, they would find their concerns faithfully articulated and interests earnestly defended.

Nigeria

Dr. Morris Iwu, the founder of Bio Resources Development and Conservation Programme provided enormous help in all the logistics for pursuing study of his very innovative experiment in benefit sharing. I must also express my thanks to Prof. Wambebe, Mr. Cosmos Obalor, Prof. Komba, Chief Dr. Omo Tosho, Mr. Kent Nnadozi, healers Mr. Alaneme Duru, Mrs. Osebi Lillian, healer Mrs. Azijah, Mr. Letusogu, farmers Mr. David Dike, Mr. Johnson Lereneous, and various members of Umowere village. In addition, Katy Moran and Stephen King of Shaman Pharmaceuticals and Dr. Bankole Sodipo deserve appreciation for providing very useful insights and materials.

Mali

The case on accessing gene Xa21 became possible through the extensive help of Dr. Pamela Ronald, University of California, Davis who had set up the first voluntary benefit-sharing fund viz., Genetic Resource Recognition Fund (GRRF). She helped me meet with different senior researchers dealing with gene bank of UC Davis, as well as others who influenced this process. Most notable was Prof. Stephen Brush, who has written extensively on the subject. He helped Dr. Ronald to set up the GRRF and, together with Dr. Ronald, tried, in vain, to persuade the university authorities to make contributions to the GRRF from all university research using third world germplasm. Prof. Kevin M. Smith, Vice Chancellor (Research) at UC Davis was very generous with his time and arranged meetings with several other colleagues in his office. It is a different matter that I failed in persuading him to have at least inter-campus dialogue on this praiseworthy model of benefit-sharing. I must also thank Prof. Coulsett, an eminent wheat breeder, Dr. Charles Ricks and several other scientists at UC Davis, who helped in getting information and insights for the study.

The wild rice from which the gene in question was taken was obtained from Mali. I must thank Dr. Bino Teme, Scientific Director, Institute of Economic Research (IER), who is in charge of agricultural research in Mali, Dr. Teme, and Mr. Dond Kone, Farming Systems Research Team leader at the Niono Research Center of IER.

My stay and interaction with local researchers was facilitated largely through the hospitality of Dr. M Diawara, heading a Centre for Indigenous Knowledge in Mali. Dr. Magassa helped to develop my understanding of the Tehlarger historical context in which knowledge systems from different parts of Mali evolved and interacted to generate niches of various kinds. I must also thank Mrs. Aisse Toure, and many other participants in the local seminar that I presented about the objectives of the study and its possible implications for international policy. Dr. M. K. Nidia Ye, Soil Scientist, and Mr. Ydounbia, Agronomist, provided additional information about Oryza longistaminata and deserve my thanks. Mr. S. Sala, a weed scientist, provided valuable insight about use of this wild rice as a food in the past, though it is considered a weed at present. I also met many farmers such as Mr. Okesamaki, Geneva Aia Ho, Ms Aminata and her grand-daughter, Ms Geneba Dialli, Ms A Coulabally, and farmers of Sasrakalla, Nanco, Niano, Senawal, Musawere villages and express thanks for their kindness and patience with my questions. As I mentioned in the case, I made sure that in every village, the purpose of study was disclosed and the respondents were encouraged to ask questions about myself, my work, background, study and my life in general. It was very interesting to learn many things about cross-cultural perspectives through such exchanges.

Dr. Gary Toenniessen, Director, Food Security, Rockefeller Foundation deserves thanks for answering several of my questions about the responsibility of Rockefeller Foundation in the matter.

India

Dr. Pushpangadan, Director, National Botanical Research Institute, Lucknow deserves my most grateful thanks for sharing many moments of anguish and anxiety that he had to go through while pursuing this unique model of benefit-sharing with local Kani tribal community. His deep insights about various technical, as well as social aspects of developing this model will need separate treatment to do justice. I have drawn upon only the essential elements of the story here. I am also thankful to Ms Anuradha who had done an earlier case study on the subject and to Dr. Rajshekaran at TBGRI who collaborated with Dr. Pushpagadan and who was very

helpful in sharing his side of the story, as well as in organizing logistics for field visit. I thank colleagues at Arya Vaidya Shala, Vivekanand Research Centre, State Forest Department and TBGRI, including its present Director, who all were very helpful in this study.

The warm understanding and interactions with Mallan Kani, and Eachen Kani and other members of their community was one of the high point of the study. Discussions with the members of Kerala Kani Samudaya Kshema Trust and residents of Kallar Mathammodhu settlement were very helpful. I also appreciate the excellent research assistance from Pradeep Singh in this study.

I am grateful to Dr. R. A. Mashelkar, Director General, CSIR and also Chairperson, National Innovation Foundation, for sharing a very valuable communication from USPTO with me, apart from many other insights in the matter. Inspirations from him have helped in sustaining the work in Honey Bee network, and making the dream of establishing a National Innovation Foundation come true.

I must also thank my colleagues Ms. Riya Sinha, Mr. Kirit Patel, Prof. Vijaya Sherry Chand, Shailesh Shukla, Jyoti Capoor, Dilip Koradia, Vijay Pratap Singh, and many others for helpful comments at various stage of the study and evolution of the ideas presented in this study.

I have earned the gratitude of many others while pursuing this study. My secretary Bhaskaran had to handle hundreds of mails on the subject, and organize every detail of travel and other aspects of the internal logistics, and do so many other things all at once, without any mistakes. I cannot imagine completing this study without this help. In addition, my colleagues Mr. R. P. S. Yadav, Bala Mudaliar, Nisha Antony, Unnikrishnan, Kajal, and Devsi Bhai, and several others unnamed ones, deserve thanks.

I am grateful to Prof. J. L. Saha, then Director IIMA, for excellent institutional support.

I also thank my colleagues in SRISTI, GIAN and National Innovation Foundation for making possible every thing that Honey Bee Network has aspired to, and which I proudly recall in this study.

Finally, I must thank my wife, Sadhana, who has kept patience with my long hours at work, and never once complained, realising the claims of those who have shared their knowledge with us and but are still to get their due.

Responsibility as usual, for any inadequacy in the study remains entirely mine and I am alone responsible for any suggestions, interpretations of ideas, and imputations made to various colleagues cited or not cited in the study.

I hope that farmers, tribals and other colleagues in Nigeria, Mali and Kerala, India will feel that their faith in me when they shared their insights with me, has been adequately respected while pursuing this study and drawing various inferences.

Anil K. Gupta

PART ONE: INTRODUCTORY ESSAY

REWARDING CONSERVATION OF BIOLOGICAL AND GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE AND CONTEMPORARY GRASSROOTS CREATIVITY

Prof. Anil K. Gupta

SECTION A
A CONCEPTUAL OVERVIEW OF INTELLECTUAL PROPERTY AND TRADITIONAL KNOWLEDGE

Traditional knowledge (TK) may be produced by individuals, by groups of individuals or by local or indigenous communities. Some of this knowledge may be kept confidential to the originator(s) and their descendants and may be accessed only with restrictions; some may be disseminated locally, but may, nonetheless, be restricted in scope or in terms of accessibility; and some of this knowledge may be shared widely within a community and with outsiders, so that the knowledge becomes public domain TK.[3] The three subsets in Figure 1 (below) refer to these three overlapping domains of TK.

Figure 1 Contested Domains of Local Knowledge

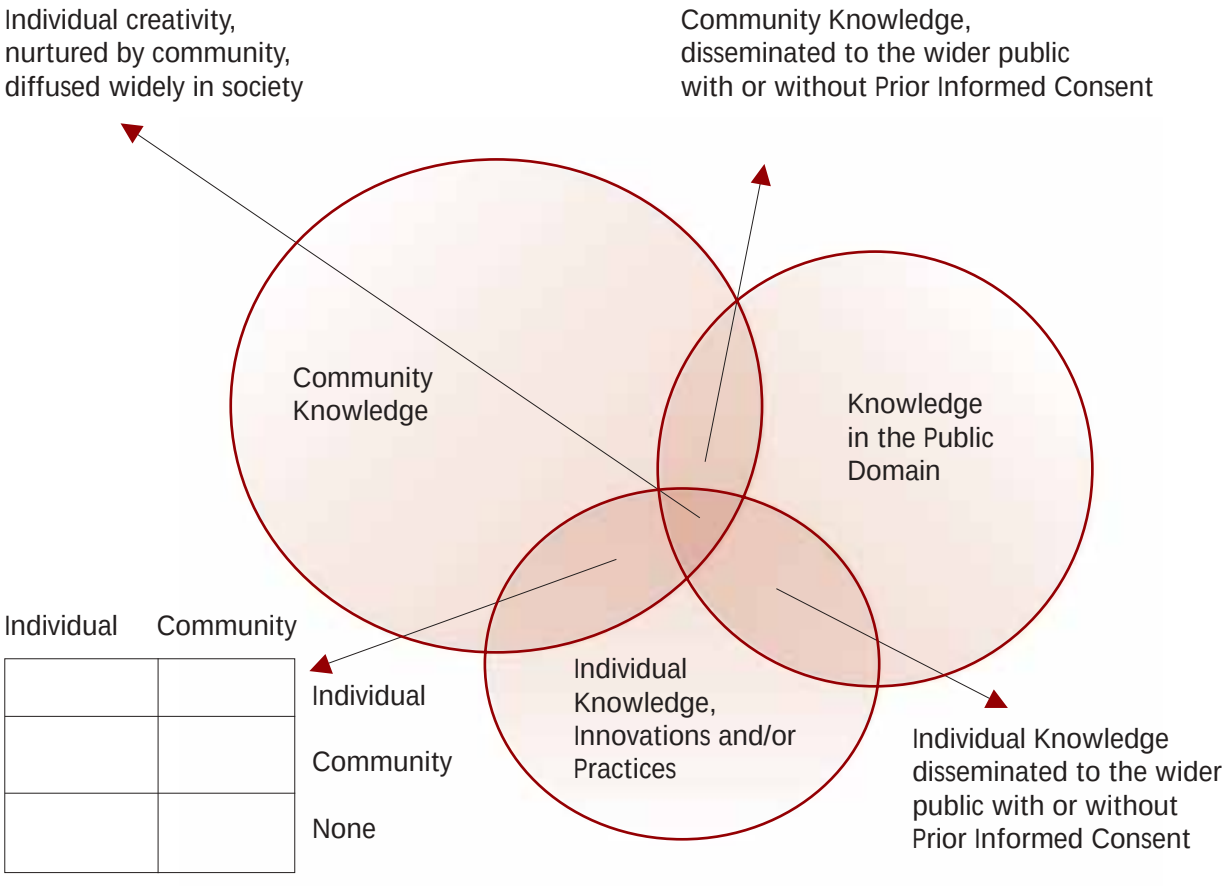


Figure 1. Source: Gupta 2001

Table 1: Contested domain of Knowledge

Private individual knowledge inherited from forefathers	K1
Acquired the skill to practice it faithfully:	
▪ Without modification, or	K1-wm
▪ With modification	K1-m
Individual rights to use the modified and unmodified knowledge according to:	
▪ Same rules, or	K1-sr
▪ Different rules	K1-dr
Knowledge known to the community	K2
Knowledge practiced by individuals if known to individuals	K1-I
Knowledge practiced by individuals if known to community	K2-I
Knowledge practiced by community if known to community	K2-c
Knowledge practiced by community even if details known to individual/s	K1-c
Known to community but not practiced by individuals or community	K2-n
Knowledge known to community and accessible to outsiders	K2-a
Knowledge known to community and not accessible to outsiders	K2-na
Knowledge known to wider public through documentation or otherwise	K3
Knowledge known to wider public and practiced by only few individual	K3-I
Knowledge known to wider public and practiced by wider public	K3-P
Knowledge known to wider public but not yet practised	K3-n

(Own Compilation, Adapted from Gupta, 1999)

Individuals may have knowledge, which they may have inherited from their forefathers (K1), and they may have acquired the skill to practice it faithfully without modification or with modification (K1-wm or m). The individual contribution in modifying TK may be treated according to the same rules as the use that may be made of the non-modified knowledge, or its use and dissemination may be governed by different rules (K1-sr, K1-dr). TK may be known only to individuals (K1), or to the community (K2), and may be practiced by individuals (K1-I, K2-I), or by the community (K1-C or K2-C), or by no one (K1-n or K2-n). In the last case the knowledge may gradually disappear due to discontinued use.

When individual knowledge is shared with the community, whilst the general relationship between, for example, a plant and its uses may be known to the community, the more specialized uses associated with the plant may still be restricted to individual experts; for instance, individual healers who know how to calibrate the dose and combination of herbal drugs according to the condition of the patient. Such an expert may, or may not, be free to share their knowledge, according to the rules of the community, since there may be taboos implying that a particular remedy might loose its effectiveness if revealed to others. Such a taboo leads to erosion of knowledge when such a knowledge expert dies without ever sharing the secret.

By way of illustration, Emmanuel and Weijer (2001) provide an example of an Amish community which can restrict the right of individual members to give consent to participate in certain research processes. In addition, there is a well-known Australian case where an art piece designed by a native individual was printed on a currency note by the Australian Reserve Bank. The community objected to such use because it argued that the individual did not have rights to assign even individually designed work to outsiders without the community's permission, since the art work was conceived after rituals and taboos sanctified by the community (Blackney, 2000).

Further, community knowledge may or may not be accessible to outsiders (K2-A and K2-NA). Different communities may have varying capability to produce, reproduce and practice the knowledge for individual or common good. Some commentators argue that the more widely knowledge is shared, the greater the probability of feedback from large numbers of people, and therefore the greater the opportunity to improve the knowledge. At the same time, the incentives for individuals to improve such knowledge may diminish in view of widespread awareness that they may not receive benefits from such knowledge. Some communities distinguish between rules governing access to biological resources, and rules governing access to knowledge related to such resources. The knowledge within a community is therefore not distributed symmetrically. Such variability not only influences the power differentials but also the extent of efficiency gains that different members of a community make by using the same knowledge differently. The communities benefit from the individual knowledge and thereby revere the local knowledge experts or healers. But this reverence may not be a sufficient motivator to encourage young people to acquire this knowledge and to take it forwards with or without improvement. There may be other factors also, such as public policy, media exposure, life style changes etc., which may affect the incentives for younger people to acquire particular knowledge. However, the point remains that the existing set of incentives may need to be modified if TK has not only to be conserved, but also allowed to develop to deal with life in the 21st century.

The third set of knowledge system includes public domain knowledge (K3), which may be practiced by individuals, or wider public or not practiced by anyone (K3-I, K3-P, K3-n). Ethno-biologists, other researchers and institutions may document individual and community knowledge and bring this into public domain. Some people have argued that even the community knowledge known only to the members of a village community should be considered public domain knowledge. However, in my view, this is not a proper interpretation. From the point of view of protection of IP, knowledge, which is reasonably accessible, can be considered public domain knowledge and part of prior art. However, it is clearly neither fair nor just to bring this knowledge into the public domain without the consent of concerned individuals or communities. What is even more disturbing is the dominant tendency on the part of outside researchers not to share what they have learnt back with the originator(s) of that knowledge after value addition, either at all, or in a local language and in a manner that is easily comprehensible.

The Honey Bee Network[4] has tried to counteract this tendency to leave the originator(s) of TK anonymous, by insisting that knowledge providers, producers and reproducers are expressly acknowledged and attributed as authors and communicators of their specific knowledge. The network also seeks to ensure that whatever is learnt from people is shared back with them in local language(s), so that people to people linkages can be established. In addition, the Honey Bee philosophy requires sharing by outsiders of any gain that may accrue to them from commercial or non-commercial dissemination of the raw or value added knowledge provided by the communities or individuals. We strongly believe in the need to protect IP of knowledge rich, but economically poor, individuals and communities. However, to provide such a protection, one would have to characterize such knowledge in such a manner that the novelty and non-obviousness could be established. This would mean, *inter alia*, a comparison with available formal scientific knowledge. The present instruments of IP can provide some help in this manner, but is limited. However, with modifications, these IP instruments could indeed go a long way to protecting the IP of individuals, as well as of communities. The greatest advantage of this system would be that the people would have incentives to disclose their traditional and contemporary knowledge and make it available to others for learning purposes. *Once this knowledge becomes a basis for livelihood, conservation, lateral learning and social networking, a knowledge society starts emerging. Once this happens the public domain provides incentives, and not disincentives, for individual and communities to share their knowledge after due information*.

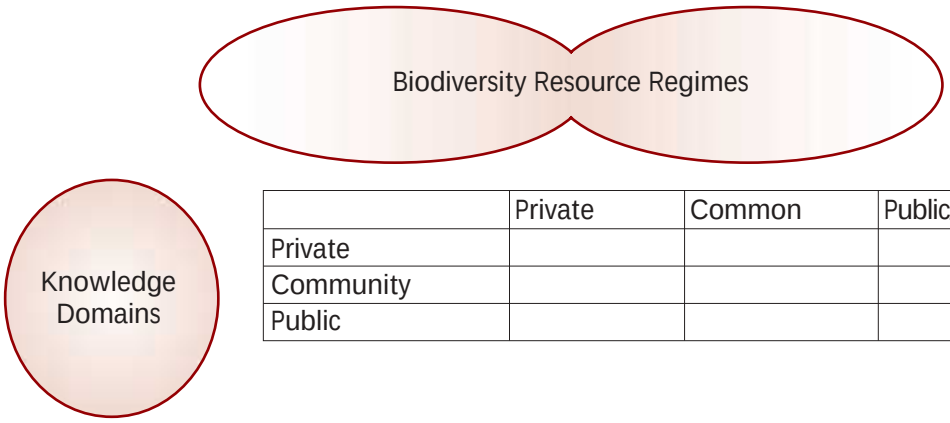
Time Frame for knowledge production and reproduction

There are different triggers, which may lead to a solution. The trigger could be a concurrent need, a continuing inefficiency or an episodic need which manifests only in the period of crisis. In a complex knowledge system, blending of knowledge produced through different triggers over varying periods continually takes place. It is important that while developing IP systems, we recognize the fact that disclosure by people of their knowledge in the recent past should not pre-empt their rights to IP protection. This may require the development of special grace period of, for instance, five years, for TK. This would mean, *inter alia*, that by communicating with outside researchers and institutions, communities would not necessarily instantly lose their rights to claim IP over inventions derived directly from that knowledge.

Right regimes and knowledge domains

We can understand the relationship between different kinds of property right regimes governing biodiversity resources and different kinds of knowledge domains (Figure 2). The knowledge of individuals would be based on plants in his or her backyard, or biodiversity in the common land, or common pond, or biodiversity in public or state owned resources, or in open access areas. The interaction between different knowledge domains and resource regimes needs to be studied carefully, so that different kinds of incentives for conserving different resource right regimes are compatible with the incentives in various knowledge domains. In some cases new kinds of contextual and actual relationships will have to evolve. Situations become more complicated when users from one country access resources in another country. The discussions in the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore demonstrate a detailed understanding of the tensions existing among different countries on the issues of IP and access and benefit-sharing. However, the more difficult and challenging issue of providing incentives within a country for different kind of resource regimes and knowledge domains has not been adequately pursued so far.

Figure 2 Resources: Right Regimes and Knowledge Domains



	Private	Common	Public/State owned	Open Access
Private				
Community				
Public				

Figure 2. Source: Gupta 2001

Transition from natural capital to intellectual property

Natural capital has provided the spur for economic progress all through the history, though its role has varied. Natural capital can be governed by social capital, some of which is also ethical capital (Figure 3).

Figure 3

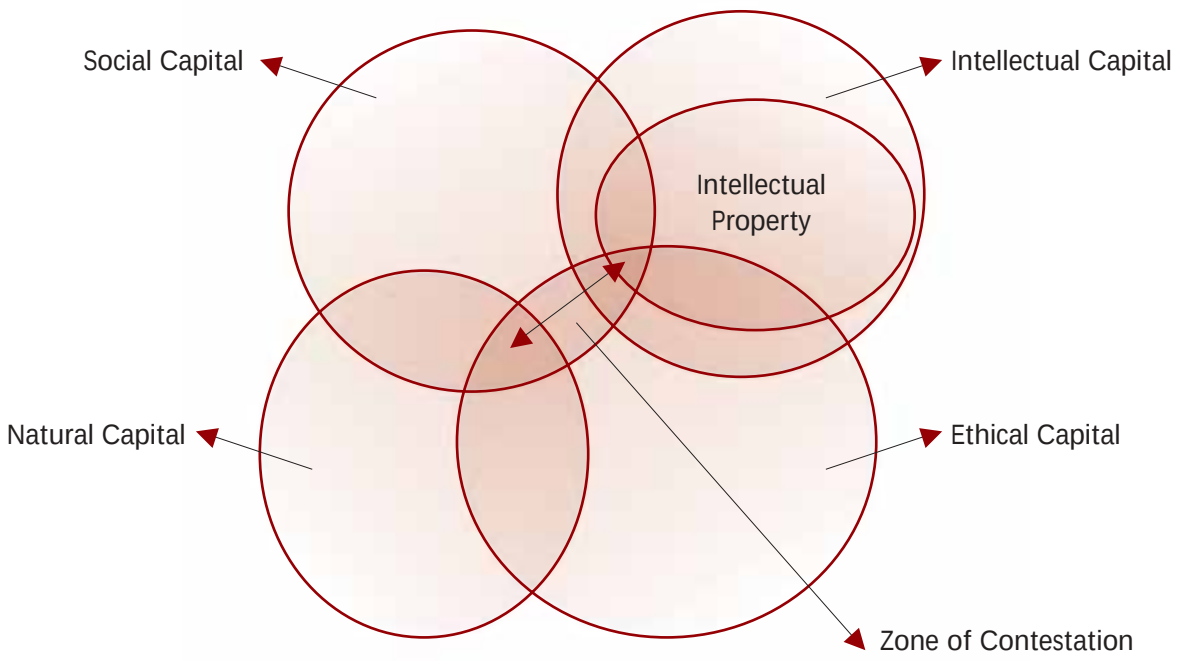


Figure 3. Source: (Gupta 2002, Own Compilation)

Social capital can be defined as community based institutional arrangements, which help in the conservation and reproduction of natural capital: i.e., essentially a trust based community capital. Ethical capital is essentially such investments and institutional arrangements that may be governed by ethical norms of accountability, transparency, reciprocity and fairness to both human and non-human sentient beings. Some of the ethical capital is a sub-set of social capital. When common property institutions follow ethical values, then an intersection of social and ethical capital occurs. Knowledge about natural capital, as well as other kinds of technological and social interactions constitutes the intellectual capital, which is embodied in literature, databases, folklore and other kinds of formal and informal sources of wisdom. Part of the intellectual capital constitutes intellectual property from which the knowledge producers can exclude others for a given period of time from commercial exploitation.

The purpose of this discussion is to emphasize that IP is only one means of conserving and augmenting natural resources and associated knowledge systems. In the absence of IP, it is unlikely that the private sector will invest resources to add value to TK. It is not our contention that private investments can alone help in conserving resources and the knowledge systems. In fact, there is considerable evidence that expansion of market institutions has led to erosion of biodiversity, as well as associated TK. It is more due to the fact that TK is not valued properly within and outside the communities. Once a commodity becomes valuable, the bidders would try to appropriate it.

Some critics suggests that commercialization of TK is contrary to the local culture and ethical values. This may well be true. However, one has to appreciate that every commodity that local communities and individuals have to buy from the market place has to be paid for. It is an ironical situation that the critics see no impropriety in commoditization of the rest of the market in which local communities have no comparative advantage. But in resources in which they are rich, commoditization is supposed to be disruptive. It is also ignored many times that the concept of IP is not inconsistent with community wide sharing of knowledge for self-use. It is only when somebody tries to enrich oneself at the cost of the community or individual innovator that the protection

could help. Therefore the communitarian spirit, which has helped conserve resources and generate respect for nature, has to be nurtured. Our contention is that this spirit will give way when options for survival require deforestation or other resource degrading livelihood options because the resource conserving options are not available. *The knowledge based approach to livelihood, and conservation of biosphere regions can indeed be evolved without causing any injury to the local institutions that have helped in conservation so long*.

SECTION B
RECENT DISCUSSIONS ON ACCESS AND BENEFIT-SHARING

This section gives a brief overview of the international instruments and fora which are relevant to the IP-aspects of biological resources and TK. Those fora and instruments include the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("the Committee") of the World Intellectual Property Organization (WIPO); the International Treaty on Plant Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations (FAO) and the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising From Their Use, which were adopted by the Conference of the Parties to the Convention on Biological Diversity.

The World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

The WIPO General Assembly decided to establish the Intergovernmental Committee in 2000. The Committee held five sessions over the period of 2001 to 2003. After its fifth session in July 2003, the WIPO General Assembly decided to renew the work of the Committee for the 2004 to 2005 biennium and extended the mandate of the Committee. To provide background on the work of the Committee, this section draws together the main activities and outcomes of the Committee, and describes the interaction between the various components of the Committee's work and related program activities of WIPO. It also sets out some of the key issues considered by the Committee, to assist in clarifying the basis for future work.

In considering the relationship between IP and genetic resources, TK and folklore, the Committee undertook information gathering, policy discussion, and practical capacity building in these three policy areas. This work highlighted the overlapping nature of this subject matter. The Committee's approach has also illustrated the benefits of interaction and feedback between the parallel processes concerning policy dialogue, pooling information and building capacity. This is shown in a concrete way in some of the key outcomes of the Committee. For example, the Committee has overseen the creation of a database of IP licensing provisions concerning access to genetic resources: this operates both as a capacity-building tool and as a substantive input into policy discussions on IP aspects of access and benefit-sharing. Similarly, the Committee collected and analyzed extensive information about various national approaches to the protection of TK. This at once creates an informed basis for policy discussions and provides a resource for assessing practical options for national and local programs aimed at strengthening IP protection of TK.

The Committee's work has built on the existing basis of consultations, including the WIPO fact-finding Missions in 1998-99 and the earlier work of such bodies as the WIPO Meeting on Intellectual Property and Genetic Resources. An active program of consultation and dialogue complemented the formal proceedings of the Committee, with emphasis on the fostering of regional dialogue, and the enhanced participation of indigenous and local communities in WIPO activities. The Committee provided a framework for interaction with other international processes concerned with IP aspects of genetic resources and TK.

This section describes the Committee's activities and highlights the integral nature of its key outcomes, which include a set of practical tools:

- for assessing policy and legal options for IP protection systems for genetic resources and TK;
- for identifying and protecting the IP-related interests of custodians of genetic resources and TK holders when their resources or knowledge are being documented;

- for the protection of disclosed genetic resources or TK against third-party IP claims, including in the patent examination process; and
- to support access providers in dealing with IP aspects of access to genetic resources.

The WIPO General Assembly[5] decided to establish the Committee in the following general terms:

> "The Intergovernmental Committee would constitute a forum in which discussions could proceed among Member States on the three primary themes which they identified during the consultations: intellectual property issues that arise in the context of: (i) access to genetic resources and benefit-sharing; (ii) protection of traditional knowledge, whether or not associated with those resources; and (iii) the protection of expressions of folklore."[6]

The Secretariat of WIPO prepared a working document to the first session entitled, "Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore" (WIPO/GRTKF/IC/1/3). Document WIPO/GRTKF/IC/1/3 provided a general survey of the issues for the consideration of the Committee at its first session and proposed general tasks. In that document, three shared characteristics of intellectual property (IP) and traditional knowledge (TK), genetic resources were identified:

(a) The concept of common heritage was originally applied to genetic resources, TK and folklore. However, ever since appropriation of such common resources or knowledge has started to generate private IP, "the public domain status of the material has been called into question";

(b) Genetic resources, TK and folklore, "constitute subject matter which transforms and evolves beyond the logic of individualized human intellectual activity." Since genetic resources can self-replicate as living resources and TK and folklore also evolve across individuals and generations, the IP model suitable for individual creativity and IP may not be suitable. Hence the suggestion for new and specific IP standards; and,

(c) Each theme cuts across a range of formal and informal innovations and creative situations. Some commentators have stated that, without creating cognate rights for informal innovations, formal innovations cannot be protected. The concept of farmers' rights under the FAO and of plant breeders rights, under the International Union for the Protection of New Varieties of Plants (UPOV), have tried to tackle these seemingly contradictory urges.

Given the fact that much of biotechnological research draws upon biodiversity, it is inevitable that there will be tensions between different systems of knowledge. Working Document WIPO/GRTKF/IC/1/3 acknowledges the ongoing innovation and creativity within TK systems. It also recognizes that, in some instances, customary law may protect TK, with or without the sanction of the state, and identifies contractual arrangements, commonly known as "Material Transfer Agreements" (MTAs) as the most common legal route for regulating access to genetic resource and benefit-sharing. Such MTAs often address IP by including clauses which address the following issues:

(a) The uses which may be made of the genetic resource(s) transferred: i.e. whether they may be commercialized, or used for education or research only, etc.;

(b) Whether or not patent applications may be filed;

(c) If so, how the benefits that may accrue from the filing of such an application may be shared;

(d) Whether any grant-back license is to be obtained, which would oblige the recipient of the genetic resources to give a non-exclusive royalty free license to the provider of the genetic resource, if it patents any technology derived from the provided resources; and,

(g) Whether publications will be deferred until after the filing of a patent application.

Following discussions on document WIPO/GRTKF/IC/1/3 at its first session, the work of the Committee has proceeded along the general lines set out in this document, but has evolved in line with successive decisions of the Committee recorded in the reports of its first five meetings.[7] The final report of the first session (WIPO/GRTKF/IC/1/13) provides a rich overview of the debate that took place on these subjects. At the end of this first session, WIPO Member States expressed support for a work program intended to advance discussion on the following three themes:

Genetic resources

The work of the Committee on IP aspects of genetic resources took two general directions. First, it considered licensing practices concerning IP aspects of access to genetic resources; and second, it considered the role of patent disclosure requirements in relation to inventions that are based on access to genetic resources.

Document WIPO/GRTKF/IC/2/3 considered operational principles for intellectual property clauses of contractual agreements concerning access to genetic resources and benefit-sharing. Further study of IP and genetic resources licensing was based on a widely-circulated survey (document WIPO/GRTKF/IC/Q.2) and the development of a database of contractual practices (based on a proposal in document WIPO/GRTKF/IC/3/4). This process had two complementary objectives: first, to create a practical tool so as to provide actual information on contracts concerning access to genetic resources to those with a practical or policy need to consider the range of licensing practices that have been employed; and second, to provide an empirical basis for proposed work towards developing guidelines or principles on the IP aspects of licensing access to genetic resources. Document WIPO/GRTKF/IC/5/9 provides a discussion on this process and some interim insights developed to date, and the on-line database that has been commissioned gives access in three languages to details of relevant contracts that have been provided in the course of this survey.

Building on earlier work within WIPO, and responding also to a request from the Conference of Parties (COP) of the Convention on Biological Diversity (CBD),[8] the Committee requested a technical study on disclosure requirements in patent law that were relevant to traditional knowledge or genetic resources used in the course of developing a claimed invention. An initial report (document WIPO/GRTKF/IC/4/11) and a draft study (document WIPO/GRTKF/IC/5/10) were developed for the Committee's consideration; these documents considered the interaction between legal systems governing access to TK and genetic resources on the one hand and established patent law in line with existing international standards, and aim at providing input for policymakers.

At its twenty-ninth Session, the WIPO General Assembly adopted, subject to certain understandings, the draft revised technical study for transmission to the seventh meeting of the COP of the CBD. Following the General

Assembly decision, the Technical Study was transmitted to the Secretariat of the CBD (SCBD) with the above-mentioned understanding attached to the Study.

The Study was subsequently issued by the SCBD as document UNEP/CBD/WG-ABS/2/INF/4 for the second meeting of the Working Group, which took place in December 2003. Subsequently the Study was formally transmitted to the seventh meeting of the COP to the CBD in Kuala Lumpur, which took further decisions on disclosure requirements in patent applications for genetic resources and TK, based on the substantive elaboration contained in the Technical Study.

Traditional Knowledge

The Committee developed a series of studies on legal protection of TK, based on some 61 responses to two questionnaires.[9] This included surveys of national experiences with IP protection of TK,[10] analysis of the elements of a sui generis TK system,[11] analysis of the definition of TK,[12] and a composite study distilling this material into a single document.[13] These documents included details of the relatively small number of national *sui generis* laws for protection of TK, and the range of experiences reported using IP laws (*sui generis* and otherwise) to protect TK. These materials are available both as the basis for continuing international policy discussions on specific TK protection, and to support national policymaking and the assessment of practical options both for the use of existing IP tools and the development of new forms of IP protection.

The Committee gave extensive consideration to the use of databases, registries and other collections and inventories for the protection of TK, and this discussion clarified that databases could be used for the preservation, positive protection and defensive protection of traditional knowledge (as well as related traditional cultural expressions (TCEs) and information about related genetic resources, both of which could form part of the material recorded and preserved in a database). The role of databases for the positive protection of TK was shown in the use of databases with security or access controls which give effect to customary laws and protocols governing the authorized access and distribution of knowledge.[14] A database of patents granted on traditional medical knowledge illustrated another way of linking positive protection and TK databases.[15]

Extensive analysis was also given to the use of databases and other collections of information in the context of general defensive protection strategies. This focussed on approaches to ensuring that existing TK was taken into account in the patent examination process. Based on responses to widely distributed questionnaires, inventories of relevant on-line databases[16] and periodicals[17] were developed to assist in the creation of tools for more ready access to publicly disclosed TK in searches for relevant prior art. This in turn led to the creation of a TK portal as a pilot version of a potential searching tool for patent examiners.[18] The purpose of this was not to induce the disclosure of TK, but to ensure that any TK already disclosed would be taken into account when potentially relevant patent claims were being assessed. This approach has been taken further in forums beyond the Committee, with steps being taken to enhance the coverage of documented TK in the minimum documentation of the Patent Cooperation Treaty (PCT) system[19] and to expand the International Patent Classification to provide for more accurate and focussed searching for relevant TK during the patent examination process.[20]

A further defensive mechanism that was considered by the Committee concerned the use of disclosure requirements in the patent system to ensure disclosure of TK (and potentially also its origin and the legal circumstances surrounding its access) that is used in the development of a claimed invention. This was studied in conjunction with comparative defensive measures concerning genetic resources used in inventions (discussed above).

The Committee's discussions on TK protection considered the wide range of potential applications of databases, registries and other collections as both positive and defensive protection tools: this ranged from databases or registries which contained information about IP rights over TK subject matter (granted under conventional or *sui generis* IP systems), through databases establish to preserve TK subject to strictly limited access based on customary protocols, to databases which may be entitled to distinct *sui generis* protection (either of the database itself or of its individual elements), and databases that facilitate access for patent examiners to TK already in the public domain.

This discussion also highlighted concerns about the need to clarify the purpose and the implications of documentation of TK and the inclusion of TK onto databases. Committee members expressed concern that when TK is documented and then published, the rights and interests of TK holders may be weakened or prejudiced, often before the full implications of documenting and especially of publishing the TK had been made clear. Given the wide range of TK documentation projects currently planned or under way, aimed at diverse goals (ranging from preservation to various forms of positive and defensive protection), and the potential damage to TK holders' interests and cultural integrity that may arise from documentation of TK, the Committee endorsed the development of a toolkit for the management of the IP implications of TK documentation.[21] This is being developed with extensive consultation with TK stakeholders and in coordination with other international initiatives, so that traditional communities may be in a stronger position to identify and defend their IP-related interests in advance of any documentation project.

The Committee has cooperated closely with other intergovernmental agencies and processes that address the interfaces between intellectual property, genetic resource policy and TK protection. These fora include in particular the CBD and the FAO. Accordingly, the next sections review developments in those fora.

The International Treaty on Plant Genetic Resources for Food and Agriculture

The 1983 International Undertaking (IU) was the first comprehensive international agreement to address plant genetic resources for food and agriculture. It was negotiated under the auspices of the Food and Agriculture Organization (FAO) of the United Nations and sought to "ensure that plant genetic resources of economic and/or social interest, particularly for agriculture, will be explored, preserved, evaluated and made available for plant breeding and scientific purposes." It was based on the "universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction".

The IU was the subject of three additional FAO Conference Resolutions. These were intended to achieve a balance between the rights of breeders (formal innovators) and farmers (informal innovators): for instance, by recognizing that Plant Breeder's Rights, as provided for by the International Union for the Protection of New Varieties of Plants (UPOV), were not inconsistent with the IU, and simultaneously recognizing Farmers' Rights. [For background information on UPOV and access and benefit-sharing see "Text Box: International Union for the Protection of New Varieties of Plants (UPOV)"].

Text Box: International Union for the Protection of New Varieties of Plants (UPOV)

The International Union for the Protection of New Varieties of Plants (UPOV) is an intergovernmental organization, established by the International Convention for the Protection of New Varieties of Plants (the "UPOV Convention"). The UPOV Convention was adopted on December 2, 1961, and revised in 1972, 1978 and 1991. The Mission of UPOV, based on the UPOV Convention, is: "*To provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society*." UPOV supports the view that the Convention on Biological Diversity (CBD) and relevant international instruments dealing with intellectual property rights, including the UPOV Convention, should be mutually supportive.

UPOV considers that plant breeding is a fundamental aspect of the sustainable use and development of genetic resources. It is of the opinion that access to genetic resources is a key requirement for sustainable and substantial progress in plant breeding. The concept of the "breeder's exemption" in the UPOV Convention, whereby acts done for the purpose of breeding other varieties are not subject to any restriction, reflects the view of UPOV that the worldwide community of breeders needs access to all forms of breeding material to sustain greatest progress in plant breeding and, thereby, to maximize the use of genetic resources for the benefit of society.

Farm-Saved Seed

The provision on "farm-saved seed" (also known as the "farmer's privilege") is an optional benefit-sharing mechanism provided by the UPOV Convention, under which UPOV members may permit farmers, on their own farms, to use part of their harvest of a protected variety for the planting of a further crop. Under this provision, members of UPOV are able to adopt solutions, which are specifically adapted to their agricultural circumstances. However, this provision is subject to reasonable limits and requires that the legitimate interests of the breeder are safeguarded, to ensure there is a continued incentive for the development of new varieties of plants, for the benefit of society. For example, certain members of UPOV apply the provision on farm-saved seed only to certain species or limit its application using criteria such as the size of the farmer's holding or the level of production.

Benefit-Sharing

Breeder's Exemption

UPOV would be concerned if any mechanism to claim the sharing of revenues were to impose an additional administrative burden on the authority entrusted with the grant of breeders' rights and an additional financial obligation on the breeder when varieties are used for further breeding. Indeed, such an obligation for benefit-sharing would be incompatible with the principle of the breeder's exemption established in the UPOV Convention whereby acts done for the purpose of breeding other varieties are not, under the UPOV Convention, subject to any restriction and the breeders of protected varieties (initial varieties) are not entitled to financial benefit-sharing with breeders of varieties developed from the initial varieties, except in the case of essentially derived varieties (EDV). Furthermore, a benefit-sharing mechanism within the legislation to grant breeder's rights, would seem to tax only "protected" varieties and, instead of creating incentive mechanisms to develop new varieties, may provoke the opposite effect, whereby breeders would not develop new varieties or would not seek protection (favoring a legally insecure environment).

The Food and Agriculture Organization of the United Nations (FAO), at its 31st Conference, on November 3, 2001, adopted the International Treaty on Plant Genetic Resources for Food and Agriculture. This Treaty (Article 13.2. (d)(ii)) recognizes the concept of the breeder's exemption, in that breeders are excepted from financial benefit-sharing whenever their products are "available without restriction to others for further research and breeding …".

Subsistence Farmers

In addition to the breeder's exemption and the research exemption, the UPOV Convention contains another compulsory exception to the breeder's right whereby the breeder's right does not extend to acts done privately and for noncommercial purposes. Therefore, activities of subsistence farmers, where these constitute acts done privately and for non-commercial purposes, are excluded from the scope of the breeder's right and such farmers freely benefit from the availability of protected new varieties.

Summary

Mechanisms of benefit-sharing should take into account the need for a relationship of mutual supportiveness in respect of the essential principles of the UPOV system of plant variety protection and, in particular, of the breeder's exemption provision.

[for a full account of UPOV's views on access and benefit-sharing see document C/37/21, as adopted by the Council of UPOV, of which this is an excerpt)]

The concept of Farmers' Rights was formulated as a retrospective equity to acknowledge the contribution which farmers have made to "conserving, improving and making available plant genetic resources particularly those in the centers of origin/diversity". The rights were vested in the international community, as trustees for present and future generations of farmers. It was proposed that they would be implemented through an international fund for plant genetic resources.

In 1992, the Agenda 21 (Chapter 14) called for the strengthening of the FAO Global System on Plant Genetic Resources, and its adjustment in line with the outcome of negotiations on the Convention on Biological Diversity (CBD). Accordingly, in 1993, the FAO Conference adopted Resolution 7/93 for the revision of the IU and requested the FAO to provide a forum for the negotiation among governments, for:

(a) The adaptation of the IU in harmony with the CBD;
(b) Consideration of the issue of access on mutually agreed terms to plant genetic resources, including ex situ collections not addressed by the CBD; and
(c) The realization of Farmers' Rights.

The negotiations for the revision of the IU in harmony with CBD, started in the First Extraordinary Session of the Commission on Plant Genetic Resources (CPGR), in November 1994. The key elements under discussion in the negotiations included the scope, and access to plant genetic resources; the fair and equitable sharing of benefits arising from the use of plant genetic resources for food and agriculture; and the realization of Farmers' Rights.

After considerable debate, the International Treaty on Plant Genetic Resources for Food and Agriculture was adopted by the FAO Conference on 3 November 2001. It will come into force once it has been ratified by 40 states.

The International Treaty seeks to establish an access and benefit-sharing regime for plant genetic resources for food and agriculture that is in harmony with the Convention on Biological Diversity by:

- Facilitating access to 35 food and 29 feed crops, the so-called "Multilateral System";
- Establishing a system of fair and equitable sharing of financial benefits resulting from the commercial use of the crops covered by the Multilateral system; and by,
- Recognizing and promoting Farmers' Rights. For instance, the treaty preserves the right of farmers to save, use and exchange saved seed.

Some developing country governments, for example, the Government of India, are already seeking to incorporate Farmers' Rights into their plant variety laws. The African Union's *African Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources*, under Part V: Farmers' Rights, contains provisions that closely reflect Article 9 of the International Treaty.

There was a considerable tension arising out of the issue of IP, finally addressed in Article 12.3(d). The source of the tension was the issue of patentability of components of genetic resources, which many developing countries contested. Accordingly, after seven years of negotiations, the issues of patenting of genetic material, and whether genetic parts of the components are also defined as resources accessed under the multilateral system, still elude consensus. Furthermore, many NGOs felt dissatisfied with the final consensus reached, since they felt that OECD countries had retained their right of IP protection over crop seeds and their genes. Many of these issues will be revisited in the world food summit after five years. At that time, a proper evaluation may take place regarding whether the provision of IP has improved or impeded food security in various parts of the world, through the presence or absence of incentives for private capital to be mobilized to add value to knowledge and resources.

The Bonn Guidelines, as adopted by the Conference to the Parties of the Convention on Biological Diversity.

One of the three objectives of the Convention on Biological Diversity (CBD), is the, "fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding".[22]

A framework for the implementation of this third objective of the Convention with regard to access to genetic resources is provided in Article 15 of the Convention. In addition, Article 8(j) contains provision to encourage the equitable sharing of the benefits arising from the utilization of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for conservation and sustainable use of biological diversity. These provisions are also linked to the provisions on access to, and transfer of technology (Article 16), exchange of information (Article 17), technical and scientific cooperation (Article 18), the handling of biotechnology and distribution of its benefits (Article 19, paragraphs 1 and 2), and financial resources and financial mechanism (Article 20 and Article 21).

In 1999, the CBD Conference of the Parties recommended the establishment of an ad-hoc Working Group, "with the mandate to develop guidelines and other approaches for submission to the Conference of the Parties and to assist Parties and stakeholders in addressing the following elements as relevant to access to genetic resources and benefit-sharing", *inter alia*:

- Terms for prior informed consent and mutually agreed terms;
- Roles, responsibilities and participation of stakeholders;
- Relevant aspects relating to *in-situ* and *ex situ* conservation and sustainable use;
- Mechanisms for benefit-sharing, for example through technology transfer and joint research and development; and
- means to ensure the respect, preservation and maintenance of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.

As a result of the work carried out by this Working Group, in particular at an expert meeting held in Bonn, Germany in October 2001, at the sixth CBD Conference of the Parties held in the Hague, the Netherlands in April 2002, Member States were in a position to adopt the so-called, "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization."

These voluntary guidelines offer guidance in the roles and responsibilities of the various parties involved in access and benefit-sharing, and are intended as a useful first step of an evolutionary process in the implementation of relevant provisions of the CBD related to access to genetic resources and benefit-sharing. In adopting the guidelines, Member States to the CBD invited Parties and Governments to use the guidelines when developing and drafting legislative, administrative or policy measures on access and benefit-sharing, and contracts and other arrangements under mutually agreed terms for access and benefit-sharing.

In relation to IP, the Bonn Guidelines notes that: the work of WIPO on IP and access and benefit-sharing should be taken into account; states that Contracting Parties should take appropriate legal, administrative, or policy measures, as appropriate, to support compliance with prior informed consent of the Contracting Party providing such resources, and mutually agreed terms on which access was granted, including, *inter alia*, 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; and states that material transfer agreements should clarify whether intellectual property rights may be sought and if so under what conditions.

The Ad-hoc Working Group will continue to meet to further the debate on access and benefit-sharing under the CBD.

SECTION C
TRADITIONAL KNOWLEDGE

Functions of Traditional Knowledge

Traditional knowledge can serve several functions, including the following:

- Semiotic: i.e., communication through symbols, art forms, crafts, etc.,
- Institutional: i.e., providing rules coded in rituals and/or other cultural and social sanctions. Some of these rituals and cultural sanctions institutionalize incentive measures for the use of traditional knowledge (TK) just as intellectual property (IP) does. These sanctions could be material such as fines or penalties or ethereal such as the fear of God;
- Configurational: i.e., the arrangement of various life processes and stages are performed according to the traditional norms generating predictability about their social outcomes;
- Utilitarian: i.e., knowledge of certain plants or animal products being used for various food, nutrition or health needs;
- Situational: i.e., during emergencies or other contingencies, codes of conduct may be specified to maintain social order and responsibility towards other life forms, including wildlife;
- In addition, TK may also have religious and spiritual functions which may, or may not, involve material objects. Since society has to adapt to emerging situations from time to time, traditional systems of culture, technology and social exchange provide some scope for experimentation, deviance and variation.

Some groups demonstrate an ability to innovate more than others, but the innovative spirit is evident in every culture, to a large or small extent. Therefore, TK systems are not just serving to maintain a *status quo*. There are also provisions for dealing with the demands of modern times. However, there are social, cultural and material forces which disrupt traditions and create either new traditions or leave a void. There are also cases where the State may outlaw certain dysfunctional and socially repugnant traditional practices,[23] though these may not completely stop the outlawed measures. One therefore should not romanticize TK, but take an empathetic yet critical look at the TK system.

There has been concern regarding local knowledge for a considerable length of time. For instance, in 1969, Verma and Singh raised questions about the continued relevance of indigenous knowledge in the context of animal husbandry. The modern health system for human beings was quite weak. For animals it was even weaker. Local communities in many parts of the tropical developing world rely on local knowledge of animal husbandry even today. This is indicative of the fact that mainstream education and public policy still do not give due attention to the peoples' knowledge system. One implication of this is the downgrading of those knowledge systems in the eyes of young people of the same communities. Once the esteem for local knowledge diminishes, there are less incentives for young people to acquire that knowledge and to experiment and rejuvenate the same. This leads to serious discontinuities in the intergenerational flow of knowledge. Once the "local experts," that is, the older generation, are gone and there are no successors, the knowledge held in trust by those individuals for future generations is lost forever. Young people are not acquiring the skills of local experts because of a lack of incentives. However, some of these skills might lead to new career options: for instance, the skills of restoring the health of degraded lands, water bodies or forests are becoming increasingly valuable as international conventions and their implementation gain momentum at a local level.

Furthermore, the increasing demand for herbal drugs, often sold as food additives,[24] has proven that global perceptions of TK-based products are changing. After all, 80% of modern plant-based medicines are used for the same purpose for which native people discovered their use (Farnsworth, 1981). Studies pursued in Nigeria found that the correlation between claims of local communities and evidence from modern pharmacological science was more than 85% (Iwu, 1999). In 1996, Chinese right-holders held about 45% of all herbal-based patents, followed by the Japanese and Russians, with 22% and 16.5% respectively[25] (Gupta, 1999).

The issue is no more whether traditional knowledge (TK) and contemporary improvements should be given importance and recognition. Most people accept that there is an urgent need for such recognition. The issues are:

(a) How do we recognize this extremely important source of solutions, or 'lead' for developing solutions to the problems of food, health and nutrition and many other challenges in the modern world; and

(b) How do we generate reciprocity among knowledge providers and resource-users, particularly the ones who have commercial goals, without stripping TK systems of their socio-cultural context?

Conceptualizing Communities

Some participants in the current debates on IP and benefit-sharing over TK assume a uniform homogeneity between all members of a local community; that is, an assumption that there is a convergence between the interests of local community leaders and those of local experts and TK holders. However, this is often very far from reality. The asymmetry in knowledge systems and related power differentials are apparent in global discourses on incentives and consultations. Such global discourses have often been dominated by the so-called representatives of indigenous communities, often themselves of Western origin, and both in identity and in their ways of approaching an issue. For instance, in various consultations by United Nations Environment Programme (UNEP) and the Convention on Biological Diversity (CBD), the more articulate indigenous people from western countries largely represent local communities. Many native communities in the west have suffered in the past and *they* should be heard. But surely, their suffering may not be higher than that of third world communities which continue to suffer far more even today. To anyone familiar with the miserable conditions in which most local communities live and strive to conserve biodiversity and associated TK systems, it should be obvious that their problems and concerns are very different from many of the problems articulated at most international fora. Moreover, the concerns of local experts and innovators within impoverished communities may be very different from those of the rest of the people. A key challenge is therefore to ensure that their concerns can be heard and addressed.

Traditional Knowledge v Modern Science

Creative and innovative traditions in various developing countries have been masked by historical misrepresentations by outsiders, as well as by domestic pedagogy and policies. Students seldom learn about grassroots or higher level inventions and innovations developed by local individuals, institutions or communities within their respective countries. When local contributions are taught, these are recalled with terminology which may generate disdain rather than respect for native genius.[26] Such explanations are, however, only one reason why the possibility of building upon grassroots traditions of invention and innovation has not been pursued in most developing countries. There are many other possible reasons for this; for instance:

- A lack of awareness about such traditions among policy planners, the education systems, and civil society at large;

- The influence of aid agencies whose work often results in increased dependency, rather than self-reliance;
- An education system which does not create curiosity and an experimental ethic, and instead reinforces a culture of compliance and conformity;
- A science and technology establishment which does not encourage local traditions, even if they are functional and viable, whether in the past or in the present;
- The increasing influence of the media, which popularizes Western images of progress, rather than indigenous notions of the same;[27]
- The lifestyles of the elite which do not inspire any respect for local knowledge systems;
- Declining respect for local healers and herbalists among their own communities;
- Declining communication between the "grand-parent generation" and the "grand-children generation", due to the disappearance of extended families and the increase of nuclear families;
- A lack of incentives for creative people at the local level, and, most importantly in this context, inadequate intellectual property (IP) rights for local communities, informal innovators, etc.

Gloria Emeagwali (1989) observes, "(m)ost of the technological creations of Africa are assigned to artistic designations. Africans find some of their scientific and technological achievements confined to fine art museums. The scientific and technical processes underlying the creation of various inventions are deliberately trivialized".[28] In short, the creativity in Africa, and other parts of the developing world, do not receive adequate attention and recognition.[29] To improve the role of IP in the benefit-sharing of TK, current IP debates need to study systematically what I have called the 'Tradition of Invention', instead of 'inventing a tradition' (Gupta, 1993).

Researchers have often tried to portray TK systems as quite different and sometimes in opposition to so-called "modern" (i.e. western) knowledge systems. Nothing could be further from the truth. Many aspects of TK systems contain at least some of the elements that make a "modern" scientific proposition valid. At the same time, many scientific institutions use traditional cultural symbols and practices to generate an extra ounce of confidence or certainty.

For instance, when a farmer decides to sow his crop at a particular time, taking various factors such as meteorological conditions, soil, moisture, temperature, etc., he is using his empirical knowledge, which generates replicable, refutable, and verifiable results. No matter who sows crops at that time under the given conditions, other things remaining the same, he or she should get the same result. Likewise, every time the same crop is sown with similar conditions, it should give similar results and if one wanted to prove this wrong, it should be possible to sow early or late and get different results. The scientific nature of much TK formed the basis and philosophy of grassroots innovators' own initiatives for benefit-sharing in their TK. This belief in the correlation between science and local innovations was the basis for the creation of the Honey Bee network a decade ago. At the same time, I and other members of this network realized that there were cultural codes and institutional mechanisms associated with certain TK systems, which ensure that the knowledge, innovations and practices are understood and explored in a given context. This is not to say that all the elements of this context are scientific in nature. Cultural contexts, based on shared beliefs, may provide a basis for dealing with a whole range of uncertainties and, at the same time, provide a common understanding of social, biological, cultural continuities.

Whenever some members of a community recognize the need for a discontinuity, a major transformation takes place. A new crop is introduced, a new implement is invented, a new variety is developed through selection or sometimes through grafting or budding: an innovation takes place. Some of these innovations over a period of time become embedded in the socio-cultural contexts. While constructing a modern building, setting up a laboratory, installing a new machine, prayers are often held in many parts of the world, as if modern technology is insufficient. It is true that causal explanation of modern scientific proposition is sought and provided in the material structures of science: i.e., verifiable principles governed by universal laws which can be tested and measured.

In certain aspects of TK systems, non-material beliefs and cultural codes are supposed to explain or guide the consequences of material transactions. For instance, a healer may not reveal his or her knowledge lest it loses its significance on being revealed. It is possible that this belief, seemingly unscientific, might have been a means of ensuring that a complex or risky recipe is not pursued or practiced by someone untrained or untutored in the art. It is also possible that it is just a superstition,[30] but, in any case, it lends a coherence to the knowledge system and the surrounding context. It is not my contention to argue that TK systems and associated institutional arrangements can never be dismembered. However, in many cases, when we take a plant or some other element of local knowledge systems out of its institutional context, even if a scientific relationship between cause and effect does not get adversely affected, the *institutional* context in which the plant is collected, for example, only when necessary and only in limited quantities, may get affected. Therefore, we may be able to develop a good and effective drug by just dealing with the utilitarian part of TK systems. But we may not necessarily maintain the restraint that may have been kept in place by some of the traditional institutions for conservation of that plant. The risk of over-exploitation of the resource itself is the reason why many groups oppose bio-prospecting by outsiders. What they miss, however, is that, in many cases, the problem is not so much with bio-prospecting, as with the institutional arrangements themselves.

The context of local knowledge systems, combining traditional skills, culture and artifacts with modern skills, perspectives and tools is not something that has only happened in the recent past. From time immemorial, new crops were introduced from one part of the world to another and cultural and ecological knowledge systems evolved while adapting these crops, animals, trees, tools, etc., into their new contexts. This is an ongoing process. What may set the traditional ways of dealing with local resources and external knowledge and inputs apart, may be a slower trial and error approach which may not necessarily be unscientific. But it may not be fully compatible with modern methods of experimentation, validation, and drawing inferences.

In some cases, the correspondence is close but in many case it may not be. However, it is possible that through flexibility, modification and mutual respect and trust, traditional knowledge experts can and may work with experts from modern scientific institutions to generate more effective solutions for contemporary problems. After all, the "tool view" of science, implying excessive reliance on specific methods of solving problems, has been known to hinder rather than to advance scientific research. Traditional contexts reflect and embed certain rules about how we relate to nature, to each other and to our inner selves, which can help in generating sustainable and compassionate approaches to solving problems. Incentives for creating a sufficiently strong desire for experimentation will become embedded when modern institutions *recognize, respect and reward* the experiments done in the past. The experiments and innovations have led to very significant and identifiable advances in our knowledge about biodiversity and other natural resources and their application in our day to day life. One can make an equally strong case for recognizing traditional art and craft forms, music and other kinds of expressions of local creativity of individuals as well as communities based on traditional as well as modern materials.[31]

Conservation of biodiversity and other natural resources over a long period of time has been possible because of the cultural, spiritual and other social institutions that have guided the relationship of local communities with the resources. Even in a context where deforestation in some countries, such as Nigeria, is about 6% per annum as against the global average of 0.2%, there are forests, streams, old trees, and lakes, which have been conserved by the people extremely well. In addition, it is not just the resources, but also the *knowledge* about these resources, which has been conserved through practice and innovations.

"Resources" include not only those materials which are visible to the naked eye, but also those which are not visible, such as micro-organisms. Okagbue[32] (1993) provides an example of TK systems around microbial diversity and its use for food processing. He observes, "(s)ince microbes and their activities are often difficult to observe and appreciate, we are often unaware of their influences on culture. These facts notwithstanding, several cultural practices designed to preserve food and other materials such as leather, wood, etc., or to protect the health of humans, and crops, are directed towards relevant microbial agents. For example, the efficacy of certain herbs traditionally used in foods and medicines has been shown to be due to the activity of specific chemical components of herbs against some pathogenic and food spoilage micro-organisms". Downes[33] (1997) refers to a U.S.A. patent 5751,1986 granted on a purported variety of the ayahuasca vine, *Banisteriopsis caapi*.[34] He adds:

> *… many indigenous groups in the Amazon hold this plant to be sacred and therefore feel that it is inappropriate for private persons to have exclusive rights over any aspect of it. Within industrial societies themselves, certain activities or entities are typically excluded from market relations. For instance, a great deal of valuable, novel information, such as scientific discoveries about the natural world, is explicitly excluded from intellectual property protection.*

Recently, the United States Patent and Trademarks Office (USPTO) revoked the patent on this plant, acknowledging that the inventor had claimed knowledge which was already in the public domain. However, later the patent was restored on the specific plant itself, excluding any claims on possible uses of this plant.

In August, 1999, the USPTO wrote to Dr. R A Mashelkar, the Director-General of the Indian Council of Scientific and Industrial Research (CSIR) assuring him that the USPTO will endeavor not to issue any patent on TK on which prior art exists. It also requested CSIR to provide copies of available documentation on Indian herbs, drug formulations in ancient texts as well as recent research so that trivial patents can be avoided. The letter continued:

> *We should, however, address the need of creating more easily accessible non-patent literature databases that deal with traditional knowledge. Perhaps an office among the developing countries should suggest this as a project for the SCIT Working Group on Standards and Documentation, working in close cooperation with the International Patent Classification (IPC) Committee of Experts. With the help of the developing countries, traditional knowledge can be documented, captured electronically, and placed in the appropriate classification within the IPC so that it can be more easily searched and retrieved. This would help prevent the patenting of turmeric, as well as karela, jamun, brinjal and other traditionally used remedies.*[35]

This shows a welcome willingness by one of the major players in the field of IP to respond to persistent criticism that it did not pay enough or, indeed, any attention to the rights of local communities. Obviously the above formulation only solves part of the problem, in that it only deals with issuance of unlawful patents on

knowledge which is already in the public domain.[36] It does not deal with the issue of protection for that TK known only to a local community and/or individual experts/innovators whose knowledge is not ordinarily in public domain. Further, many critics have stated that the thousands of patents on common uses of plants from tropics granted by USPTO should not have to wait for opposition by concerned communities of country and that the USPTO should take up, on its own initiative, a review of all these patents and revoke all wrongly granted patents.

Knowledge systems for survival and sustainable biodiversity management

It has been generally believed that the TK systems of local communities and indigenous peoples are holistic in nature. Centuries of association with the environment have produced a deep understanding of the inter-relationships among the different elements of a landscape or a habitat. Because fluctuations in the environment require adaptive responses, communities have developed a wide range of diversified survival strategies at intra and inter-household levels as well as at a community level. However, local and indigenous knowledge systems, while generally holistic, have some reductionist elements. In order to cope with the complexity of ecological change, some people in the community specialize by knowing more and more about less and less. Such specialized expertise requires focusing, targeting and steering strategies on specific themes or aspects of nature. A good archer may be good because s/he does not look at all at the interconnections between target, the wind and the world around and instead focuses only on the target. This kind of reductionist approach helps in developing a sharp shooting skill.

Nonetheless, as a generalization, so-called "western" science is biased in favor of reductionist relationships, whereas local knowledge systems are biased in favor of systemic linkages and a holistic perspective on nature. Where efficiency of resource use has to increase so as to cope with increasing population pressures or scarcity, fluctuations in the environment, or other contingencies, then a blending of formal and informal science may be necessary. Achieving sustainability in resource use requires the fusion of sacred with secular, formal with informal, and reductionist with holistic views (Gupta, 1995, 1996, 1998).

The production of knowledge, and its application, takes place in a given socio-ecological context, through innovations over a long period of time. It has been suggested that this context influences, and to some extent shapes, the world views of people (Gupta, 1981, 1987, 1988), which in turn influence the heuristics[37] used for generating new solutions and knowledge (Pastakia, 1995). The heuristics are similar to decision making rules which are also accompanied by choice. Local and indigenous knowledge systems are not static. They evolve, adapt and transform dynamically with time. New materials are incorporated, new processes are developed, and sometimes new uses or purposes are evolved for existing TK. Hence, there is a need for rewarding not only TK, but also contemporary innovations. The concept of Traditional Resource Rights (Posey *et al*., 1995), implying recognition of primarily customary rights, does not do full justice to the individuals who are responsible for contemporary creativity and innovation, although it does provide a useful way of looking at community rights in conjunction with basic human rights. Depersonalizing the process of knowledge production and reproduction limits the type of incentives considered and results in concentrating the resources only in the hands of governments or, in rare cases, of local community leaders.

The conceptualization of indigenous knowledge as an autonomous subset of local knowledge, evolved through interaction among local communities, individuals, and their environment over a long period of time, is problematic on two accounts:

(a) Firstly, there always are interactions with other knowledge systems, through trade and other exchanges from time to time, incorporating elements of these outside systems with or without their contextual incorporation;
(b) Secondly, TK is not only produced collectively nor is it always inter-generational in nature.

I have argued (Gupta, 1980, 1984, 1987, 1988, 1989, 1992-2001) that TK may be produced locally, and sometimes indigenously, by individuals without any interface with the community or outsiders. Similarly, contemporary knowledge may be built upon TK, but may be developed autonomously. Merely because a particular innovation builds upon a traditional reserve of knowledge produced within the community or outside does not invalidate or minimize the contribution of the individual in the contemporary context. The possibility of such contributions being recognized by modern IP systems is obvious, notwithstanding the transaction cost involved therein. The complexity introduced by the conceptual framework presented in Table 1 earlier in this study is indeed real and, to date, has not received enough attention either in the literature or in policy dialogues.

There could be many other variations in the production and reproduction of TK by individual or communities. For instance, TK produced by some individuals in the past, such as a variety selected by some specific farmers, may be reproduced by a community which grows this variety and which may or may not provide feedback to the original developer. Likewise, a landrace may be developed through the collective effort of a community, but may be reproduced by only one or two individuals. The assignment of IP in these varied situations will have to follow different kinds of modalities and institutional arrangements. Just as variations have already taken place in the evolution of Plant Variety Acts through acceptance by the International Union for the Protection of New Varieties of Plants (UPOV) of new concepts, such as, "wild discovered plants" having a DUS property as a new variety (Gupta, 1999), there is a similar need for modifications and adaptations in IP laws to reward different kinds of contributions by individuals and communities in long past or recent times, through improvement or innovations in local materials, knowledge systems, or external materials or knowledge systems or a combination of the above.

In addition, it is my view that there is little purpose served by engaging in lengthy debate on the comparison or contrast among so-called indigenous or western science or knowledge systems, since I have always believed that there is only one science; each has drawn upon the other to varying extent in different places (Periera and Gupta, 1994, 1995, Honey Bee, 1993, 4(4) and 1995 5(1)). The variants are, good and bad science. On the other hand, the methods of developing scientific practices are quite different when comparisons are made between various cultures and communities. Likewise, the criteria of evaluation of an experimental result are also varied and there is much greater tolerance among local communities, of empirical practices, without knowing their scientific causes.[38] Moreover, those communities, some of which have kept local experts poor by not valuing their TK adequately, are unlikely to pass on to such experts externally-generated incentives. This does not mean that community institutions are to be avoided while developing incentive distribution mechanisms. Much will depend upon the situation specific balance of power among different stakeholders involved in the conservation of genetic and biological resources and associated TK systems.

Differences between functional and causal knowledge systems

Farmers have been known to do the right things for wrong reasons.[39] Their practices do not become invalid merely because a supposed causal connection has no known factual basis. Even in modern science, there are effective medicines for which the causal mechanisms came to be known only after a long history of use: e.g.,

the aspirin. A knowledge system should not therefore be downgraded merely because of such limitations. Rituals and some symbolic totems may be ways of constraining particular healing strategies, lest they be used in inappropriate cases, doses or situations. For example, it is suggested that some medicines work better when consumed slowly with the tip of a finger. Apparently, the intention is to suggest consumption of only as much quantity as the tip of the finger can contain. In a way, a ritual has incorporated a dosage.

A marriage between local and exogenous knowledge, and between formal and informal science, will succeed only on the basis of reciprocal respect and a well-deserved restraint in exploring their logical bases. Hence, many local knowledge systems emphasize the questions that *should not be* asked rather than those that *should be*. Modern minds reject such boundaries to inquisitiveness, but the sacredness of certain kinds of knowledge rests on faith and its power. It is true that superstitions particularly those that cause definite harm to local communities, as well as those that generate other kinds of social or ecological biases, have to be tempered with a scientific attitude. It is not easy to determine when faith becomes a source of superstition. Thus, there is a great need for exercising care in understanding and especially in attempting to influence local conservation practices. In their attempts to unravel the mysteries underlying local faiths, outsiders can erode the power of local experts and institutions without putting anything better in their place.

Local beliefs in the power of spiritual icons have helped conserve sacred groves, lakes, mountains, etc., all over the world. These sacred beliefs are linked sometimes to very basic functional needs. For example, the need to protect the mouth of the rivers; i.e., the points at which rivers originate, are considered sacred almost all over the world. Not much will be gained by dismembering the sacred fiber from the profane one. The two are intertwined like the double helical DNA structure (Gupta, 1993). Conventional intellectual property rights can protect folklore, if national legislation for the purpose exists. They can also protect the uses of various biodiversity elements, even if removed form a local context, and can protect symbols, music, other icons considered sacred by the local community.[40] Reductionist knowledge, by itself, has rarely generated the social responsibility required to guide collective behavior towards conservation. *The sacredness of certain sites, species and symbols must be respected, even if modern minds find this incomprehensible or even irrational (Gupta, 1993)*.

Bridges between formal and informal knowledge systems

Many international consultations and studies on knowledge systems have identified a need to distinguish among different types of knowledge, and also recognize the need for building bridges between local or indigenous knowledge vis-à-vis formal scientific knowledge (e.g. Atte 1989; Gupta 1989, 1991, 1995, 1997, 1998; SRISTI, 1993; Singh and Verma, 1969; Honey Bee, 1990-99; Skolimowski, 1981; Berkes 1988; Brokenshaw, Richards, 1985; Biggs, 1980; Warren, and Werner (eds.), 1980). Both formal and informal science is capable of producing abstract, as well as practical, knowledge, although the latter tends to produce more of the practical kind. Different incentives might nurture different types of knowledge. For instance, material-individual kind of incentives may include IP as one kind of incentive. Because of industrial application, these may be either licensed or worked to generate commercial returns. But, as I will show later, there are a whole range of other incentives which need to be considered; for instance, material, collective or non-material, individual and non-material collective. In some situations, a portfolio of the above may be appropriate.[41]

However, the same knowledge systems can pursue different functions simultaneously, in various combinations. For instance, a fishing community might use classificatory skills to deal with variations in the movements of fish and locations of spawning sites. It might use indicators for spotting the sites where fish will be found in

abundance at different times of the year. It might have to use systemic linkages to relate temperature, wind velocity, turbidity of the water and behavior of the fish, to decide how far to go in the ocean without courting too much risk or uncertainty. One way to understand the complexity of knowledge systems is to link the functions of nature with processes of 'sense making'; i.e., drawing meaning from empirical observations. Berkes (1988) provides a strong argument for sensitivity in 'sense making'. He observes:

The traditional ecological knowledge of the Cree is empirical knowledge, as in the observations of the "disappearance of animal in extremely cold weather, the way black bears try to cover their tracks before denning, the sensing and the avoidance of (predatory) otters by the fish. However, the "sense" the Cree make of empirical knowledge is not scientific, mechanistic, or analytic (re: Skolimowski, 1981). That is not to say that the Cree approach is either superior or inferior to the Western scientific one, but it is different … the Cree model of caribou cycles shows a better fit with the actual caribou population dynamic in Quebec – Ungava Peninsula than does the current scientific model.

Diversity, complexity, simultaneity and change in ecological systems are codified in knowledge and practices through language and culture (Gupta 1989). Just as the Inuit is recognized for having the highest number of words for classifying snow, fishing communities have many words for distinguishing and discriminating different kinds of sea conditions, fish spawning sites, etc., (Johannes, 1981). Conceptually, any community, which is dependent upon a resource for its survival, as mentioned earlier, has to develop a pattern or a set of categories to deal with variations in the availability of that resource. For example, farmers have a rich taxonomy for clouds and soils and, in some cases, for insects and other animals. Leather workers have taxonomy for leather, carpenters for wood and likewise fishing communities for water and aquatic life.

Languages and Biological and Knowledge Diversity

Generally, a community classifies the variability in a natural phenomenon on which it is dependent for its own survival into discrete categories, so as to manage that resource efficiently. Since language is the means for expressing such knowledge, the number of words for such variability in a given language tends to be higher when the dependence of the community on the same resource is high, by comparison with when the dependence is low. Therefore, a coastal fishing community may have a much higher number of words for waves, just as farmers in rain-fed environments or mountainous regions have a higher variety of terms for explaining soil diversity. TK systems in such cases can contribute to a better understanding of the environment and underlying sources of variation.

The inter-relationships between different components of ecosystems are also pursued differently in TK systems, compared to the modern ecological or other disciplinary studies. For instance, three indigenous communities in Alaska and four in Chukotka Russia were studied by Huttington and Myrin[42] (1995) to analyze their knowledge about beluga whales. They studied the timing, location and movements of beluga whales around each community and described, in detail, how the status of ice, fish, wind, and the presence of killer whales affected the belugas. During their discussions with the local community members, the researchers realized that these discussions often veered towards some other, seemingly unconnected, subject. However, on further enquiry, these seemingly unconnected subjects often proceeded to be valuable sources of TK. For example, one digression concerned beavers. Beavers, a local respondent informed them, build dams in the streams where salmon and other fish spawn. When the beaver population expands, the spawning habitat of salmon may be reduced. In turn, this affects the belugas, which feed on salmon. Hence, as these authors pointed out,

TK cannot be preserved merely by documentation. It requires the combining of knowledge with experience, which in turn means conserving the way of life which produced the knowledge (Gupta, 1999).

In another example, Merculieff (1990), Commissioner of the Sea Otter Commission, Alaska, raised a fundamental issue about the politics of defining resource boundaries and the legitimacy of the particular ways of local people in dealing with these. Distressed at the poverty of many of the First Nation peoples of Alaska, he decried the tendency of "Animal First" activists to deny such peoples their autonomy in pursuing a sustainable co-existence in their ecological context. Merculieff observed:

> *They do not understand that in their desire to protect animals, they are destroying culture, economic and spiritual systems which have allowed humans and wild life to be sustained over thousand of years… Their (Animal First) concept is based upon a belief that animals and humans are separate and they project human values into animals. Ours is based on the knowledge from hundred of generations which allows us to understand that humans are part of all living things – and all living things are part of us. As such it is spiritually possible to touch the animal spirit, in order to understand them. Our relationship with animals is incorporated into our cultural systems, language and daily lifestyles. Theirs is based upon laws and human compassion … Because we are intricately tied to all living things, when our relationship with any part of such life is severed by force, our spiritual, economic, and cultural systems are destroyed, deep knowledge about wild life is destroyed, knowledge which western science will never replace… I leave you with this last thought – we have an obligation to teach the world what we know about a proper relationship between humans and other living things.*

It is very important to understand and to appreciate that different indigenous and local communities develop knowledge systems through a tradition of invention and also develop languages through which to articulate their knowledge systems. If a language dies, then a knowledge system may partly or completely die at the same time. Hence, the conservation of language becomes a crucial factor for conserving taxonomies, because each word, conceptually speaking in the context of a natural resource, is a category. Modern science will benefit a great deal, and so will the ability of humans to understand their environment and to cope with it, if the scientific basis for these categories is better understood. The etymological roots of different words might elucidate the process of codification of knowledge over time in languages, as influenced by exogenous knowledge systems, migrations, wars, and other social interactions. Palomares, Garilao and Pauly (1998) provide an interesting study of local names of the fishes in the Philippines drawing upon the FishBase database[43] maintained at the International Centre for Living Acquatic Resource Management (ICLARM). They present the rather counter-intuitive insight that, in subsistence fisheries, 50% of the species do not have Philippino language names, whereas in the commercial fisheries as many as almost 90% had such names. Since the number of species named by subsistence categories was only 34 as against 455 in the commercial categories, the difference may be explained by the possibility that subsistence categories of fish were not so crucial to the survival of a community. But the commercial categories were apparently very crucial, and thus the variety of names.

Formal science, in its effort to generalize boundaries over large time and space, often masks finer categories. Local knowledge systems (LKS) often do the opposite. *LKS help in distinguishing small variations in phenomena and do so within relatively small habitats*. The better the resource management strategies in LKS fit with local environmental conditions, the lower the negative externalities on the environment may be. However, this local focus also means an inability or limited ability of local communities to deal with wider connections. *For the sustainable development of this planet, both telescopic and microscopic visions are needed: the ability to see*

connections among larger systems and to appreciate interconnections at micro levels; in other words, we need both reductionist science and a holistic vision.

The Production and Reproduction of Knowledge

The process of local knowledge production and reproduction may differ. Production of local knowledge can be through the discovery of problem-solving on a small scale, in an episodic manner, or through interaction with wider knowledge systems, ranging from, for example, networking with kin to networking with external partners.

In a dynamic knowledge system, some knowledge will inevitably be lost on account of changes in access to resources, and changes in socio-ecological conditions, or changing perceptions of needs. In a vibrant culture, much of the knowledge that is passed down from one generation to another depends upon social structures and its ability to change with the time. Knowledge related to livelihood strategies is embodied in practice. Once the livelihood strategies themselves undergo change due to reduced or modified access to the underlying natural resources, as has happened in most developing countries, the Local Knowledge Systems (LKS) becomes fragmented, and may not be adequate to take care of a given resources in a sustainable manner. Cultural knowledge is embedded in rituals, folklore, art and other cultural and social artifacts and processes. Local experts may reproduce some other specialized forms of knowledge, such as making and retting nets or fish traps, individually, rather than at the community level.

Knowledge that is embodied in practices usually takes the form of skills which are learned. Skills can be repetitive and non-repetitive. "Judgmental" skills are often scarce. Examples of such judgmental skills are weather forecasting, judging the quality of diamonds (diamond polishing using labor intensive methods has grown into an important off-farm employment in many of the villages of Gujarat, India), cattle judging, diagnosing human and animal ailments and problems of soils, lakes, and finding out potential sites with rich fish population, etc. Individuals who possess such skills may become recognized as local experts. Some skills are embodied in the practice itself and can be converted into specific know-how capable of being applied for industrial applications by anyone well versed in the art. However, there are other skills which are embodied in a person as a type of tacit knowledge. The latter can be kept either as trade secret or as personalized knowledge. The former can benefit from the application of IP, whereas the latter may be covered by trade secret protection only.

The Performance of Indigenous Knowledge

The performance of indigenous knowledge has been reviewed by Richards (1987). Performance from an indigenous perspective might include a number of functional criteria that are considered by formal science as less relevant: e.g., risk management, contributions to system maintenance, soil health, etc. The same practice could have different impacts on the natural resource base, depending upon the criteria emphasized by a community while deciding the appropriateness of a practice in a given cultural and spiritual context. The values underlying the choice of criteria serve as a guide for dealing with each other (social equity), with non-human sentient beings (i.e., other life forms capable of feeling and having consciousness), and with nature (ecological responsibility) and the super-natural (ethereal or spiritual beliefs). For instance, in July 1998, the Canadian government permitted certain Inuit communities to kill a bowhead whale, a protected species for the last 65 years, for consumption, as well as for ceremonial purposes. This permission resulted from data provided by The

Bowhead Traditional Knowledge Study, coordinated by Keith Hay of the Nunavat Wildlife Management Board, which revealed the existence of approximately 350 bowheads, rather than a "few tens" believed to exist by scientists. This larger number made the national government's permission to kill one whale a year for ceremonial purposes quite sustainable. TK, embedded in a culture and embodied in practice, can serve as one important mechanism to preserve and pass on sustainable livelihood strategies to future generations.

Communities give expression to their belief systems, norms, values, and ideologies through folk art, crafts and rituals, taboos, myths, symbols, etc. These values are reflected in their livelihood strategies, which are also closely integrated with local institutions, social networks, kinship networks and knowledge systems. The non-functional aspects of such knowledge also influence performance. The prompts, or cues, as Richards (1988) observes, provide a kind of road map on which act is played and replayed. Thus the cultural context in which interactions may take place among different community members may be provided by non-functional aspect of roles, rituals, and responsibilities. The knowledge, as Rengifo (1990) has argued, then occurs. It does not have to be crafted.

The Ecological Context of Traditional Knowledge

The ecological context in a given region, or for a given community, defines the nature of environmental risks or threats. A drought, a flood, erosion of biodiversity, or an increase in salinity levels are examples of threats. The regions that have low exposure to such threats are preferred by markets and are therefore at an advantage in land-based community strategies. Given the low transaction costs of exchanging resources in these regions, the adaptive responses of their households are fast. Their social structures are also different to those of disadvantaged regions that have higher perceived or real exposure to risks or threats.

In Table 2 below, I have enumerated the key contrasts that characterize the advantaged regions (market-dependent and dominated) by comparison with the disadvantaged regions (nature-dependent and dominated). The market dependent communities are the ones in which most exchanges are mediated through markets. The commoditisation of labor, products, and skills is high. In contrast, the communities that draw their major sustenance through use of natural resources, often without much value addition, are defined here as nature-dependent communities. The regions where each type of community predominates are also contrasted here. The market-dependent regions are the high growth green revolution regions and commercial fisheries, while the nature-dependent regions are rainfed drylands, hill areas or forest fringe areas and small scale fisheries.

Table 2

	Market dominated	Nature dominated
Communication System	Digital	Analogue
Pooling of resources	Very low	Very high
Reliance on common properties	Low	Very high
Settling of books of account	Very short term	Long term
The proportion of households headed by women	Very low	Very high
Women's participation rates	Very low	Very high
Reciprocities	Specific	Generalized

Source: Gupta, 1992, 1995

One particular dimension of this contrast between nature-dependent communities and market-dependent communities, is the comparison between analogue and digital systems. Analogic communication implies metaphorical communication, while digital implies very precise ways of communication. The redundancies are low in the latter while high in the former. Many local experts have a symbolic language through which they communicate their understanding of a problem. Many scientists and policymakers do not appreciate this basis of communications and jump to the conclusion that such expertise involves more 'mumbo jumbo' than actual skills. In some cases, this might be so, but to generalize this over entire bodies of TK in contemporary institution contexts is quite inadequate. The persistent neglect of traditional ecological and technological knowledge, as well as contemporary creativity of local communities and individuals, should be avoided. Bridges built between knowledge that has evolved through generations of interaction between humans and nature on the one hand, and the western scientific scholarship evolved over several centuries on the other, will enrich both. The fair trial of contemporary creativity by formal scientists will enlarge the repertoire of those institution builders, who want farmers and fisherfolks to have low-cost, nature-friendly technologies, coupled with institutional structures restraining greed and maintaining respect for the rights of the unknown and unknowable, such as the future generations of a community.

Many times, the motivation for even a contemporary innovation is not entirely utilitarian from a human point of view, though the invention may be extremely useful for human beings. Amrutbhai Agravat, a farmer-artisan of village Pikhor, District Junagadh, Gujarat innovated a tilting bullock cart in which the burden on the bullocks was reduced considerably because of the introduction of four, rather than two wheels. The added advantage of this tilting mechanism was that one could pour the manure directly into furrows instead of putting it in one place and then distributing the manure manually through baskets. Here the concern for the well-being of the bullocks may not be captured in the incentives for the invention *per se* and yet, this concern was an important factor behind the invention.[44]

Logic of Long-Term Conservation

Communities and individuals who have long conserved biodiversity have not done so entirely on the basis of utilitarian logic. The efficiency of ethics may sometimes be tempered by the inefficiency of technology used by local communities. That is, while the local communities may not like natural resources to be exploited beyond their sustainable limits, they may use non-sustainable and inefficient technologies. Use of such technologies in the wake of unfair competition with well equipped market forces may lead them, for example, to use unsustainable technologies for catching fish, such as fishing by the use of dynamite.[45]

Extractive uses of biodiversity can sometimes be less conducive to the long-term conservation of a species, even though the norms and values guiding the extraction may be very noble. This happens when poachers, combined with impoverished local communities, may bring a species to near extinction, even though local extraction by the communities may be much less than that by outsiders. Once ethical values, cultural norms and belief systems become weak, the inefficiencies of extraction methods may start generating negative feedback effects; that is, the restraint for extracting diverse resources within their sustainable limits becomes weaker.

The important point to note is that improvement in technical methods may not necessarily lead to evolution or restoration of ethical norms. The challenge is therefore to devise incentives that fulfill four conditions of sustainability:

- Access to biodiversity for local communities, so as to ensure their sustainable livelihood systems, should take priority over access for outside institutions or individuals;
- Assurances should be given to individual healers or other local experts, communities, and other stakeholders of sustained access to the resources and viable collective responsibility for using biodiversity;
- Traditional skills and abilities should be blended to convert biodiversity resources into investments with or without value addition; and
- Cultural lifestyles and value systems should be conserved in such a manner that basic needs are met without impairing the life support systems of local communities.

Value Chain for Traditional Knowledge

Unless arrangements are made for sharing value-added knowledge and benefits from value-added gains (made possible by converting local knowledge into economically profitable investments or enterprises), collectors have no ethical right to collect such knowledge. A second requirement should be that research results and lessons learned in the process of value addition should be shared with the knowledge providers in the local languages and in an easily understandable manner. Codes of conduct for gene-bank managers, researchers, funding agencies, and other development managers should provide for such sharing in an unequivocal manner. Local communities have already paid a heavy price because the designers of dams, hydropower projects, waterways, commercial prospectors of biological resources, and landfill programs that have damaged wetlands have ignored their knowledge and institutions. These communities must not be dispossessed of the only resource left with them their knowledge.

Incentives for Conserving Biodiversity and related Knowledge, Innovations, and Skills

Biodiversity cannot be conserved by keeping people poor, even if, historically biodiversity survived largely under such conditions (Gupta, 1990). Some studies (Gupta, 1989, 1991, 1997) have shown that many communities which conserve diversity have remained poor because of their superior ethical values. This happens when healers refuse to request or accept any compensation or payment for their services provided to individuals within and outside their community. Further, when they decide not to pluck more plants than are necessary for immediate use, they forego an opportunity of accumulating wealth by processing the herbal diversity in larger quantities and selling or dispensing it to others for consideration. By comparison, there are others at the same time, both local people as well as large national and international corporations, who have no hesitation in extracting biodiversity without taking care to regenerate the same. One of the challenges is to modify ethical positions that threaten biodiversity and, at the same time, to ensure improvements in livelihood prospects for indigenous peoples, through the implementation of the CBD and relevant IP conventions. These communities will then continue to conserve biodiversity along with their associated ethical and cultural values.

The rate of erosion of local knowledge about biodiversity has never been so high. There are several factors which explain this: changing family structures, from extended to nuclear families; consequential weakening of the links between the grand-parent generation, which holds much of this knowledge, and the grand-children generation;[46] a diminished esteem for this knowledge in primary school curricula; the transition from a largely oral to a largely written or documented culture; and the inability or unwillingness of many older healers and herbalists to share their knowledge or agree to its transcription, or to transcribe it themselves. This

unwillingness arises in many cases because outsiders, such as ethnobiologists, have extracted local knowledge and have subsequently commercialized it or published it without any attribution, reciprocity, or associated benefit-sharing, and thus have offended local communities.

Knowledge erosion is a threat as serious as resource erosion itself. The reasons are obvious. If there is no knowledge about given resources, plants become weeds. It becomes not only difficult to locate what is useful or known, but also the incentives for conserving what is not known is much reduced. In ecological economic terms, the option values decline if the probability of finding something useful in the current generation is lower because of the loss of knowledge about the resources. Conserving biodiversity without conserving associated knowledge systems is thus like building and maintaining a library without a catalogue. It is true that users of such a library might develop a catalogue over a long period of time but meanwhile the users would suffer. By analogy, biodiversity users, who are without a knowledge base, will not benefit from centuries of experimentation and knowledge accumulation by local communities and indigenous peoples. It is true that formal scientific knowledge of plants and animals is diverse and rich. However, the bases upon which different communities have classified and organized their traditional knowledge and practices are similarly complex and dynamic.

There are three crucial assumptions underlying this perspective:

- First, not all knowledge, innovations and practices prevalent in a community are communal in nature. There are individuals who have great expertise in various aspects of local knowledge, but that knowledge may only be known by that individual or, in part, by the local community;
- Second, not all the knowledge in use by a community is traditional in nature. There are many examples of contemporary innovations by local communities, developed collectively or individually;
- Third, local knowledge can be conserved perhaps in a more sustainable and dynamic manner if the associated cultural values and ethical institutions contributing to conservation of biodiversity are also conserved and/or strengthened. Sustainable and dynamic conservation would mean conservation in a manner that permits the knowledge to grow through constant experimentation and innovation rather than simply being maintained as a fossilized form of historical knowledge, produced at one point in time and carried forward by succeeding generations.

Incentives for the conservation and sustainable use of biodiversity will have to be sufficiently flexible and diverse so as to provide for the growth and development of the traditional as well as the contemporary knowledge that is held by individuals as well as groups. The same, or similar, incentive structures or philosophical assumptions cannot provide adequate motivation to conserve what exists and to restore what is lacking. Devising appropriate incentives is challenging because many local communities lack access to resources for some basic needs and are impoverished. Factors that have contributed to the links between high biodiversity and poverty are discussed by Gupta (1989, 1991, 1993). In addition, SRISTI (1993) has noted the following factors (see also Gupta, 1990, 1992):

- Biodiversity is high in rain forests, mountains, some arid and semi arid areas, humid areas, primarily due to diversity in soil, climate and other physical and social structures;
- Poverty is high, because markets are often unable to generate demand for diverse colors, tastes, shapes and qualities of natural products. Products of mass consumption, particularly when processed by machines, have low variability because throughput by machines has to be of uniform quality and maturity level. For instance, when processing tomatoes to make tomato-ketchup, local varieties will often not be suitable, because these are not synchronous in maturity, have uneven ripening status and

therefore their taste, color and flavor can not be standardized. In addition, the cost of packaging and labeling, transportation, and display in a supermarket of a wide range of varieties of, for example, tomatoes, will obviously be higher than the costs of only one variety. Consumers who do not demand a range of varieties, either because they have not been exposed to such a possibility or are unwilling to pay any extra costs, also contribute to lower demand of biodiverse products;

- The regions of high diversity also have very poor public infrastructure, in tandem with weak private market forces, because the people have limited surplus to attract public servants and are less articulate and organized at the creation of political pressure;
- The low demand for the ecological and technological skills of these communities characterizes them as 'unskilled' labor, fit for being a part of the urban slums, squatters, or other similar work force. Once the knowledge system is devalued, cultural and social decline follows. The tenuous relationship with nature is ruptured. Ecological degradation spurred by various external resource extractors is aided and abetted by many poor, as well as not so poor, people for whom survival in the short term seems possible only through eco-degrading strategies. Thus, when the demand for local biodiverse products is low, the exchange value will drop, consequent purchasing power will decrease, and poverty is bound to follow. Supplies for basic needs also get constrained, due to administrative and political apathy towards people in these regions where population density is low and, thus, the number of votes and other kinds of political pressures are lower.

Incentives for conservation and value-addition

To overcome many of these constraints, four kinds of incentives for rewarding innovations have been proposed (Gupta, 1991, 1995, 1997). The framework for designing these four incentives results from the interaction of two variables:

- Nature of benefit, whether material or non-material; and
- Target of benefit, whether individual, including a group of individuals, or community.

Table 3

Target of Benefit		Forms of Benefit	
		Material	Non-Material
	Individual	1	2
	Collective	4	4

(a) Individual – Material

These rewards are in material form paid to individuals, such as royalties from patents, copyrights or trademarks, biodiversity user fees, monetary rewards, equipment, fellowships, land assignment etc. They could arise from those who license technologies of herbal, or animal-based recipes, created by individuals.

(b) Individual – Non Material

These non-material rewards could include: invitations to lecture in schools, centers of learning and research

opportunities; invitations to conferences; workshops attaching the name of the innovator to the innovation, an incentive frequently used by the local communities themselves; photographs placed in village or district councils; press coverage. For example, for the last ten years, SRISTI has awarded the SRISTI *Sanman* (honor) to outstanding innovators at grassroots level. The National Innovation Foundation (NIF)[47] now provides national awards for similar purposes. Other SRISTI collaborators, such as SEVA at Madurai, provide similar awards at a regional level.

(c) Community – Material

These rewards can be quite important, since they can help generate the right signals and encourage the mobilization of collective action, which is so important for conservation. The instruments of such rewards can include: trust funds; priority in the development or allotment of local infrastructures, such as schools, health care system, access roads etc.; free or easy access to data banks; access to external expertise; community awards; community grants/ risk funds; external aid in developing common property assets; marketing intervention for organic produce, etc.

(d) Community – Non-material

These can be rather difficult to implement, but may have quite an endurable impact, particularly when the rewards affect the values of the communities in a positive manner. Rewards may include: policy changes that ensure a greater control over local natural resources; the removal of perverse incentives for conservation (that is, indications which encourage non-sustainable use of resources); favorable policy environments for eco-friendly products; conservation practices; media attention; community awards; capacity building through the transfer of technology; the building up of negotiation skills; inclusion of TK innovations and practices in the school curriculum, which may help to raise social esteem for local, eco-friendly practices and innovations, etc.

The magnitude, manner and form of incentives or benefits may influence the degree of involvement of the local communities or individual innovators in future projects of biodiversity conservation.

- Incentives could be in cash or kind, conditional (linked to research) or unconditional;
- Community incentives could be of a direct nature, or they could be indirect. They could be provided at a single point in time, or over an extended period of time;
- Incentives could be provided by external agencies or by the local communities themselves. The improved status of the innovators on account of social recognition may, or may not, be associated with a greater say in decision making at the societal level; and
- Incentives may focus on empowerment of local communities so that they may have better negotiating skills and better knowledge for conservation of local resources. Alternatively, the incentives may be targeted directly at conservation. Incentives targeted at the community may lead to action either at the community level or even at the individual level.

A framework for access to local biodiversity and knowledge systems

Access to biodiversity can be looked upon from the perspective of its uses, as well as the methods of access:[48]

Table 4: Access Framework

Returns		Access	
		Extractive	Non Extractive
	Non-commercial	1	2
	Commercial	3	4

(a) Non-commercial – Extractive

The samples are extracted for taxonomic or ecological analysis, without any commercial purpose in mind: e.g. for academic research and studies by individuals, institutions, and/or public and government organizations. Recent examples of such studies include a request from The Department of Plant Science, Oxford, United Kingdom to the Indian Ministry of Environment & Forests to conduct field studies and the collection of certain specimens of flora from South India.[49] A similar request was made by The Royal Botanical Garden, Edinburgh, Scotland to conduct field studies and collect flora from Sikkim, India.

(b) Non-commercial – Non-extractive

An example might be access to biodiversity, in order to describe eco-systems or local knowledge systems: for instance, studies carried out by the Zoological Survey and Botanical Survey of India in order to document the biodiversity of India; or ethnobotanical studies documenting knowledge of ethnic communities about plants. It is, of course, possible that this information may be put to commercial use later, or the sites described may later become sites for economic extraction or eco-tourism, but if, at the time of documentation, the intention behind the request for access was of a non-commercial nature, then the case will fall within this category.

(c) Commercial – Non-extractive

This category refers to the extraction of local biodiversity-related knowledge systems, rather than the physical extraction of biodiversity itself. Sometimes, this knowledge is used for commercial gain by pharmaceutical firms and other commercial prospectors: for instance, the negotiation of a benefit-sharing agreement between the Kani tribe and the Indian Tropical Botanical Garden Research Institute (TBGRI), who used the knowledge of the Kani to enable the screening of a particular therapeutic drug is a well known example in India. Furthermore, databases, such as the Natural Products Alert Database (NAPRALERT), which contain a range of information, including ethnobotanical data on selected plants, can be accessed by commercial companies on payment of a fee.[50]

(d) Commercial – Extractive

This is a form of access where a commercial organization, local community or cooperative extracts components of biodiversity for a commercial purpose; i.e., this involves the physical extraction of biodiversity, either for direct use of that biodiversity or to use that biodiversity to produce value added products. The extraction of medicinal

plants by firms to produce medicines, the working of bamboo forests by the paper industry for use in pulp production, are examples of this category. The Merck-INBio deal in Costa Rica is another well-known, and well-documented, example. In summary, Merck, a pharmaceutical company, receives screened natural samples from the National Institute of Biodiversity of Costa Rica (INBio) for further research and development. Similarly, the use of medicinal herbs and plants by an individual herbalist to treat patients may also be termed as an extractive and commercial access.

Local v external

The term, 'local' refers to geographical limitations, meaning that certain resources may be extracted or used by the communities living around those resources. They may, or may not, have formal property rights over those resources. Thus, a local context would be a tribal community living in or around a forest, and dependent on locally available resources for its survival. The external agents could include companies or scientists or others located in nearby cities or abroad. The difference is in scale and spatial distance. The scheme presented below is one way of looking at these contrasting situations in an effort to understand the underlying tensions:

Table 5

Extractor Location		Access	
		Local	External
	Local	1	2
	External	3	4

(a) Local Extractor – Local Use

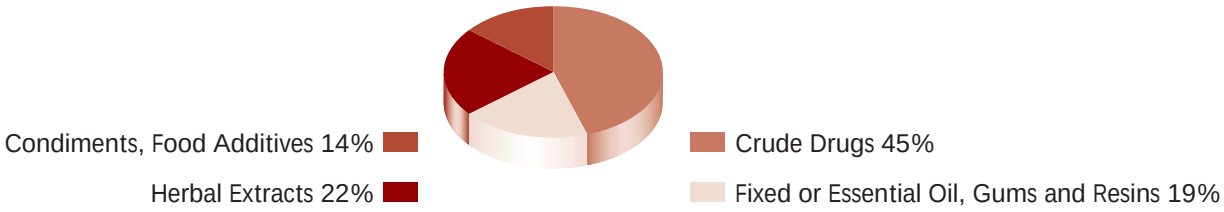
The use of locally grown biodiversity by a community for its own consumption, or of biodiversity owned by that community for its own consumption, may constitute category 1. Collection of leaf litter from social forestry to be used as fuel by tribal communities in Orissa, India, or the use of bamboo found in the local forest for construction of houses by local and indigenous communities are examples of such modes of access. An Exim Bank Occasional Paper estimates the local extraction and consumption of herbal plants to the tune of Indian Rupees (Rs.) 600 million per year.

(b) Local Extractor – External Use

The economic significance of Indian biodiversity can be gauged by the fact that the domestic trade in medicinal herbs and its extracts is in the region of Indian Rupees Rs. 3 billion and is increasing.[51] The medicinal herbs are extracted by the local people and reach the industry through middle men. They are used for the production of value added natural products.

Nonetheless, a recent World Bank study pointed out the poor returns on natural resources to India and its local extractors, and cited the example of "*Tetu Lakda*" twigs. These twigs are available in India at Rs. 9/Kg ($0.26/Kg), while its extracts are sold in the international markets at Rs 500,000/Kg ($15,000/Kg).

Utilization of Indian Medicinal Herbs: Domestic Market Segments



Policy guidelines and protocols should look into these disparities in benefit-sharing and enthuse and motivate the private sector to bridge these gaps. In some cases, if motivation does not work, sanctions may have to be called for. The current demand for medicinal plants is being met, in part, from cultivated sources; however, wild specimens remains the major source of medicinal herbs. The world trade in medicinal plants and related products is estimated at US $5 trillion by the year AD 2050. To meet the increased demand, cultivation of these species, and use of tissue culture or cell culture techniques, need to be promoted. This is a must, as the current level of extraction from the wild is not sustainable. The private sector has to take the lead in this area and policy measures for biodiversity conservation should include incentives for such investments.

(c) External Extractor – Local Use

An example of such an interaction would be the collection and use of "*sabai*" and "*bhabar*" grass for pulp making in India by the paper mills. The grass, that is also fit for rope making, may also be sold to the local people. Another example would be the collection of long bamboo by paper mills operating inside the forest for sale to the local people via the forest corporation.

(d) External Extractor – External Use

An external extractor, such as a paper mill or a non-timber forest produce contractor, may use labor from outside the local communities to prospect biodiversity, which is then transported to an external location for value addition or processing. The local communities have minimal or no role to play in such extraction, though they may suffer the consequences of resource depletion and degradation.

Modes of extraction and diversity

A regulatory regime cannot be designed uniformly for different kinds of extraction options at varying scales for various commercial and non-commercial purposes. The table below defines the interaction of various types of biodiversity with different access regimes, governed under various property right laws.

Table 6: Modes of Extraction and Diversity

		Biodiversity Extractors				
		Fauna	**Flora**	**Microbial**	**Genetic**	**Bio-chemical**
Foreign	Commercial					
	Non-commercial					
Domestic	Commercial					
	Non-commercial					

Access to biodiversity *per se* should be distinguished from access to genetic resources, despite the difficulty to draw the line between both categories. This is due, in part, to the fact that the monetary gains arising out of the use of genetic resource are significantly higher than those arising from physical access to biological resources.

Glowka (1998) reviews various proposed legislation, agreements or executive orders on the subject of the regulation of access to genetic resources. For instance, in the Philippines, the National Commission on Indigenous People (Administrative Order No.1, 1998, Philippines)[52] provides the following specific guidelines for The Protection and Promotion of Indigenous Systems and Practices (IKSPs):[53]

- Indigenous Cultural Communities (ICCs) and Indigenous Peoples (IPs) have the right to regulate the entry of researchers into their ancestral domains/lands or territories. Researchers, research institutions, institutions of learning, laboratories, their agents or representatives, and other like entities, shall secure the free and prior informed consent of ICCs and/or IPs before access to indigenous peoples and resources is allowed;
- A written agreement shall be entered into with the relevant ICCs and/or IPs regarding the research, including its purpose, design and expected outputs;
- All data provided by indigenous peoples shall be acknowledged in whatever writings, publications, or journals are produced as a result of the research. Relevant ICCs and IPs will be definitively named as sources in all such papers;
- Copies of the outputs of all such researches shall be freely provided to the relevant ICCs and IPs; and
- The relevant ICCs and IPs shall be entitled to royalties from the income derived from any of the research conducted, and any resulting publications.

Variance in sources

Different species of biodiversity occur on land and in water and are governed by different kinds of property right regimes. A regulating authority should have different rules according to the source and the extractor(s) of the resource.

Table 7: Governance and Access

		Source Regime					
		Terrestrial			Aquatic		
		Private	Public	Common	Private	Public	Common
Foreign Extractors	Commercial						
	Non-commercial						
Domestic Extractors	Commercial						
	Non-commercial						

The property right regime that governs a particular resource influences not only the constellation of stakeholders, but also the possibility of disadvantaged communities and individuals benefiting from a resource-centered benefit-sharing mechanism. Further, benefit-sharing need not be seen only among international users of resources and knowledge, but among by the domestic users. After all, a tribal community or individual healer gets no respite from the fact that the exploiter is from within the community or country and not from abroad. In many developing countries, a great amount of damage to biodiversity and, sometimes, the greatest exploitation of local communities has been caused by domestic interest groups.

SECTION D
LITERATURE REVIEW

Intellectual Property, Traditional Knowledge and Benefit-Sharing in Different Cultural Contexts

The need for a low transaction cost system of intellectual property (IP) protection for TK is obvious, and yet most global dialogues on intellectual property rights have not yet embarked upon such a system. Article 23.4 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides for negotiations to be undertaken in the Council for TRIPS of the World Trade Organization (WTO) on the establishment of a multilateral system of notification and registration of geographical indications in the context of wines. There is no reason why such negotiations should be restricted only to wines and not be broadened to include TK, as well as contemporary innovations of local communities and individuals.

There are many other policy and institutional modifications that are called for in existing IP laws. It is not my argument that removing the imperfections of IP regimes will, by itself, generate economic rewards and social esteem for local, knowledge-rich, but economically poor people; the role of non-monetary incentives may be sometimes more important. However, the biotechnology, drug, and other value-adding industries have not yet shown sufficient interest as stakeholders in generating models of voluntary benefit-sharing. Does this imply that they believe that future gains in biotechnological products may be made only on the basis of public domain biodiversity?

Machlup, (1958) provides a succinct historical review of the debate on patents in the late 19th century in Europe and America, and provides various arguments that were used to oppose patents at that time among developed countries, including ethical considerations. Following the depression, the rise of protectionism and nationalism and the "willingness of patent advocates to accept a compromise", the anti-patent movement collapsed. The idea of a compulsory license evolved as early as 1790, but did not become part of patent wisdom at the Patent Congress held at Vienna World's Fair in 1873, thereby enabling inventions to be used more widely by licensing them to others at a reasonable cost. Machlup also notes that the discussion on registration systems has taken place for over 100 years and reviews this debate and summarizes various considerations that were brought into the discussion.[54] He observes:

> *Under the registration system, the validity of a registered patent is examined only if an interested party attacks it in the court and asks that the patent be invalidated. Under the examination system, the patent is issued only after the patent office has carefully examined the patentability of invention. This examination may include so-called "interference proceedings", when the Office finds that two or more pending applications seem to claim, "partly or wholly" the same invention so that the priority of one inventions has to be established. The so-called "Aufgebotssystem", examination-opposition-system provides for an interval of time after publication of the specifications examined and accepted by the official examiner and before the issuance of the patent, in order to enable interested persons to oppose the patent grant…. The registration system administratively is the cheapest. But may burden the economy with the cost of exclusive rights being exercised for many inventions which, upon examination, would have been found non-patentable. In favour of the examination systems, it has been said that it avoid a mass of worthless, conflicting, and probably invalid patents, onerous to the public as well as bona fide owners of valid patents; that it prevents the fraudulent practice of registering and selling patents similar to the claims being patented by others; and that it drastically reduces the extent of court litigation (1958).*

Machlup (1958) also reviewed several suggestions for reform of the patent system, some of which are still relevant in the 21st century: for instance:

- In lieu of making inventions freely accessible to all, rewards should be awarded to patentees of a sufficiently high level to give general satisfaction to the inventors and those who have invested in their inventions financially. The rewards will have to be fixed, according to the "assessed values created by the invention" (Michael Polanyi, 1944)[55];
- In this scheme, instead of making an annual "participation payment" to the licensers (in addition to the reasonable royalties received by them from licensees) the government would buy the patents outright and open them to all, free of royalty (Hamilton, 1957).[56] Another variant of this suggestion entails the option for government to purchase any patent at a reasonable price, if it was interested in making it available for general use;
- Proposals for giving bonuses are said to be as old as the patent system itself;[57]
- Government should finance research and development. If society wants innovation, such innovation must be paid for.

In different countries, combinations of incentives system have been applied. Even countries with strong patent systems have recognized the importance of a government's investment in research, national awards and, in occasional cases, the possibility of compulsory licenses. The examination system has been for disclosure, rather than for invention or novelty, as in the case of Switzerland. The Swiss experience has been that the percentage of patents, which worked in the national system, was similar to the international patent system. Machlup (1958) quotes a famous analogy regarding car brakes. Car brakes permit a motorist to drive a vehicle at speed. Unlike these brakes, a patent may put brakes on others regardless of "how fast or cautiously they proceed". Machlup concludes that, based on the evidence available, the implications for strengthening or weakening different features of patent law will not be the same for a non-industrialized country, as for a newly industrialized country. In the post GATT phase, the consensus has veered towards harmonization of patent laws world-wide, though some exemptions and more lead time has been given to developing countries. History shows that the debate being witnessed now is not new, and has never provided clear answers.

Coombe (1998) reviews the interface between IP, human rights and sovereignty in the context of indigenous knowledge and conservation of biodiversity. She reviews the universal declaration of human rights, International Covenant On Civil And Political Rights (CCPR) 1966, and International Covenant on Economic, Social and Cultural Rights (CESCR) 1966. In the context of IP, the CESCR provides that an author can benefit from the protection of moral and material interest resulting from any scientific, literary or artistic production. Coombe observes that, historically, civil and political rights were believed to be absolute and immediate, whereas economic, social and cultural rights were thought to be more "programmatic" in nature, and could be realized gradually. The former were considered justicable, while the latter were considered more political in nature. Coombe quotes Scott Luckie, who argues that the permeable nature of many human rights, "should have long ago laid to rest sentiments divorcing, rather than merging, civil, cultural, economic, political and social human rights" (Luckie 1998).[58] Coombe notes that, when reporting on the realization of rights under Article 15 of the CESCR, a state is asked to describe the steps it has taken to realize, "the right of everyone to take part in the cultural life which he or she considers pertinent and to manifest his or her own culture. Coombe also notes that all the 130 member states of the CESCR, "have international human rights obligations to ensure that the intellectual property rights recognized in their jurisdictions are established, granted, exercised, enforced, licensed, and otherwise used in a fashion that does not infringe upon the human rights recognized in the two international Covenants". Despite the fact that over 180 countries have ratified the

CBD, which mandates under Article 8(j) the use of local knowledge, innovations and practices through involvement and approval of local communities, the tensions on this account remain.

The application of IP laws to TK and innovations hinges on how traditional or indigenous knowledge is conceptualized. Brush (1996) includes all folk or popular knowledge preserved in local and traditional practices as indigenous knowledge. Agrawal (1995) decries the tendency to view indigenous knowledge as a counterpoint to western or scientific knowledge. This has been very obvious to the readers of Honey Bee newsletter for over ten years. Honey Bee Network has questioned this dichotomy and has always argued for building bridges between formal and informal science. The assumption is that science is a post-industrial revolution western construction. Studies by Needham on the evolution of science and technology in China and the research work on plant science by Mazumdar (1925), and Singh and Verma (1969) clearly demonstrate that the localization of knowledge takes place through practice in different parts of the world. Likewise, the scientific principles of refutability, generalizability and falsifiability have been at the core of scientific knowledge produced by local communities. Mere abstraction or lack of it does not confer on a practice, a label of a superstition or a conjecture. Lack of causality, likewise, is not a limitation just of local knowledge. The use of aspirin for a headache has been part of modern scientific knowledge for a long time, without the knowledge, until recently, of how aspirin actually worked to reduce or remove the headache.

So far as abstraction is concerned, there is much in agronomy and other plant sciences in which empirical knowledge is generalized without providing the entire rationale of a given practice. Farmers have produced such knowledge for ages. So long as this knowledge produced predictable, functional and context specific results (some of which were also context free), the scientific basis of the knowledge remained only to be articulated. This became essentially an issue of logic and language. Boiling milk at least three times without allowing it to spill over by alternate heating and cooling has been an old practice for extending the life of milk. By doing this at frequent intervals of few hours, one could keep milk fresh for days without using refrigerator. Women farmers and the villagers who developed this method of keeping milk fresh did not articulate the underlying principle or the theory, as was done by Louise Pasture, who also added pressure to the milk. The practice did not become unscientific because the underlying rationale was not articulated in modern scientific language.

Thus, the issue is one of generating a vocabulary which may help to connect different knowledge systems, and which will recognize, as part of that process, the limitation and strengths of each system. There is no question about peculiarities of method, some of which dissolve on careful scrutiny. For instance, many good breeders considered breeding as much an art as science, in the sense that they always look for plants that matched their selection criteria. This is a function that many traditional farmers have also performed while selecting their varieties. Some methods of developing scientific information are common among both local communities and formal scientific institutions, even if the criteria of evaluation may differ quite significantly; for instance, grafting to improve a horticultural plant, selection to improve self-pollinated crops, as well as some of the cross-pollinated crops, and selection followed by bulking and re-selection are all common methods of plant breeding.

In some cases, the shortsightedness of formal scientific systems can also be seen in local knowledge systems. These issues are clearly linked. After all, chile, tomato, tobacco, potato and many other crops were introduced to Asia only about 500 years ago. Local knowledge gradually evolved around these crops, with significant cultural, socio-economic and socio-ecological variability. The point is that a local community, whether settled from outside, or evolved indigenously in a given region, does not have any compulsion to test their technologies over a wide region. Therefore, given the close relationship between local technologies and specific ecological

conditions, generalizability across large spatial units may be poor by design. This does not make the specific practices any less scientific.

Coombe (1998) acknowledges that:

> *… opposition between dominant and indigenous culture are often over-simplified, blurring the actual fluidity and permeability of knowledge and cultural boundaries. Just as dominant cultures appropriate knowledge from indigenous ones, indigenous knowledge itself contains knowledge shared between cultures, as well as information brought by colonists, settlers, and traders.*

This view, as I have said before, has been the basis of our movement in Honey Bee network and also that of several other attempts (Warren (1989), Varma and Singh (1969)). For instance, Dr. Y.P. Singh, who supervised some of the earliest post-graduate theses on indigenous knowledge in mid 1960s, raised the issue of whether "indigenous animal husbandry knowledge was relevant today". In the mid 1970s, Dr. Singh supervised another doctoral thesis, by Dr. Hira Nand, on indigenous dryland agriculture knowledge.

There is an old tradition of building bridges between different knowledge systems. Gaya Prasad Singh, (1915) drew attention to the practice of storing potatoes under coal in Frankfurt, Germany and compared that with a local practice of storing seeds under a cot in a diffused light and relatively cold environment. This concept was later popularized globally by the International Potato Research Centre (CIP, Rhoades, 1984). There are many other researchers such as Mauris Iwu (1989), Atte, Paul Richards(1985), Hira Nand(1979), etc., who have pursued the same line of thinking; that is, of linking different knowledge systems.

DeWalt (1994) reinforces the notion that, "those who use and develop indigenous knowledge systems (*mutables immobiles*), and those who develop and apply scientific knowledge system (*immutable mobiles*), are constrained by the way in which they have been trained to think and contexts in which they live. The key is to provide both knowledge systems with more opportunities in which they can inform and stimulate one another" (1994).[59] Thurston (1992) has demonstrated the potential of doing so in the case of plant diseases. The TAPP database developed by him traces the local and ancient knowledge on plant diseases documented over the last 500 years. Richards (1985) showed similar potential in case of rice, pests and many other agricultural practices. Warren (1991) has also argued for similar need of complimentarity among formal and informal knowledge systems.

The challenge of applying existing IP laws to local knowledge, innovations and practices also stems from the conceptualization of local knowledge as essentially a cultural and community construction. Having carried out a review of various IP instruments together with applicability to different kinds of local knowledge, Posey and Dutfield (1996) conclude that:

> *IPR laws are generally inappropriate and inadequate for defending the rights and resources of local communities. IPR protection is purely economic, whereas the interests of the peoples are only partly economic and linked to self-determination. Furthermore, cultural incompatibilities exist in that traditional knowledge is generally shared and, even when it is not, the holders of restricted knowledge probably still do not have the right to commercialize it for personal gain.*

Posey and Dutfield suggest, instead, a concept of Traditional Resource Right (TRR), which recognizes, "the inextricable link between cultural and biological diversity and sees no contradiction between the human rights

of indigenous and local communities, including the right to development and environmental conservation" (1996). It is obvious that existing IP systems were not designed to address the variety of rights that are included in the concept of TRR. Accordingly, so far as the rights of the communities are concerned, which are collective and deal with knowledge produced in past, these may have to be dealt with by new instruments.

The Crucible Group (1994) has suggested the concept of "Community Intellectual Property Rights" (CIPR), to enable local communities to assert their "rights to seed", such that no outside company or institution could use their knowledge or resources without their permission. This is a proposition in line with Article 8(j) of the CBD, and some aspects of the FAO's Farmers Right Concept. The Crucible Group also suggested a need for national legislation, an international database for tracing germplasm, possibly through the CGIAR system, and the appointment of a "public defender" to mediate or to act as ombudsman. The Third World Network (Nijar, 1994) has suggested a model Community Intellectual Right aimed at preventing the privatization and usurpation of the rights and knowledge of the communities. It further proposed that local community leaders might act as trustees of the community, and that farmers rights should be held in perpetuity. A "registry of invention" was also suggested, which could be linked to a community biodiversity register (Kothari, Ashish, Pathak, N, Anuradha, R.V., and Taneja, B., 1998, Gadgil, Ghate and Rao, 1999). This knowledge would lie in the public domain. Subsequently, Ghate, Gadgil, Rao (1999) have modified this concept to include only public domain knowledge in the community registers, and to specifically cite in the register the name of local experts, but not their knowledge or innovations. This modification was made in response to the suggestion by Gupta (1998) that, by recording the knowledge of experts in a public domain register, the ability of those experts to claim any IP over that knowledge may be exhausted. So far as CIPRs were concerned, the purpose of preventing others from patenting would be achieved by publishing local knowledge and by making such publications available to patent offices.

Stephen Gudeman believes that IP is another type of market force which may further erode an already endangered commons (1996).[60] He does not believe that the technical essence of local knowledge can be abstracted from the context of its use, and tested in a laboratory, to develop something of common use. He argues that if scientists could not validate a particular knowledge, they might consider it faulty. He observes, "Scientists draw a distinction between *res cogitans* (thinking being without spatial extension) and *res extensa* (material things as extended substance), between the mental and the material, intellect and emotion, knowledge and context" (1996). Undoubtedly, Gudeman is partly correct. Large number of scientists have treated local knowledge in such a manner. At the same time, the fact that 74% of plant derived human medicines are used for the same purpose for which local communities discovered their use, (Fransworth, 1981) proves that scientists have not hesitated in drawing upon local knowledge, when appropriate. Obviously, the evidence only shows how great the potential of using local knowledge may be, even out of its strict socio-cultural context.

Coombe (1998) agrees with Gupta's proposal (1997) that, "every patent office in a Western country should insist that the patent applicant declare that the knowledge and resources used in a patent have been obtained lawfully and rightfully". Lawful acquisition means that the prior informed consent of local communities and creative individuals has been ensured, assuming that the donor country has laws requiring such consent and approval. Rightful acquisition involves an ethical enquiry into a corporation's compensation practices. Coombe feels that Western governments, who are party to the major Human Rights Covenants, should ensure that, "private parties subject to their jurisdiction do not violate the human rights of others, such a premise is congruent with commitments to rights of subsistence, to enjoy the fruits of one's labor, privacy, environmental sustainability, and cultural integrity (although not all of these rights are necessarily implicated in every such

taking)". She feels that the lawful and rightful disclosure requirements may be awkward, if not politically impossible, to enforce, particularly if they were to be imposed as an absolute barrier to the patent protection. She suggests that, in the shorter term, this requirement need not include any minimum criteria. For instance:

> *… a corporate applicant might simply disclose that the source country impose no legal consent requirements, and that it has made no arrangements for compensation. To the extent that this information is made part of the public record and published by member State governments, it would provide leverage for indigenous peoples, NGOs, concerned consumers, interested citizens, and the media to put political pressure on patent holders to improve their research and development practices congruent with developing human rights norms. Over time, some corporations might recognize the publicity values and goodwill to be accrued by greater transparency and might set increasingly higher standards to develop market distinctions.*

Dutfield[61] (2000), in an extensive review of various initiatives, including peoples' biodiversity registers, community intellectual property rights and SRISTI's local innovation databases, concludes that the relevance of the international IP regime to the CBD is beyond doubt. The questions which he feels are unresolved include the following:

- It is not certain that increased availability of IP protection will automatically lead to greater levels of innovation in society. Innovation and creativity flourish in many parts of the world without any (western) IP laws.[62] On the other hand, allegations are increasingly made that too much IP protection of basic research can stifle innovation (see Heller and Eisenberg 1998);
- The role of IP in the erosion of agro-biodiversity has been the subject of some polemical debates, yet we still do not know how far biodiversity is affected by intellectual property rights for seeds, plant varieties and/or agrochemicals. But it can be argued that we cannot afford to wait for conclusive proof one way or another before making decisions on the design of environmentally-sound intellectual property rights. It is vital to consider whether, and how, the precautionary principle may be applied in the IP context, to minimize the risks;
- Some evidence suggests that most technologies supportive of biodiversity conservation are in the public domain. However, with respect to those which are not, it is unclear whether IP hinders or encourages their transfer to developing countries;
- It is widely accepted that the application of TK and technologies can add value to genetic resources. While patents are clearly unsuitable mechanisms to protect the rights of TK-holders, the use of other IP may, in some circumstances, be feasible.

So far as the issue of erosion of agro-biodiversity as a consequence of the use of IP is concerned, the evidence in the post-green revolution era in most developing countries is unequivocal. The erosion has been caused primarily by the public sector induced high yielding varieties, none of which have been protected by either the patents or plant variety acts, since the same have not been applicable. In Western societies, this supposition may have been valid. It is also true that large number of private seed companies and traders have used advanced lines as well as new varieties developed by public sector R&D labs without any reciprocity of compensation or payment of royalty. The result has been that public sector R&D institutions have had to depend primarily on government for resources, and thus their creativity and autonomy have been adversely affected. The application of different kinds of IP would have made these institutions recover returns on their investment in R&D and in due course have more dynamic and vibrant organizational culture. Obviously, so far

as the right of communities and local farmer breeders is concerned, it would require specific institutional innovations to reduce transaction costs and at the same time enhance incentives for contributing their know-how and resources to the public and private R&D institutions where applicable. In many cases, farmer-bred varieties can generate incentives for the individual farmer breeders provided they can protect their IP and use it for commercializing their innovation or disseminating it without any cost to others.[63] The response to other questions requires adaptation of the current IPR regime which CBD and WIPO are currently exploring.

Blakeney[64] (1999) reviews various mechanisms for the protection of indigenous knowledge, and seems to endorse a suggestion made by of Gollin (1993), that access legislation should ensure that any user of biodiversity pays a fee to the individual or community that discovered or traditionally used a particular species. Lesser[65] (1998) has suggested that a registry of traditional uses of genetic material be maintained in sufficient detail to permit their identification. Koon[66] (1998) regrets that the current IP legislation of Malaysia does not have any special provision for protecting TK and has suggested a proposal to introduce a special provision in this legislation to protect the end-products of traditional medicine and treatment. Williams[67] (1998) reviews the issues in New Zealand, with particular reference to the Wai 262 claim, presented by multiple tribes concerning the use of Maori knowledge systems and the protection of their sacred wisdom.

In Brazil, Wolff[68] (1998) describes Bioprospecting Law No.1235 of July, 1997 of the state of Acre and Law no.0388/97 of the state of Amapa. In the law of the State of Acre, bio-prospecting is allowed, subject to an access agreement between the State, the applicant for access and the furnisher of TK or the domesticated agricultural crop. The State will be represented by the Department of Environment of the State of Acre. The law also provides that, "no individual rights of intellectual property registered inside or outside the state which are universal knowledge held by local communities or which have been acquired without certificate of access and the state exit license will be recognized". Draft Bill No.306/95, introduced by Senator Silva, deals with the recognition of the rights of indigenous persons to IP, arising from bio-prospecting activities. It was approved by the Brazilian Senate on November 4, 1998 and is currently under evaluation by the National Congress. The draft Bill creates a Commission for Genetic Resources and provides for fair compensation between an applicant, an access agency, the furnisher(s) of TK, and any other parties to the access contract. Article 36 of the draft Bill provides that a contribution would be made to a special fund from the compensation amount for strengthening conservation, research, and inventory of genetic resources.

Blakeney, while reviewing the position in Australia, cites two recent cases *Yumbulul v. Reserve Bank of Australia*[69] and *Milpurrurru v. Indofurn Pty. Ltd*[70]., in which IP law failed to recognize community interests. In the case of *Yumbulul*, the representatives of the Galpu Clan located in north-east Australia tried to prevent the Australian Reserve Bank from reproducing the design of the Morning Star Pole on a commemorative bank note on the basis that the Pole had reportedly been created by one of the member of the Clan, "who had obtained his authority and knowledge to create the Pole through initiation and revelatory ceremonies". In the view of the Galpu, the individual artist was obliged to the community, and thus the Clan could prevent the use of the design of the Pole in a culturally offensive manner. The trial judge felt that the artist who had created the Pole was within his rights to dispose off his IP rights through a legally binding agreement. He lamented that, "Australia's copyright law does not provide adequate recognition of aboriginal community claims to regulate the reproduction and use of works which are essentially communal in origin."[71] In the case of *Milpurrurru v. Indofurn Pty. Ltd*, damages were awarded to a number of Aboriginal artists for breach of copyright by those who had wrongfully reproduced their designs on carpets.

Sadjo (1992) suggests, drawing upon the work of property rights theorist Demsetz (1967) and Coase (1960), that the externalities generated through the inefficient market outcomes of access to genetic resources may be "corrected" through negotiations among the affected parties, particularly if transaction costs are not very high. Contractual arrangements may be able to specify various concerns that each of the parties to the transaction may have, as distinct from the approach of deriving these concerns through property right laws. Swanson[72] (1998) looks at property right issues in the same context and observes, "existing IPR system creates incentives to invest in R&D at the end of the industry (the plant breeding sector), but is not generating investments in the earlier parts of the industry (the genetic resource providers)". This happens, Swanson suggests, because farmers in developing countries do not have property rights on their genetic resources, and have no direct incentive to invest in diversity, and because the plant breeding industry, which is located primarily in the developed world, does not feel it necessary to justify their own independent investments in conservation of *in-situ* diversity in developing countries, due to lack of control or rights over this diversity in developing countries. In an earlier study, Swanson found that around 55% of breeders felt that having an in-house collection of germplasm was better and gave more stability than investment in *in-situ* conservation. The remaining breeders considered cost to be important factor. Accordingly, Swanson considers lack of incentives for seed industry in developed countries to invest in developing countries as a case of "property right failure".

This formulation has obvious limitations, since lack of property rights need not be the major barrier to investment in conservation of *in-situ* diversity. Contractual arrangements, as suggested by Sadjo above, could, to some extent, achieve the same results, so long as developing country governments provide legitimacy to these contracts and help in their enforcement. The argument that efficiency needs ownership is valid, but it cannot be the case that efficiency needs private ownership in each case. After all, there is enough literature to show that common property right institutions can generate very efficient and viable outcome given appropriate rules that address boundaries, resource allocation and rules for conflict resolution (Gupta, 1984, 1998). Ostrom (1993) elaborates this system of rules in much greater detail, and suggests eight issues to be addressed, including the demarcation of boundaries. The point still remains that the seed industry needs to learn ways of dealing with local institutions having customary rights, rather than well defined property rights. It is true that recognition of community rights in national legislation will be a prior condition for legitimizing a contractual approach and encouraging possible investments by seed and other biotech industries in *in-situ* conservation. For the sake of argument, one can even suggest that the users of biodiversity need to deal with current diffused status of property rights in developing countries with much greater responsibility and reciprocity, rather than using this ambiguity as an excuse for not fulfilling ethical and institutional responsibilities towards conservators of diversity.

Ben-Dak[73] (1999), when considering the community compensation process, prefers compensation at the enterprise level, instead of at the general level of human infrastructure. He notes that a licensor can participate with local partners in the production of value-added products, and can share certain distribution rights with the licensee. He also suggests that product development assistance can be provided as a part of initial compensation to the group providing knowledge and resources. He describes the experience of the global technology group (GTG) of UNDP, working in collaboration with the Center for Scientific Research into Plant Medicine (CSRPM) based at Mampong/Akwapim in Ghana. Initial phytochemical screening of *Capparis erithrocarpos* by CSRPM, in collaboration with the U.S.A. based HealthSearch Inc.(HIS), revealed an analgesic and antipiratic effect. Through various contacts mediated by the GTG, CSRPM entered into a licensing agreement and patent process with HIS. Finally, HIS applied for patents on a derivative of Capparis in the U.S.A. and, as a result, original CSRPM members became a stakeholder in a newly formed company, Ghana Industrial Holding Corporation's Pharmaceutical Company Limited. Benefit-Sharing included, "capacity building in

Ghana, the transfer of technology to Africa, and the new availability of medicine continent wide and the fostering of local entrepreneurship".

Leisinger[74] (1999) considers urgent evolution of binding national and international regulation as necessary for fair compensation to gene-rich developing countries. He also recommends that, in the absence of, "binding national regulations, seed corporations should not take a free right, but look at the issue in the way of a tacit licensing agreement and set aside the usual percentages of sales for the support of agricultural research in developing countries".

Richard Gerster[75] (1998) looks at the issue of intellectual property rights from the point of view of a European Non-Governmental Organization rejecting the further extension of worldwide patent protection. Likewise, he also argues for elimination of obligation under Art.27.3 of TRIPS agreement to provide protection for plant varieties.

Sherwood, Scartezini and Siemsen[76] (1999) make several recommendations for increasing inventiveness in developing countries: those who pursue inventions in developing countries should have access to the international literature on the subject; access to risk capital; and should have the support of qualified patent attorneys. They also recommend that patent offices should postpone their fees under certain conditions to promote inventiveness. They feel that if these recommendations were accepted in developing countries, inventors would be able to reduce patent acquisition cost, and would be more likely to file high quality patents and to mobilize funds.

Merges and Nelson[77] (1990), in an extensive review on the economics of patent issues, recognize the depressing effect of a broad-based patent on other inventors working in a similar field. Their view is that the information disclosed in a patent application should be matched with the claims being made by the examiners. This is an extremely important point, given the tendency in the recent past for broad-based patents to be issued in Europe and the United States. It becomes especially relevant in view of the January 19, 2000 ruling of the U.S.A. appeals court[78] which, "determined that seeds, as well as the plants grown from them, are patentable under 35 U.S.C. 101". Although the patent office had already granted plant and seed patents, it was not until this ruling that patentability was firmly established.[79] Breeders will not be able to use such patented plants for further breeding. This will also affect the rights of communities, which may have conserved the germplasm, and thus may have provided a large proportion of the unchanged germplasm of the patented seed.

The empowerment of local knowledge experts will require the building of bridges between formal and informal science. Reform of TRIPS is a process involving reform of knowledge producing and networking institutions in any society. The process of producing or defining new knowledge having industrial applications is closely linked to the mechanism for its protection. The kind of growth that has taken place, or is likely to take place, in a given sector or field of technology invariably influences the evolution of a legal system to protect the property rights in that field. For instance, the emergence of biotechnology influenced the kind of protection that researchers in the field have been able to obtain in the U.S.A and Europe. Likewise, developing countries will have to view their comparative advantage in various fields of knowledge, appreciate the mechanisms of recognition, reproduction and networking of this knowledge and provide appropriate incentives through IP, as well as other instruments. Collective intellectual property rights have a specific meaning in the context of developing societies, where a large majority of people still survive primarily through access to natural resources. It is in this context that reform of TRIPS becomes a process of reforming knowledge producing, reproducing and networking mechanisms.

The asymmetry in rights and responsibilities of those who produce knowledge, particularly in the informal sector, and those who valorize it, usually in the formal sector, has become one of the most serious and contentious issues. There are possibilities of securing some of the interests of grassroots innovators and traditional communities within global trade regimes, provided the ethics of extraction can be factored into the calculation of respective incentives or disincentives for cooperation among different stakeholders. To do so, some of the fast-emerging and expanding technologies like information and communication technologies (ICTs) will have to be adapted to the needs of local communities and individual grassroots innovators.

Making Intellectual Property systems accessible to small innovators and local communities[80]

The debate on the relevance and appropriateness of the conventional IP regime for plant varieties and the use of local biodiversity, without or without the use of associated knowledge systems, has become very emotive in recent years. Many people do not believe that current IP regimes can provide incentives to local communities and creative individuals. They term the attempts of the large corporations, generally multinational corporations (MNCs), to access biodiversity without sharing any benefits with local communities as 'Biopiracy'. Many others oppose the current IP regime on the basis that it commodifies knowledge which reportedly has "always" been in the public domain for universal benefit. The high costs of hiring patent attorneys also makes the present patent system out of reach for most grassroots innovators. The absence of any institutional framework in most developing countries to provide information about IP, extend help to obtain patents for individuals or communities, and oppose the patents by others on the knowledge traditionally known to local communities, have further alienated the moderates and hardened the attitudes of the conventional opponents.

The arguments of those who do not see any role for existing IP systems, and the provisions of the TRIPS Agreement in particular, in the protection of TK can be summarized as follows:

- All knowledge held by people relating to biodiversity for treating various ailments of humans and animals, producing vegetative dyes, developing local land races, etc., is held in common by the local communities. This knowledge is supposed to have been transferred by one generation to another over very long periods of time with, or without, some value addition by successive generations;
- The knowledge should be held in the public domain and should not be allowed to be monopolized by MNCs (though the behavior of the public sector and of private, national drug companies is no different from MNCs);
- The relevant existing IP regimes, in particular the patent system, evolved for the protection of industrial inventions, and are therefore not suitable for biological processes and products;
- Since the knowledge has been developed over several generations, why should the present generation be entitled to reap the rewards derived from that knowledge, if any?;
- Why should governments be entitled to any benefits from the commercialization of patented products when the resource and the knowledge were actually preserved and provided by individuals or communities?;
- While process patents can be provided, product patents impede research, generate excessive monopolies to one or a few inventors, make the technology or products out of reach of common people due to price increases, and discourage the expertise of successful reverse engineering in Third World countries.

There are many other arguments on ethical and efficiency grounds against the patenting of life forms, and also against the products derived from common knowledge without any reciprocity towards knowledge generators or providers in one or more countries.

The following dimensions of the role of intellectual property rights in benefit-sharing among communities, as well as individual healers, should be considered:

- Not all knowledge held by people in biodiversity rich, but economically poor regions and communities, is:
  - Traditional;
  - Carried forward in a fossilized form from one generation to another. Rather it has been improvised by successive generations;
  - Collective in nature; and
  - Even if known to communities, is reproduced by everyone in that community.
- Knowledge of considerable economic importance can be produced, reproduced and improvised by individuals through contemporary innovations;
- TK should receive certain kinds of protection if incentives have to be generated to conserve not only the knowledge, but also the institutions of its reproduction and to encourage intergenerational transfer;
- Given the high rate of success in formal research based on locally identified uses of plants and other components of biodiversity, the transaction costs of formal Research and Development (R&D) systems in private and public systems are reduced considerably. The R&D institutions should, in turn, share the benefits that may accrue from commercialization of derived and protected products. In some cases, local communities or individuals, as the case may be, should be considered co-inventors of the new, value-added products;
- The newness and non-obviousness of TK should be seen in the light of available repertoire for that particular purpose. If the prior art in a given field of knowledge does not provide documentary evidence of a technology evolved by a local community as a part of its TK system, should that knowledge, having industrial application, not be considered new and inventive for the purposes of patent protection?;
- Local knowledge should be considered new for the purposes of prior art since outside communities/companies may not have had access otherwise. The norms regarding the destruction of novelty due to publication of local knowledge should be reconsidered and modified so that incentives to share the knowledge by local communities with outsiders are not affected adversely. A special grace period should be provided. The European Union has been discussing the issue of one year grace period given to inventions published in the preceding year. The U.S.A. already has such a grace period. What is being proposed here is that TK published, say in the last five years may be allowed to be protected, so that the local communities do not feel betrayed by the researchers who documented their knowledge and exhausted their rights through publication without their informed consent;
- Large number of local experts are extremely knowledgeable though very poor. They know far more than anybody else in their respective villages and have expertise to prepare various solutions. Others may know such knowledge but they may not have contributed to it, except by giving an opportunity for testing. To that extent they should have a small share in the benefits and entitlements. But the entitlements of an expert could not be on a par with the rest of the community;
- Every patent office should insist that a patent applicant declares that the knowledge and resources used in the relevant invention have been obtained "lawfully" and "rightfully". This last point may require legislation in both developed and developing countries to ensure proper disclosure by a corporation or individual seeking patent protection. "Lawful" acquisition will, of course, depend upon the laws and regulations in place in the source country, and may, for instance, require the need to consider whether prior informed consent of relevant local communities and creative individuals has been obtained.

"Rightful" acquisition may involve consideration of ethical issues. For instance, even if a local community had not originally required monetary compensation for sharing biological material or associated knowledge, might a potential applicant for a patent be bound by ethical conduct to set up a trust fund or other forms of monetary reciprocity for an affected local community? If a country does not have any applicable legislation in place, as, for instance, India, then material and knowledge may be acquired lawfully but not rightfully.[81] Weera Worawit (2000) notes the requirement under the European Union Directive of 1998 requiring patent applicants to disclose, where appropriate, the information on the geographical origin of the material, although the granting of patent will not be affected if a source is not disclosed. He regrets that while it was clearly considered important to address the issue of access to genetic resources, nonetheless little progress has been made in modifying the established patent regime. In a study done as a part of the working group on biotechnology to the WIPO 35-50, member countries stated that, "they did not plan to introduce legislation to ensure the recording of such contributions".

Cottier (1999) has suggested that, in the next round of the TRIPs review, a TIPS (Traditional Intellectual Property Rights Systems) should be negotiated. In some aspects, TIPS would be similar to the proposed Community Intellectual Property Rights system. In other parts, TIPS would be akin to the current patent system, except that TIPS would resolve the issues of public domain and prior art issues by considering TK as new and inventive, so long as it is known only to a small group of people.

Downes and Laird[82] (1999) address what they consider to be the inherent contradictions between existing systems of IP and traditional cultural property rights and customary laws. They suggest that:

… geographical indications and trademarks have the potential to respond to some of these concerns more effectively than do other intellectual property rights. Rights to control trademarks and geographical indications can be maintained in perpetuity. They do not confer a monopoly right over the use of certain information, but simply limit the class of people who can use a certain symbol.

They continue by stating that geographical indications and trademarks can be used by producers to differentiate their products, according to various criteria such as the sustainability or traditional nature of production, and thus create specific market niches and appeal to the consumers.

Downes and Laird also consider the increasing use of registries by indigenous peoples and local communities, "… as tools to promote, protect, and either claim rights over or prevent appropriation of traditional knowledge". They recognize one of the key problems that can arise when oral TK is recorded in an electronic format by formal scientists and others; namely, that the final text may be unduly influenced by the culture and knowledge systems of those mediators. They review three such registries: the SRISTI registry, the Inuit of Nunavik registry and a registry compiled by the Dene in Canada, while looking at IP options for such registries and summarize their concerns as follows:

Thus, any future steps to define legal rights relating to traditional knowledge in databases will need to respond not only to concerns about protection of database makers interests, and not only to concerns about protection of indigenous and local communities interests in their knowledge, but also to concerns about the broader interest of all social groups in access to and exchange of information.

An additional problem is that the sui generis *rights desired by database owners extend beyond the conventional scope of copyright, such that owners would have rights to prevent others from using information, even when that information is not creative or new, simply because it is contained in the database. Similarly, indigenous and local communities' interest in traditional knowledge extends beyond protection of new information to encompass protection of knowledge that has been held for as long as centuries, simply because it is held by the given community. A corresponding expansion of intellectual property rights could take a great expanse of information out of the public domain. While specific database owners and communities might benefit from such protection, society as a whole, including indigenous and local communities, might suffer from vastly expanded restrictions on access to the growing amount of information taken out of the public domain. If nothing else, special measures to protect indigenous and local communities' knowledge should be designed carefully so that they respond specifically to the interests and values relating to such knowledge and communities, and do not go farther.*

Long (2000) suggests that discussions on incentives for innovation should not assume that scientific research is a linear process. Therefore, a patented product could not be considered as a final consumer end product. The greater the content of information in an innovation, as opposed to its physical features, the higher the positive externalities. The property so produced could be used in various ways and an innovator could not recover the cost of revealing all the information. If such is the case, then society could expect lesser or sub optimal level of disclosure of information in an innovation (Dam 1994 in Long 2000). Therefore, the tension is between expecting researchers to produce public goods, without being sufficiently rewarded for it, and encouraging researchers to withhold information or obfuscate the information in legal and technical ambiguities, so that the purpose of building upon patented knowledge for research purposes is defeated.

The emerging pattern of genomics and consequent biomedical research implies that future IP in genetic resources may be very complicated. It will become difficult to isolate precisely the contribution of each actor in the value chain, or the value of each attribution. Patents on basics research would affect adversely downstream innovations, and consequently the ability of firms with limited financial resources to enter the knowledge domain. If it is assumed that smaller firms are more creative and innovative, the implications could be that larger firms and bigger corporations might block the future scope of innovation by protecting some basic building blocks of basic innovations. Therefore, the provider of genetic resources may insist on joint IP from the derived products, so that such tendencies can be kept in check. The use of IP in a complex, technological chain will pose new challenges to the designers of incentive systems so that they are fair to both the providers and the recipients of genetic resources and associated TK.

Ten Kate and Laird (2000) have reviewed the potential commercial uses of biodiversity. In their view, the biggest difficulty in generating transparent negotiations between international business and national government is the absence of a "focal point on access to genetic resources". They found that most companies interviewed on the subject felt that, if the procedures were too bureaucratic to follow, they would no longer seek access to genetic resources in developing countries. Instead, they would pursue alternative approaches, such as synthetic chemistry, or using their own existing collections. The end-users also desired a flexible access process, in terms of the variety of users of genetic resources. Different users might impose varying transaction costs and generate different kinds of benefits. Uniform guidelines would not do justice to the variety of users and user conditions. Access agreements should provide clarity on the rights that recipients might have on the transfer of received materials to third parties. Some companies interviewed stated that academic and government institutions should be regulated as the same way; in contrast, other companies said that there should be clear

distinction in any guidelines between collection for commercial research and collection for scientific research. The authors have suggested that a share of benefits should go for conservation, the need for legal certainty, and the need for governments to enforce access regulations fairly and uniformly. The authors felt that it was not easy to analyze whether an agreement among two parties was fair and equitable since the perception of the parties concerned would be a relevant and important consideration. They suggest several process and content indicators which could be taken into account while assessing whether specific access and benefit-sharing mechanisms could be considered fair and equitable.

Dasgupa, Utkarsh and Gadgil (2001) state that there should be mandatory disclosure of material transfer agreement with the providers of knowledge, public scrutiny of IP applications, prior to any grant of rights, disqualification of IP applications that fail to duly acknowledge any related-grassroots knowledge and innovations, and disqualification of IP applications that seemed to threaten biodiversity-related grassroots knowledge, innovations or practices. In addition to these measures, they also plead for evolving mechanisms to protect grassroots innovations through petty patents and other similar IP instruments. Their arguments about bio-piracy and the decline of agro-biodiversity need some reflection. They observe that the existing IP regime may encourage monoculture in agriculture. However, the evidence of the green revolution shows that the maximum decline in agro-biodiversity in the last 30 years took place because of the varieties developed and disseminated by public sector R&D and extension institutions without any protection whatsoever. The issue of conservation of agro biodiversity is more complex and requires a whole range of institutional incentives and arrangements to promote conservation.

Nino, Bernal and Contreras (2000) have written about Venezuelan experiences in this regard. In May 2000, Venezuela adopted a law on biological diversity which provided for the conservation of cultural diversity through the recognition and protection of TK (Article 39). TK Holders could oppose the granting of access to genetic material or traditional knowledge or projects on biotechnology in their territories, where their consent had not been obtained. Likewise, they could ask for a halt to the activities that they feared might affect their cultural heritage and biological diversity (Article 44).

Pacon (2000), while reviewing a Peruvian proposal on the protection of TK, explained how, in 1996, the Peruvian government had established five groups to carry out the following tasks, in consultation with Peruvian indigenous communities: analyze the organizational structure of indigenous communities; identify mechanisms of benefit-sharing; prepare inventories of genetic resources; prepare regulations for access to genetic resources and protection of TK; and develop capacity building among indigenous communities. A draft proposal was published in October 1999 for comment. A revised proposal was published in August 2000. The main components of the revised Peruvian proposal are as follows:

- The proposal only addresses biodiversity-related TK;
- The objectives of the proposal are to promote, respect, preserve and protect TK, to promote equitable benefit-sharing and the use of TK for benefit of humanity;
- Indigenous communities in possession of TK are given protection, without undue emphasis being laid on the identity of the original creators of this knowledge;
- The proposed rules and regulations should be applied to collective knowledge only. In those cases where more than one community possesses the same knowledge, both communities will become co-holders;
- Those accessing TK of a community must seek prior informed consent (PIC) for access and share fairly and equitably all benefits. PIC is required for scientific research as well as for the commercial exploitation of the resources. In the latter case, a license agreement must also be obtained;

- Public domain TK knowledge does not belong to any indigenous community, and, therefore, does not require PIC or a license agreement for its exploitation. However, a contribution must be made to a fund for development of TK;
- TK rights are unlimited and continue from one generation to another;
- A confidential register of TK will be maintained and only those authorized by the communities will have access to it. The register is not compulsory but is declaratory of rights. Patenting of the registered knowledge is possible only with the permission of national patent institution;
- A License Agreement must stipulate, *inter alia*, the percentage of royalties that would accrue to the communities in lieu of their knowledge. The suggested minimum rate is 0.5% of the gross sales. The registration of the agreement is desirable but not obligatory;
- When knowledge is shared by more than one community, and they cannot all agree to the terms of a License Agreement, a development fund may be created for the benefit of all the concerned communities. A committee, comprising community representatives and government nominees, would decide on the distribution and destination of benefits.

Pacon (2000) further discusses the relationship between TK and IP. The proposed protection regime makes it impossible to obtain a patent based on TK, where the patent applicant has not first obtained PIC. The proposed arrangements are aimed at reducing the transaction costs and making communities capable of negotiating a fair access and equitable benefit-sharing agreement.

Latiff and Zakri (2000) provide an example of a State level initiative which has implications for other developing countries. The Sarawak region of Malaysia contains extremely rich and diverse natural resources. When the National Cancer Institute, United States of America (U.S.A.), discovered a chemical compound, calanolides, in a local plant, the State formulated and passed the Sarawak Biodiversity Centre Ordinance 1977, and then the 1998 Sarawak Biodiversity (Access, Collection and Research) Regulations. The Sarawak Biodiversity Council, set up February 1998, is now responsible for regulating, "access to, collection of, study and research on, experiment, protection, utilization, and export of the State's biological resources".

Kumar (2000), looking at the situation in Sri Lanka, endorses a proposal made by Drahos (2000), and further developed in a report to European Union Directorate on Trade. The proposal recommends the establishment of a global bio-collecting society, similar to a copyright collecting society, to act as a depository of TK. It is similar to the proposal made by SRISTI for INSTAR (SRISTI, 1993). The proposed Society would not only license the use of TK to potential users but also monitor the use, ensure the collection, and distribution of royalties among the holders of TK, and establish a dispute settlement mechanism.

Mbeva (2000) reviews the interface between IP and TK in Kenya and observes that the current system of IP does not adequately protect TK. Kamil (2000) notes a similar lack of progress in the protection of TK through existing systems of IP in Indonesia.

Solomon (2000) draws upon Maori traditions in New Zealand and pleads for the strengthening of existing customary laws, instead of imposing uniform IP laws. Historically, custom has been supplanted by statute, and is recognized only when so required by a specific statute. As a community on the margins of New Zealand society, Maori failed to influence the law making process and ensure that their customary practices were included or recognized by statute. Furthermore, given the existence of several national bodies representing Maori it would be a challenge to get them all involved in a consensus framework. This makes it very difficult,

and sometimes impossible, to determine who had the authority or mandate to represent and make decisions on behalf of people. The traditional tribal structures sometime conflicts with urban Maori authorities over the issues of resource allocation. This complicates the process of obtaining prior informed consent. Solomon suggests that a Tikanga Maori Framework of Protection could ameliorate the situation, funded by the Federal Government. This would consist of, *inter alia*:

- Evolution by Maori, in consultation with government, of a system to protect and promote resources reflecting their cultural values and ethos;
- The design of flexible structures to take into account collective rights as well as the rights of individual creative people.[83]

In a study prepared for Intellectual Property Policy Directorate, Canada, Brascoupe and Endemann (1999) look at the issue of IP and aboriginal people in Canada. There are several ways in which indigenous communities have tried to protect their rights. For instance, the Inuit Circumpolar Conference have developed community guidelines for scientists and businesses wanting to access their TK. Their informed consent is required, while documenting or sharing their knowledge or photographing or using aboriginal symbols. The Scientists Act of Northwest Territories (NWT) requires all scientists conducting research in NWT to obtain a license from the territorial government, before beginning any research. The scientists are required to disclose the purpose of their research, maintain confidentiality, explain the use of data and how findings will be shared back with the communities. This Act has helped in establishing the principles of prior inform consent in Canada.

Nonetheless, Canadian Aboriginal communities are seeking protection broader than currently permitted by the Canadian Copyright Act. The Copyright Act does not allow legends and stories belonging to a community to be protected in perpetuity. The aboriginal communities would like to have rights to their cultural heritage indefinitely. They also want to protect their moral rights, which means even the copyright owner is not allowed to distort, mutilate or otherwise modify the work that may tarnish the creators' honor or reputation or right of integrity. Similarly, it cannot be used in association with any product, service, cause or institutions, which is prejudicial to the creators' reputation without permission. Likewise, aboriginal peoples prefer longer term protection for their designs and marks. Many aboriginal business and organizations use the provision of trademark to promote their products. Similarly, they have also protected the certification marks. For example, the Cowichan Band Council has received a certification mark for the words and design, '*Genuine Cowichan Approved*', so as to protect articles like sweaters.

Guedes and Sampaio (2000) provide an outstanding Brazilian example of the resurrection of an almost lost tradition associated with multi-colored corn, which disappeared after Kraho Indians shifted to modern varieties in 1970s. When their agriculture became mono-culture and traditional varieties were lost, they realized that they not only lost approximately 300 rituals, which synchronized with rhythms and routines of growing seasons, but also lost community routes, soil productivity, and their self respect. The rice mono culture, they realized, was a disaster. When the elders wanted to re-established their traditional crops, they could no longer find any corn seed. With the help of IPGRI, Embrapa had organized expeditions in 1978 to collect local germplasm. Almost twenty years later in 1995, small quantity of corn seed was given back to Kraho community. This was a profoundly emotional moment. Slowly and slowly with the re-introduction of corn, the native pride also resurfaced. The skills and knowledge developed over generations could be narrated again to the children, because there was a biological context. Between 1995-1999, seeds of several other crops were returned to the Kraho community. This led to a cooperative agreement between government and local communities to document their knowledge about their medicinal plants, so that value could be added and benefits could be shared. More native communities are

coming forward to participate in such partnership. This is an excellent example of how a TK system can be revived, restored and revitalized by fusion with modern institutions and incentives.

Australia, in its communication to the World Trade Organization on a review of Article 27.3(b),[84] has provided a thoughtful perspective. Australia acknowledges the importance of broader issues relating to access to and control of genetic resources, protection of TK and their relationship with advances in technology. It shares the international concern on the subject, and supports the encouraging progress being made by the Word Intellectual Property Organization Inter Governmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. Australia suggests that, if an amendment has to be made to TRIPS, it should be in Article 29, which stipulates conditions to be fulfilled by patent applicants. It is here that the concern for disclosure, prior inform consent, use of TK, equitable benefit-sharing, etc., could be addressed. It, however, suggests that amendment under TRIPS should be considered only after a complete survey of the situation has been made and options examined. At the same time, Australia has released draft legislation to the public, which provides for management of access to genetic and biochemical materials found in native plants and animals in federal government areas, such as commonwealth national parks. As per this draft, bio-prospectors would be required to obtain a permit to ensure the collection of biological material in a sustainable manner, ensuring benefit-sharing with access provider and ensuring that benefits arising from the use of indigenous knowledge about plants and animals are shared with the relevant indigenous communities.

The Australian government is conscious of the need to protect indigenous intellectual and cultural property (ICIP) within Australia. The government feels that, in order to avoid creating extra regulatory burden, procedures and system that might stifle innovation and creativity, the possibility of using existing legal framework for increased protection for ICIP should be explored, before enacting new systems. For instance, Australian copyright laws has provided effective protection for indigenous design illegally reproduced on T-shirts, carpets and other commercial products.

Eight case studies in Australia involve a range of IP issues:

- The unauthorized use of photographs in any form violating copyright, performer's rights and law of passing off;
- The unauthorized reproduction of spiritual rock art images for use on clothing and other merchandise involving licensing of TK and copyright;
- The use of a certification trademark by the National Indigenous Art Association of Australia for certifying indigenous art and art products and discourage fake products;
- The increased use of trademarks by indigenous art centers and galleries;
- A study to examine the extent to which indigenous groups have used design laws to protect their indigenous cultural expressions;
- The examination of a recent decision of the Australian Federal Court, in which the use of work an aboriginal design on a carpet was found to infringe the rights of the original indigenous artist;
- The unauthorized reproduction of an indigenous artist's work, embodying a community design on imported fabric; and
- A dispute over an alleged infringement of a trademark involving an art gallery and indigenous instrument maker.

The draft amendments to the Australian Environment Protection and Biodiversity Regulations 2000, Access Permits and Benefit Sharing Arrangements, requires a party seeking access to biological resources in

Commonwealth areas to apply for an access permit. While the assessment process is under way, the applicant would be required to negotiate a benefit-sharing contract covering commercial and other aspects of the agreement with the providers of the biological resources. The Minister would issue the permit after ensuring that an environment assessment has been carried out, the proposed access is ecologically sustainable and consistent with the conservation of Australian biodiversity, any submissions from interested persons and organizations have been taken into account, and a benefit-sharing contract has been drawn up involving prior inform consent of any indigenous owner of the biological resource, mutually agreed terms and adequate benefit-sharing arrangements including protection for and valuing of indigenous knowledge and, if possible, some allocation of benefit for biodiversity conservation in the area concerned. The purpose of the Access and Benefit-Sharing Scheme is to minimize transaction costs, maximize certainty, ensure transparency and accountability, permit flexibility, avoid duplication, and to ensure that the interests of aboriginal rights in land and resources are respected.

Mgbeoji (2001) reviews the legal literature on plant and TK-related patents and argues for communal patents to be issued to block the granting of future patents on the resource so protected, and to empower the local communities to negotiate fair terms for access and benefit-sharing. Mgbeoji recommends the creation of an office of public defender of this community patent to monitor the global misappropriation of TK and to make the necessary international representations. He is critical of most proposals to use an international registry of traditional uses or to adapt existing systems of IP to the needs of TK holders, and makes the following comments:

- He doubts whether all bio-prospectors would be prepared to pay for TK or genetic material that could be obtained by payment of a small, token sum or for free. Further once the basic information has been obtained, the current patent system, in his view, gives ample scope for small modifications to that TK or those resources, enabling patents to be obtained on the information or genetic materials so obtained;
- He considers that the registry of uses approach perpetuates the unfair economic paradigm, in which indigenous people are seen as just the "producer of raw material and importers of finished products";
- The intellectual effort of indigenous people in generating and conserving genetic diversity is underplayed or denied by the registry of uses approach;
- IP systems are preferred over contractual arrangements, based on the registry. The contract model neglects the immense asymmetry in the negotiating power of commercial firms and local people, raises the problem of privacy of contract; and places undue trust in the bureaucracy overseeing licensing arrangements.

Intellectual Property and Folklore

Farley (1997) looks at the applicability of IP to the vast area of folklore produced by indigenous communities and considers whether existing copyright laws are too limited in their scope to deal with the protection of folklore, and whether new instruments are required. He argues that indigenous motifs are used to sell everything from Japanese Automobiles, such as the Mazda Navojo, to Barbi dolls and yet no compensation has ever been paid to the originating communities. The author suggests that folkloric art has several common characteristics; for instance, it is passed between generations orally, it may not be attributable to any one individual or set of authors, and it is being continuously utilized and developed within the indigenous community.

In fact, this definition may not represent the true situation. There is a scope for individual assertion or articulation of art forms within a tradition or setting, which is quite distinct and can be attributed to an individual. Likewise, a community may provide a repertoire within which an individual may operate or beyond

which, an individual may perform or draw or create. Farley underplays these individual excursions, which are making new demands on traditional boundaries. There is a general desire on the part of indigenous communities to have an authority to deny certain use of their art which would violate their spiritual beliefs. For many indigenous people, "heritage is the bundle of relationship, rather than a bundle of economic rights" (Farley). This may be true. Yet the fact remains that the same people have to operate in commodity market where they have to pay for various goods and services that they acquire from outside. Since the aspirations of different members of the community are invariably asymmetrical, therefore the need for acquiring external goods and services is also unequally felt. Consequently the motivations to move from the ethereal to the material in conceptualizing folkloric traditions may also vary.

Farley (1997) observes that there are some countries, which have tried to provide protection for folklore in their copyright laws.[85] For tradition that has lasted thousands of years, protection for a hundred years is not sufficient protection. Therefore, the first problem that emerges in using modern IP laws for TK is *the limit of duration* for which the protection is available. The second problem is the *requirement of originality*. Traditional art forms tend to reward faithful reproduction.

My contention, however, is that many communities, such as the Zuni in North West America, the Madhubani painting tradition in Eastern India and the Patan textile tradition in Northern Gujarat do permit originality and innovation. For instance, the Patan silk sari tradition dates back 700 years, when 250 families were invited by the King of Patan to set up their silk looms in Patan. Among the three surviving families of this traditional art and cultural form, there is indeed a very rich knowledge base. This knowledge includes the technology of weaving a textile which has same pattern on both the sides through a system of double ikkat using vegetative dyes. About 135 years ago they started using synthetic dyes in their silk saris. Then about 35 years ago, they realized that original tradition required vegetative dyes, and so they reverted to the original tradition, ignoring a discontinuity of more than 100 years.

This illustrates that traditional forms of art and culture can accommodate discontinuities in specific elements of tradition, and yet maintain the overall context of the traditional form of art and culture. Therefore, it seems that Farley's contention that originality is foreign to indigenous art and culture, is not true generally, and is certainly not universally true. What is true for certain communities can in no way be called an essential feature of traditional art and culture. In Madhubani paintings originating from Mithula, the lady artists have used new motifs, including modern vehicles and other artifacts in the traditional style of painting. This is, of course, an original expression and does not detract from the traditional forms and expressions characteristics of that culture and region. Farley acknowledges that, in some indigenous art work, there could be sufficient variations worthy of copyright. However, the question he raises that is quite valid is that *variations could be protected, but continuity would be considered in public domain*. This kind of "thin copyright", Farley rightly submits, may not provide reasonable protection.

On the issue of community rights, Farley clarifies that joint authors must in fact collaborate in the preparation of work, and they should also intend to merge their contributions into an inter-dependent part of the unitary whole. In a community, therefore, only those members involved in the creation of joint work can be joint authors. The rest of the clan or community, Farley submits, "could not be considered co-authors unless they actually contributed to the creation of the work" (Farley 2000:27). He suggests serious damages in the case of unfair use of the knowledge, art or culture of the Indian communities. If the damages are not substantial, then the unauthorized use may not be checked.

The Tunis model law on copyright (1976) does not require fixation as a condition to provide protection. The Model Provisions for National Laws on the Expression of Folklore (1982) developed by UNESCO and WIPO, have never been adopted by any country or multilateral organizations and thus have no legal force. Farley quotes the working group on the IP aspects of folklore protection as requiring three criteria to determine whether a use is unauthorized:

- Whether the intent is gainful;
- Whether the use was made by members or non-members of the community from where the expression has been derived; and
- Whether the use is outside of the traditional context of the usual use,

and finishes by stating that, given the variety of competing interests, and the variety of competing motives, it is not easy to decide what would be the best option for the future of indigenous culture and art.

CONCLUSION

In conclusion, there are several ways in which indigenous knowledge, innovation and practices can be protected, so that the informal knowledge systems continue to grow and symbiotically interact with modern science and technology:

- Current IP systems should be reformed to make them accessible for small grassroots innovators, by, *inter alia*, reducing transaction costs for small innovators and TK holders/providers;

- Informational asymmetries in formal and informal knowledge systems should be overcome through IT applications, and the development of an international registration system for grassroots knowledge, innovations and practices;

- Dedicated green venture promotion funds and incubators for converting innovations into enterprise should be established;

- The mandate and responsibility of CGIAR institutions should be reformed to make it obligatory for international agricultural and natural resource management institutions to accord priority to adding value to local innovations, acknowledge the creativity and conservation contribution of local communities and TK experts;

- The role and responsibility of international financial institutions and United Nations agencies should be reconsidered to take into account ethical, institutional and financial support for grassroots innovations and local knowledge systems;

- An International Fund should be created to:

  (i) Support the establishment of National Innovation Foundations in developing countries, along the lines of the Indian Honey Bee experience;
  (ii) Compensate innovators for those technologies which then could be disseminated widely as a public good. We should not expect innovative communities and individuals to subsidize the global welfare, not because they would not like to do this, but because then it would not be sustainable, since young people will not be motivated to learn and acquire skills, knowledge and insights under threat of erosion;
  (iii) Share, in local languages, the knowledge concerning the IP rights being obtained by other communities, so that all communities can be watchful of their rights and prevent them being trampled upon by others;
  (iv) Give awards to local innovators, so that respect, recognition and rewards for grassroot innovations may inspire other communities and individual experimenters to develop even more valuable green solutions; and
  (v) Create a technology exchange for linking innovations, investments and enterprises across the world, and thus harness the power of globalization for good of local knowledge rich economically poor people.[86]

1 This paper draws upon an extensive literature review carried out by the author for a study by the Ministry of Environment and Forestry, Government of India, to develop a framework for a *sui generis* system for the protection of Traditional Knowledge related to biodiversity and genetic resources. Responsibility for the views expressed, however, rests solely with the author and no organization with which he is related or which has sponsored this study, including WIPO and UNEP, bears any responsibility.

2 Chair Professor of Entrepreneurship, Indian Institute of Management, Ahmedabad; Coordinator, SRISTI; Editor, Honey Bee newsletter; Executive Vice Chair, National Innovation Foundation, Department of Science and Technology, Government of India, Ahmedabad. Facsimile: 91796307341;
E-mail: anilg@sristi.org. Web-Sites: http://www.sristi.org, http://www.gian.org, http://www.nifindia.org.

3 The term "traditional knowledge *strictu sensu*" is used by the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore to mean "the content or substance of traditional know-how, skills, practices and learning, while recognizing that this content or substance may be considered integral with traditional ways of expressing the knowledge and the traditional context in which the knowledge is developed, preserved and transmitted." (see document WIPO/GRTKF/IC/5/12, para. 44.)

4 See http://www.sristi.org and http://www.sristi.org/knownetgrin.html.

5 See documents WO/GA/26/6, paragraph 13, and WO/GA/26/10, paragraph 71.

6 See document WO/GA/26/6 para. 14.

7 See documents WIPO/GRTKF/IC/1/13; WIPO/GRTKF/IC/2/16; WIPO/GRTKF/IC/3/17; WIPO/GRTKF/IC/4/15.

8 See document WIPO/GRTKF/IC/4/11 for details of earlier WIPO work and the CBD request.

9 See document WIPO/GRTKF/IC/2/7 and WIPO/GRTKF/IC/Q.1

10 See documents WIPO/GRTKF/IC/2/9, WIPO/GRTKF/IC/3/7, WIPO/GRTKF/IC/4/7 and WIPO/GRTKF/IC/5/7

11 See documents WIPO/GRTKF/IC/3/8 and WIPO/GRTKF/IC/4/8

12 See document WIPO/GRTKF/IC/3/9

13 See document WIPO/GRTKF/IC/5/8

14 See document WIPO/GRTKF/IC/3/17, para. 158.

15 See document WIPO/GRTKF/IC/3/17, para 160.

16 See document WIPO/GRTKF/IC/3/6.

17 See document WIPO/GRTKF/IC/3/5.

18 The TK Portal of Online Databases: http://www.wipo.int/globalissues/databases/tkportal/index.html

19 See documents PCT/CTC/20/5; PCT/MIA/7/3 and PCT/MIA/7/5.

20 See document IPC/CE/32/12.

21 See documents WIPO/GRTKF/IC/4/5 and WIPO/GRTKF/IC/5/5.

22 See Article 1 of the CBD.

23 For instance: the practice of *Sati*, i.e., a widow burning herself on the pyre of her husband; or child marriage; or taboos on women's participation in certain activities.

24 In 1996, the sales of over-the-counter herbal drugs was estimated to be about $US3.5 billion in Germany alone, about $US7 billion in Germany, Spain, UK, Italy, France, Netherlands (Blumenthal, *et al.*, 1998, in King, *et al.*, 1999). In 1998, sales of herbal drugs were 55.4% higher in the U.S.A., than in 1997, and 11% higher again September 1999 (Blumenthal, 1999).

25 These figures are based on the Derwent Pharmaceutical database.

26 For example, the 'minor millets', a group of plants such as 'ragi', 'kodo', finger millet, fox tail millet and other such small millets crops, which provide the major means of subsistence to millions of poor dry farming households, are called 'inferior millets', despite the fact that these are actually superior to many other grains in nutrition and other agronomic characteristics.

27 The attribute 'indigenous' is used in this paper to refer to, "originating in and characterizing a particular region or country; native": Webster's Encyclopedic Unabridged Dictionary of the English Language, New Revised Edition, Gramecy Books: New York, Avenue l, 1989. It is not used in the technical sense of the Working Group on Indigenous Populations of the United Nations High Commissioner's Office for Human Rights or Convention 169 of the International Labor Organization, that is, as meaning, "The existing descendants of the people who inhabited the present territory of a country wholly or partially at the time when persons of a different culture or ethnic origin arrived there from other parts of the world, overcame them and by conquest, settlement, or other means reduced them to a non dominant or colonial situation; who today live more in conformity with their particular social, economic, and cultural customs and traditions than with the institutions of the country of which they now form a part, under state structure, which incorporates mainly the national, social, and cultural characteristics of other segments of the population which are predominant" (Working definition adopted by the UN Working Group on Indigenous Populations').

28 Gloria Emeagwali, Science and Public Policy, Journal of the International Science Policy Foundation, United Kingdom. Volume 16. no.3.1989. See modified version of this paper: "Eurocentrism and The History of Science and Technology" available at: http://members.aol.com/afriforum/colonial.htm 1999. This quotation is from the modified internet version and is not found in the original paper.

29 Only recently Sir J. C. Bose, a pioneering Indian plant physiologist, and inventor of several electronic instruments, was credited with the invention of the telegraph, rather than Marconi, as we had learned since childhood: see The Telegraph, Calcutta, October 31, 1997. "As for the claim that Bose's primacy was acknowledged at an international IEEE conference in June in Denver, this refers to the 1997 IEEE MTT-S International Microwave Symposium. The MTT-S did organize an historical exhibition and Special Session on Bose in honor of his centennial. However, they did not take a position on Bose's primacy": Robert Colburn, ISEE History Research Center, Rutgers, personal communication, February 3, 2000.

30 How many of us have said, 'touch wood' or expressed similar superstitious slang while dealing with uncertainties? The point is that, even in our modern life, there are so many black holes of irrationality which co-exist with rational beliefs.

31 In many Mali villages, food storage vessels are made of dry gourd skins. These sometimes get cracked or broken. A Bela woman would stitch these pieces together with plastic cords so that these natural biomass-based vessels can last longer. This is an excellent example where the culture of recycling and repair, which is so integral to traditional communities, combines a traditional vessel with modern plastic cord. Likewise, in a workshop in the Chittradurga district of Karnataka, India, a creative carpenter once shared an innovative solution (I regret having misplaced his name). He had a wooden plough made of acacia wood. When the shears became worn out, he still wanted to use the same plough since the acacia wood is scarce in that area. However, he wanted to put a shoe of metal on the worn-out shear. He began to look for different materials and waste iron pieces. Finally he found that the waste spring leaves or suspension springs of automobiles provide the right material having the appropriate combination of weight, torque, durability, etc. Similarly, the automobile repair workshops on the roadside use soap to plug small holes in the radiator. It is this approach of combining a traditional resource with modern materials that sometimes may not happen so obviously in the modern laboratories and academic research institutions. However, this process *per se* is not totally unknown to the modern methods of problem solving.

32 Richard Okagbue, "The Scientific Basis of Traditional Food Processing in Nigerian Communities" in G.T. Emeagwali, African Systems of Science, Technology and Art, Karnak House, London, 1993. See at web site http://members.aol.com/afriforum/okagbue.htm#AFPT.

33 Downes, David R. Using Intellectual Property as a Tool to Protect Traditional Knowledge: CIEL Discussion Paper, November 1997.

34 Glenn M. Wiser,1999, PTO Rejection of the "Ayahuasca" Patent Claim: Background and Analysis, Washington: Center for International Environmental Law, http://ciel.org/ptorejection.html

Wiser sumamrises the case,"Loren, S. Miller obtained U.S.A. Plant Patent 5,751 on June 17, 1986. The patent granted Miller's rights over a purported variety of the Amazonian vine, *Banisteriopsis caapi*, also known as ayahuasca. Miller dubbed his variety 'Da Vine'. The patent was granted on the basis of Miller's claim that Da Vine represented a new and unique variety of *B. caapi*, which was distinct from other forms primarily because of the color of its flower petals. Miller stated that he had obtained a cutting of the plant from a 'domestic garden in the Amazon rain-forest of South America.' He added that he was investigating the plant for its medicinal value".

35 I am grateful to Dr. Mashelkar for sharing this letter with me and authorizing me to quote it so that the discussion on the subject moves forward rather than remaining locked in an old position. All those groups which are opposed to the patents on traditional knowledge *per se* would find above quoted formulation helpful in so far as it enables prevention of anyone getting a patent on public domain traditional knowledge. However, as we would argue later, such a position would not bring much economic or other benefits to the communities and also may not contribute to the continuance, growth, and vibrance of the traditional knowledge systems. It is certainly acceptable to prevent public domain knowledge being patented but, unless value addition in this knowledge is protected, how would investment in product development take place, and, furthermore, how will the surplus to be shared fairly and equitably with the knowledge and resource providers be generated?

36 The USPTO also agreed to correct the status of US Patent 5,401,504 issued on the use of turmeric for wound healing. All the six claims were cancelled after the Indian government provided prior non-patent literature on the subject. Likewise, the patent issued on Ayahuasca, a plant used by Amazon community, was revoked, although it was later restored without any use claims being made.

37 The heuristics as a concept is defined by Webster's Encyclopedic Unabridged Dictionary as, "serving to indicate or point out; stimulating interest as a means of further investigation". However, it is used here in the sense of thumb rules for taking decisions. The underlying thumb rules are simple ways in which complex problems are resolved.

38 We have used aspirin to control headache for decades without knowing the causal reason. Thus even in the modern science, functional relationships are accepted as valid scientific concepts even if the exact causal mechanism is not known.

39 In a field study in Mahendra Garh district, Haryana, India in 1984, I observed that some farmers grew coriander around the field of chick pea. They believed that the coriander helped in repelling pests. M Pimbert at ICRISAT when informed about it, did some studies at ICRISAT and found the coriander did not repel the pests. It attracted in fact the predators of the pests. The ultimate result about control of pest was correct, but the causal reason assumed by farmers was incorrect (Gupta, 1985).

40 Perhaps, just as we have trademarks and service marks, we may have to develop a category *of sacred marks* which will be restricted for use by specific communities or their representatives or the ones authorized by them. This provision can provide considerable psychological and spiritual solace to the communities which feel aggrieved by unauthorized and improper use of sacred marks. In an Australian case, a native community felt aggrieved when a carpet manufacturer used their sacred signs authorized by an individual artist on the carpet. The community felt that the individual was not authorized by the community to contract the use of signs designed during spiritual ceremonies to anybody outside without communities permission. The court did not agree with this submission as mentioned later in this paper (Blackney 1999). Also, see: (1995) 91-116, CCH Australian Intellectual Property Cases, 39,051 and (1991), 2 Intellectual Property Reports 481 at 490.

41 I have described four kinds of incentives (Gupta, 1989; Sristi 1993, 1995): material; individual, material and collective; non-material individual; and non-material collective.

42 Henry P Huntington and Nikolai I. Mymrin, 1995, Traditional Ecological Knowledge of Beluga Whales, An Indigenous Knowledge Pilot Project in the Chuckchi and Northern Bering Seas, Anchorage: Inuit Circumpolar Conference-Alaska. See: http://nmnhwww.si.edu/arctic/html/tek.html.

43 See: http://www.fishbase.org/search.cfm

44 A patent has been filed by SRISTI, on behalf of the innovator, for this cart, and three entrepreneurs have already been granted licences of approximately $US1,000 and $US700 to reproduce the cart in specified Gujarati districts. This is the first time in India that an easily replicated technology has been licensed by entrepreneurs for small areas, such as districts. Since a patent has been applied for, there is therefore the opportunity to check unauthorized imitations. SRISTI has filed several more patents in India and in the U.S.A., with the *pro bono* help of patent lawyers.

45 In this method, fisherman use dynamite to kill or numb all the fish in a particular river or stream. This method does not discriminate between large and small fish and helps in maximizing catch in minimum time. In contrast, traditional practices, which use nets that cannot contain fish of less than 4 x 4 inches, are extremely sustainable.

46 The parents' generation is often alienated from these knowledge systems already, due to the heavy influence of modernity.

47 The National Innovation Foundation (NIF), set up by the Department of Science and Technology, Government of India, to replicate the Honey Bee experience all over the country received about 1,600 innovations and examples of TK in its first year of operations (NIF, 2001). In second year it received more than 13,000 entries. This led the Union Finance Minister to announce in the Indian Parliament on 28 February, 2002, that it was empowering the Small Scale Industrial Development Bank of India (SIDBI) to set up a National Micro Venture Fund in consultation with NIF to help convert innovations and TK into viable enterprises. NIF had already decided to set up four additional Grassroots Innovation Augmentation Networks (GIANs) across India. A GIAN is a type of incubator first established by SRISTI and IIMA in collaboration with the Gujarat Government in 1997 to convert innovations into enterprises and act as incubator for grassroots green innovations. See: www.nifindia.org; www.gian.org.

48 See also the Pew Ethical Guidelines, 1993; Gupta, 1994 a, b.

49 The Indian Ministry of Environment and Forests granted access to these Institutions on the following terms and conditions: (i) Only those species listed in the request shall be collected; (ii) The specimens collected will be used only for the purpose listed in the request; (iii) A scientist from the Botanical Survey of India will be present on all the field visits; (iv) MoEF permission will be sought before publishing any research results; (v) In case the research has potential for commercial exploitation another agreement must be signed; (vi) Transfer of specimens or of the research finding to a third party without prior permission of MoEF is prohibited.

50 This service is provided free of cost to developing countries.

51 Source: Exim Bank Occasional Paper No.54.

52 Office of the President, National Commission on Indigenous Peoples, Administrative Order No.1, Rules and Regulations Implementing Republic Act No.8371, otherwise knows as, "The Indigenous Peoples' Rights Act of 1997."

53 These guidelines do not distinguish between national researchers and international researchers, as is the case in access legislation proposed by the Indian government.

54 I address at a later stage in this paper the issue of registration system in the light of recent experience.

55 Michael Polanyi, "Patent Reform", Review of Economic Studies, Vol.XI (1944) P.67

56 Walter Hamilton, The Politics of Industry, New York: Knopf, 1957, p.70

57 It is important to mention that opposition to the monopolistic features of patents has not come from socialists, but mainly from economists believing in free enterprise and free trade.

58 Scott Luckie, "Another Step Towards Indivisibility: Identifying the Key Features of Violation of Economics, Social and Cultural Rights": 20 (1), HUM, RTS, Q 81, 82 (1998).

59 Billie R. DeWalt, 1994, Using Indigenous Knowledge to Improve Agriculture and Natural Resource Management, Human Organisation, 53, (2), 123-131.

60 Stephen Gudeman, "Sketches, Qualms, and Other Thoughts on Intellectual Property Rights", in Valuing Local Knowledge: Indigenous People and Intellectual Property Rights, S.B. Brush & D. Stabinsky, eds., quoted in Coombe, 1998, Op.cit.

61 Graham Dutfield, 2000, Intellectual Property Rights, Trade and Biodiversity: Seeds and Plant Varieties, IUCN and London: Earthscan Publications Ltd.

62 The knowledge, innovations and practices of indigenous peoples and local communities, for example, are seldom protected by existing intellectual property systems.

63 It should up to individual farmer innovators to decide whether to disseminate their innovation through commercial, or non-commercial, channels. Knowledge rich, but economically poor, innovators cannot be expected to subsidize a society which has not contributed either to the conservation of agro-biodiversity or has not facilitated the role of farmers vis-à-vis the cultivators of high yielding varieties.

64 Michael Blakeney (Ed.), 1999, Intellectual Property Aspects of Ethnobiology, London: Sweet & Maxwell.

65 W. Lesser, 1998, Sustainable Use of Genetic Resources under the Convention on Biological Diversity. Exploring Access and Benefit Sharing Issues, Wallingford, CAB International, 127-135.

66 Ong Chui Koon, 1998, "Intellectual Property Protection of Traditional Medicine and Treatments in Malaysia", in Blakeney (Ed.), Op.cit. 155-172. Koon favors a *sui generis* system, which should ensure that larger public interest has precedence over commercial interests.

67 David V.Williams, 1999, Traditional Knowledge Systems and Intellectual Property Rights, "Talking Past Each Other: Current Issues in New Zealand", in Blakeney, (Ed.) Op.cit., 123-138.

68 Maria Thereza Wolff, 1999, "Indigenous Peoples and the Protection of Genetic Resources in Brazil", in Blakeney (Ed.), Op.cit), pp.173-182.

69 (1991) 21, Intellectual Property Reports 481.

70 (1995) 91-116, CCH Australian Intellectual Property Cases, 39,051

71 (1991), 2 Intellectual Property Reports 481 at 490.

72 Timothy Swanson, Property Rights Issues Involving Plant Genetic Resources: Implications of Ownership for Economic Efficiency, CSERGE Working Paper GEC 98-13, Norwich: University of East Anglia

73 Joseph D. Ben-Dak, "Rights, Compensation, Indigenous Knowledge Systems and the Strategy of Global Intellectual Property Management: The Challenge", in Thomas Cottier, Peter Widmer and Katharina Schindler (Eds.) Strategic Issues of Industrial Property Management in a Globalizing Economy, AIPPI Forum Series, Hart Publishing.

74 Klaus M.Leisinger,, "Ethical and Ecological Aspects of Industrial Property Rights in the Context of Genetic Engineering and Biotechnology", in Thomas Cottier, Peter Widmer and Katharina Schindler (Eds.) Strategic Issues of Industrial Property Management in a Globalizing Economy, AIPPI Forum Series, Hart Publishing.

75 Richard Gerster, 1998, "Patents and Development: A Non-Governmental Organization View Prior to Revision of the TRIPS Agreement", The Journal of World Intellectual Property, Vol.1.No.4,pp.605-619.

76 Robert M.Sherwood, Vanda Scartezini and Peter Dirk Siemsen, "Patents for Third World Inventors: Proposals for 21st Century Improvement", Patent World, May 1999. Http://216.3.116.71/PW/artres.htm

77 Robert P Merges and Richard R Nelson, "On the Complex Economics of Patent Scope", The Columbia Law Review, 1990:839.

78 *Pioneer Hi-Bred International Inc. v. J.E.M. Ag Supply Inc.*, No. 99-1035.

79 Victoria Slind-Flor, "Plants Protected by Patents: Federal Circuit's ruling clarifies confusion in the law", The National Law Journal, January 31, 2000.

80 Based on Gupta, Anil K, 1996, Rewarding Creativity For Conserving Diversity In Third World: Can IPR Regime Serve The Needs Of Contemporary And Traditional Knowledge Experts and Communities in Third World? Paper presented in AIPPI Forum (September 10-14, 1996) on Ethical and Ecological Aspects of IPRs, Interlaken, Switzerland, on 13 September, 1996, since published in Cottier *et al*., 1999.

81 This argument has arisen in the context of Art 15.5, as well as Articles 8(j) and 10(c), of the CBD. Prior informed consent is required only of parties to the Convention i.e the contracting nation states, and not of the knowledge and resource providing communities. Under Article 8(j) however, the approval and involvement of local

communities and individuals is required for ensuring the equitable sharing of benefits. Whether that will happen, in reality, will depend upon the legislative environment and local institutional capacity in each country.

82 See, for instance: Kari-Oca Declaration 1992; Indigenous Peoples' Earth Charter 1992; Mataatua Declaration 1993; Greaves 1994; Brush 1996; Posey & Dutfield 1996; COICA/UNDP Regional Meeting 1994.

83 The issues raised by the WAI 262 claim in New Zealand are also fundamental to the resolution of many issues and complexities mentioned here. Air New Zealand carpeted large areas of its airport with the Koru sacred designs, and these were walked on thousands of passengers. After complaints from Maori, the carpets were removed. The sacred signs and marks of Maori are often used without their permission in various official documents. Maoris are not against the fusion of tradition with modern to promote national interest. But they desire a due process of law to permit such exchanges.

84 IP/C/W/310, October 2, 2001.

85 Kenya (1975), Tunisia (1967), Chili (1970) and Bolivia (1978).

86 See, for example, the demonstration window at http://www.sristi.org.in/te/index.php

PART TWO: CASE STUDIES

Case Study One: Mali

Gene patents and the Genetic Resource Recognition Fund:
Sharing benefits from use of plant genetic resources by agro-biotechnological inventions and traditional agricultural practices

Overview

The subject of this case study is the role of intellectual property rights in the benefit-sharing arrangements surrounding the gene Xa21 of *Oryza longistaminata*, a wild rice from Mali, which was isolated, cloned and patented at the University of California at Davis. A specimen of *Oryza longistaminata* was originally accessed in Mali and transferred to a rice research program in India, where its resistance to bacterial rice blight, one of the most serious rice diseases, was identified. The blight resistant specimen was transferred to the International Rice Research Institute (IRRI) in the Philippines, which determined that the resistance was coded by a single locus called Xa21 and bred the resistance into cultivated rice varieties by conventional breeding methods. One such variety was then acquired by the University of California at Davis, where gene Xa21 was mapped, sequenced and cloned. After a patent application was filed and granted for the cloned gene, a Genetic Resource Recognition Fund (GRRF) was established at UC Davis to share with the stakeholders in Mali and other developing countries the benefits arising from the commercial utilization of the patented gene. This intellectual property-based benefit-sharing mechanism provides that the licensee of the patent over Xa21 shall annually pay a certain percentage of sales of products and derivatives of Xa21 into the GRRF for a specified number of years following the first year of commercialization. The Fund shall be used to provide fellowships to agriculture students and researchers from Mali, the Philippines and other countries where the wild rice is found, so as to build capacity in the donor country. At the time of conclusion of this study, however, no funds had yet been received by the GRRF. There are presently no plans at UC Davis to mainstream this model for accessing biodiversity and sharing benefits with gene donor countries. Within the overall policy of UC Davis and its own claims on such benefits, it remains at the discretion of individual researchers to decide how he or she wants to share the benefits and with whom. Patent US5859339, which forms the subject of this case study, is attached as Annex 3.2.1 of this case study.

Figure 1 – *Oryza longistaminata* growing in a river bank in a swampy area on a river bank in Mali.

The story of *Oryza longistaminata*, a wild rice from Mali, is a story of struggle between different strands of consciousness. Some farmers and policy makers in Mali consider it only as a weed, whereas there are other parts of the population depend on it for their subsistance. The field study indicates that the most impoverished parts of the population, the rural landless poor, are the ones who collect, conserve and utilize *Oryza longistaminata* for their subsistence. But these conservers of *Oryza longistaminata* or "*Kamlo*" (in local language, implying "rice from the river") are not aware that they have helped in conserving a wild rice which is the donor of a unique gene, Xa21, which now confers resistance against bacterial diseases throughout the world. The effects of the biotechnological invention which is based on gene Xa21 from *Oryza longistaminata* could be the increase of food security due to increased bacterial blight resistance in major crops. Intellectual property rights which were granted over this invention provide an important mechanism for the sharing of monetary and non-monetary benefits arising from this use of the plant genetic resource.

Some of the issues addressed in this case study are:

- to what extent can patenting and licensing of the cloned version of Xa21 help in generating resources for benefit-sharing with the communities in Mali and other countries involved in conservation of the wild rice
- to what extent will these conservers benefit from their contribution towards conservation
- does our appreciation of TK and its socio-cultural context help in better appraising
  (a) the institutional arrangements for benefit-sharing and
  (b) the role that intellectual property rights can play in such benefit-sharing arrangements.

Intellectual property rights play a central role in a benefit-sharing mechanism that was established at the University of California at Davis, USA, namely a Genetic Resource Recognition Fund. Even though no payments have yet been deposited in the Fund by genetic resources users, the case offers numerous lessons to be learnt about the role of intellectual property rights in benefit-sharing and about ways in which this role could be further strengthened to improve equity and ethics. Patent US5859339, which forms the subject of this case study, is attached as Annex 3.1 of this case study.

Institutional Context

Biotechnological advancements make it possible to incorporate specific genes from one crop or specie into another, conferring on them specific advantages either for dealing with various environmental stresses, including resistance to pest and diseases, or for improving productivity through better nutrient utilization. Advantages arise from genetic engineering not only in the agricultural sector but also in medicine. The commercialization of new products generates questions about who should benefit, in what proportion, and

Figure 2 – The International Rice Research Institute (IRRI), Manila, Philippines Area View.

when. The University of California at Davis has set up a Genetic Resource Recognition Fund to ensure that "part of the royalties derived from licensing of academic discoveries using developing countries' materials can be used to fund fellowships for developing nation scientists" (Ronald, 1998)[1].

The institutions of the *Consultative Group on International Agricultural Research* (CGIAR), such as the International Rice Research Institute (IRRI) in Manila, have maintained *ex-situ* germplasm collections from various parts of the world to improve crop productivity. These institutions distribute not only the germplasm but also the improved lines among various developing countries to aid respective crop yield improvement programmes. However, the access to the germplasm of these institutions is not restricted to developing countries only. Public and private sector research and commercial institutions from developed countries can also access these germplasm collections. After the CGIAR collections have come under the governance of World Bank, every recipient of the germplasm from CGIAR Centers is in principle obliged to sign a Material Transfer Agreement (MTA). In the post-Rio phase of agricultural germplasm collection and exchange,[2] there has been a general decline in the rate of deposition of germplasm by various developing countries in the gene banks and a consequent decline of exchange (Hawtin, 1999, pers.comm.). This decline might indicate a decreasing confidence of the potential gene providers, i.e., germplasm contributors, in the international pool. The fact still remains that these international gene banks play a very important role in ensuring continued food security and the productivity of national crop improvement programmes. There are instances when international germplasm collections have helped in rehabilitating national germplasm diversity which was damaged due to natural disasters and wars, as was the case in Cambodia.

Text Box 1:
The CGIAR Centers: An overview

The Consultative Group on International Agricultural Research (CGIAR), established in 1971, is an informal association of fifty-eight public and private sector members that supports a network of sixteen international agricultural research centers. CGIAR's mission is to contribute to food security and poverty eradication in developing countries through research, partnership, capacity building, and policy support. The World Bank, the Food and Agricultural Organization of the United Nations (FAO), the United Nations Development Programme (UNDP), and the United Nations Environment Programme (UNEP) are cosponsors of the CGIAR.

CGIAR centers conduct research programs in collaboration with a full range of partners in an emerging global agricultural research system. Food productivity in developing countries has increased through the application of research-based technologies. Other results include reduced prices of food, better nutrition, more rational policies, and stronger institutions.

The CGIAR focuses on several major research thrusts, including:

Increasing Productivity. The CGIAR strives to make developing country agriculture more productive through genetic improvements in plants, livestock, fish, and trees, and through better management practices. One important feature of the CGIAR's productivity research is its focus on building into plants greater resistance to insects and diseases that adversely affect productivity and the stability of production in the tropics.

Saving Biodiversity. The CGIAR holds one of the world's largest *ex-situ* collections of plant genetic resources in trust for the world community. It contains over 500,000 accessions of more than 3,000 crop, forage, and agroforestry species. The collection includes farmers' varieties and improved varieties and, in substantial measure, the wild species from which those varieties were created.

The CGIAR has placed its collections under the auspices of FAO within the International Network of *Ex Situ* Collections. The terms of the agreements signed between the FAO and CGIAR Centres, stipulate that the germplasm within the in-trust collections will be made available without restriction to researchers around the world, on the understanding that no intellectual property protection is to be applied to the material. Samples of the in-trust germplasm are thus made available by the individual Centres under a standard Material Transfer Agreement (MTA).

Notwithstanding the controversies about the rights of communities and countries in the germplasm contributed to the international gene banks, the norms of equity and ethics require a reciprocity to be established among donors and recipients of the germplasm and specific genes. The Commission on Genetic Resources for Food and Agriculture (CGRFA) at the Food and Agriculture Organization of the United Nations (FAO) has recently adopted the International Treaty on Plant Genetic Resources for Food and Agriculturein Rome has been engaged in discussions on the revision of the International Undertaking on Plant Genetic Resources. *Oryza longistaminata* is a plant genetic resource for food and agriculture (PGRFA) in the meaning of the International Undertaking (IU) the International Treaty on Plant Genetic Resources for Food and Agriculture.

The International Undertaking and International Treaty on Plant Genetic Resources for Food & Agriculture

The International Undertaking is the first comprehensive international agreement dealing with plant genetic resources for food and agriculture. It was adopted by the FAO Conference in 1983, (Resolution 8/83), as an instrument to promote international harmony in matters regarding access to plant genetic resources for food and agriculture. One hundred and thirteen countries have adhered to the Undertaking, which seeks to "ensure that plant genetic resources of economic and/or social interest, particularly for agriculture, will be explored, preserved, evaluated and made available for plant breeding and scientific purposes". The text of the IU is provided in Annex 1.33.2.3 to this case study. Since November 1994 the Commission on Genetic Resources for Food and Agriculture of the FAO (CGRFA) has been working on a Revision of the International Undertaking to bring it into conformity with the provisions of the CBD (see Text Box 2).

In November 2001 the International Undertaking was revised into the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGR).

Text Box 2:
The Revision of the International Undertaking Treaty on Plant Genetic Resources for Food and Agriculture

What are "plant genetic resources for food and agriculture"?
The Treaty defines them as "any genetic material of plant origin of actual or potential value for food and agriculture".

What are the Treaty's objectives?
Its objectives are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits derived from their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security.

What is the Multilateral System for Access and Benefit-Sharing?
Through the Treaty, countries agree to establish an efficient, effective and transparent Multilateral System to facilitate access to plant genetic resources for food and agriculture, and to share the benefits in a fair and equitable way. The Multilateral System applies to over 64 major crops and forages. The Governing Body of the Treaty, which will be composed of the countries that have ratified it, will set out the conditions for access and benefit-sharing in a "Material Transfer Agreement".

What are the conditions for access in the Multilateral System?
Resources may be obtained from the Multilateral System for utilization and conservation in research, breeding and training. When a commercial product is developed using these resources, the Treaty provides for payment of an equitable share of the resulting monetary benefits, if this product may not be used without restriction by others for further research and breeding. If others may use it, payment is voluntary.

How will benefits be shared?
The Treaty provides for sharing the benefits of using plant genetic resources for food and agriculture through information-exchange, access to and the transfer of technology, and capacity-building. It also foresees a funding strategy to mobilize funds for activities, plans and programmes to help, above all, small farmers in developing countries. This funding strategy also includes the share of the monetary benefits paid under the Multilateral System.

How does the Treaty protect Farmers' Rights?
The Treaty recognizes the enormous contribution that farmers and their communities have made and continue to make to the conservation and development of plant genetic resources. This is the basis for Farmers' Rights, which include the protection of traditional knowledge, and the right to participate equitably in benefit-sharing and in national decision-making about plant genetic resources. It gives governments the responsibility for implementing these rights.

Who benefits from the Treaty and how?

All benefit, in many ways:

- Farmers and their communities, through Farmers' Rights;
- Consumers, because of a greater variety of foods, and of agriculture products, as well as increased food security;
- The scientific community, through access to the plant genetic resources crucial for research and plant breeding;
- International Agricultural Research Centres, whose collections the Treaty puts on a safe and long-term legal footing;
- Both the public and private sectors, which are assured access to a wide range of genetic diversity for agricultural development; and
- The environment, and future generations, because the Treaty will help conserve the genetic diversity necessary to face unpredictable environmental changes, and future human needs.

When will the Treaty come into force?

The Treaty will come into force ninety days after forty governments have ratified it. Governments that have ratified it will make up its Governing Body.

The role of intellectual property rights in the context of plant genetic resource utilization has been contentious, in particular regarding the patenting of genes derived from naturally occurring germplasm. Some believe that patenting of genes leads to private control over life forms which have not been generated by human efforts. There are others who believe that the efforts required to isolate, modify and express a specific gene for a specific purpose constitute inventions and innovations with enormous advantages in improving the productive potential of crops. These scientists also believe that without compromising on environmental and other social effects, the tools of biotechnology should be used just like any other scientific tool to improve food security in the developing world. The debates surrounding the patentability of genes are not in themselves the subject of this Study and shall therefore not be discussed in detail here.[3] However, it shall be emphasized that the patenting of genes *per se* poses a less severe dilemma than the dilemmas posed by the persistence of poverty, hunger, malnutrition and inequity.

Technology can indeed influence the institutional arrangements for sharing benefits, if the asymmetry in the comparative advantages of gene donors and gene recipients is very high. However, the same technology can lend itself to different institutional arrangements for ensuring widely divergent social outcomes. Therefore, technology cannot be considered to be the sole determinant of its potential social and economic impacts. Given the current state of asymmetry in the above-said comparative advantages, the case for greater accountability on the part of gene receiving institutions and countries has been repeatedly made. All stakeholders, including the biotechnology industry, the scientific community, and the gene donor countries and communities are seeking to achieve legal certainty, accountability and equity in benefit-sharing. This case study illustrates one such attempt.

Intellectual Property Rights

The Xa21 gene

Figure 3 – *Oryza longistaminata* growing near a Bela Community village.

Figure 4 – IRRI maintains extensive breeding programs. *Oryza longistaminata* was bred there.

Rice is the crop which fulfills the basic food needs of the largest number of people in the world. It is estimated that almost 50 per cent of the potential rice yield in the world is lost to diseases caused by bacteria, fungi and viruses (Ronald, 1998). One of the most serious bacterial diseases of rice in Africa and Asia is reported to be bacterial blight, caused by the bacteria *Xanthomonas oryzae pv. oryzae* (Xoo). The famous Bengal Famine in 1940s was caused by rice blast and since then Indian scientists have been acutely aware of the dangers which diseases and pests pose to food security. Consequently, the search for genetic sources of resistance to major diseases and pests has been a major research priority with rice scientists. One such effort of an Indian scientist, Dr. Devadath, to find disease resistant rice led him to an individual of the wild rice specie of *Oryza longistaminata* (originally misidentified as *Oryza bharatii*, Kate and Collins, 1998:2, Richards, 1996). This resistant sample of *Oryza longistaminata* was brought to the International Rice Research Institute (IRRI), Manila for breeding purposes in 1978 (Khush, *et al*., 1991). Scientists at IRRI, namely Dr. G. Khush, Dr. R. Ikeda, and other co-workers, introduced the resistance found in the above sample into cultivated varieties using traditional plant breeding methods. They discovered that the resistance was contributed by a single locus called Xa21 (Ronald, 1998). In 1990 Prof. Pamela Ronald in the United States of America mapped this locus at Cornell University in the laboratory of Dr. S. Tanksley (Ronald, *et al*., 1992).

Prof. Ronald describes the history of this technology thus,

> *Tanksley's group had recently completed construction of a rice genetic map with support from the Rockefeller Foundation which had facilitated mapping efforts worldwide (McCouch* et al*., 1988). From 1992 to 1995 high resolution mapping, DNA library construction, cloning and sequencing was carried out at the University of California (UC) Davis leading to the isolation of a few candidate clones carrying Xa21. This work was supported by the US Department of Agriculture, the National Institute of Health and the Rockefeller Foundation.*

A collaboration with Lili Chen at the International Laboratory for Tropical Agricultural Biology (ILTAB) in La Jolla, CA, USA co-directed by C. Fauquet and R. Beachy, was formed to transform a susceptible rice variety, Taipei 309, with the candidate Xa21-carrying clones. The resulting plants were assayed at UC Davis for bacterial blight resistance. One of the candidate clones conferred high levels of resistance to bacterial blight in transgenic plants. The coding region was located on the transformed piece of DNA and named Xa21 (Song et al*., 1995). A patent application covering the Xa21 sequence was filed in 1995. Once cloned, there was tremendous international and commercial interest in using this gene to develop modern crop varieties. Species of Xanthomonas infect virtually all crop plants (Ronald, 1998).*

It was expected by Prof. Ronald and her colleagues that this cloned gene Xa21 may help improve productivity not just in rice but also in other important crops such as wheat, maize and barley through conferring the capacity for disease control. She also observed,

It is likely that without a patent application on file there would be less commercial interest and therefore less overall investment in developing the gene for use in these other crops. Ultimately, deployment of such engineered varieties could reduce the application of pesticides to the environment.

During discussions with Prof. Kevin M. Smith, Vice Chancellor (Research) at UC Davis it was learnt that the total revenue from patents was about USD 6 million of which about fifty per cent were from research related to strawberry, a major crop of California. In the case of *Oryza longistaminata* a patent application was filed after the the invention of Xa21 was made and the patent became a pivotal tool for the benefit-sharing arrangements that were instituted for gene Xa21 and the plant genetic resource of *Oryza longistaminata*.

The Patent US5859339

On June 7, 1995, the Regents of the University of California filed a patent application (no. 475,891) for "Nucleic acids, from oryza sativa, which encode leucine-rich repeat polypeptides and enhance xanthomonas resistance in plants." The patent application contains 24 Claims, 6 Drawing Sheets, and a Sequence Listing for 15 Sequences of nucleic acid base pairs and amino acids for which they code. The inventors named in the application are Prof. Pamela C. Ronald, Davis, CA; Guo-Liang Wang, Davis, CA; and Wen-Yuang Song, Davis, CA. The Abstract of the application states that,

The present invention provides nucleic acids encoding polypeptides which confer resistance to Xanthomanas spp. The nucleic acids can be used to produce transgenic plants resistant to the pathogen.

The patent was granted by the United States Patent and Trademark Office (USPTO) on January 12, 1999. The patent is classified according to the International Patent Classification (IPC) under Maingroup 5.00 ("Flowering plants, i.e. angiosperms") of the IPC Subclass "New Plants or Processes for Obtaining Them; Plant Reproduction by Tissue Culture Techniques" (Subclass A 01 H). More detailed information on the International Patent Classification is provided in Box 4.

The application cites 10 references, including 9 publications of non-patent literature and 1 foreign patent document, namely the "international" patent application WO9307279A1 which was filed under the Patent Cooperation Treaty (PCT) on "Inductible Plant Defense Gene Regulatory Regions from Potato and Rice, Uses thereof, and Assays". The Patent Cooperation Treaty is administered by the World Intellectual Property

Organization (WIPO) and makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing an "international" patent application. For more detailed information on the Patent Cooperation Treaty see Text Box 3.

Text Box 3:
The Patent Cooperation Treaty (PCT)

The PCT was concluded in 1970, amended in 1979 and modified in 1984. It is open to States party to the Paris Convention for the Protection of Industrial Property (1883). The Treaty makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing an "international" patent application. Such an application may be filed by anyone who is a national or resident of a contracting State. It may generally be filed with the national patent office of the contracting State of which the applicant is a national or resident or, at the applicant's option, with the International Bureau of WIPO in Geneva.

For more detailed information on the PCT see Text Box 7 in Case Study Three on Nigeria.

Subsequent developments, however, do not meet the level of commercial exploitation foreseen by Prof. Ronald's initial optimism. For whatever reasons, the companies which had licensed the gene for commercial exploitation either did not utilize it or generate any commercial returns from its application. They have not deposited any money in the Genetic Resource Recognition Fund for the past three years.

So far as the environmental impact of transgenic rice containing the Xa21 gene is concerned, more evidence would be needed to see whether (a) pesticide use for cultivation of the transformed rice is less, and (b) whether any gene drift from transgenic rice to its other wild or cultivated relatives could take place.[4] It may be useful to mention that blight is not a problem with rice in the US although it is a serious problem in most developing countries.

Text Box 4:
International Patent Classification (IPC)

The International Patent Classification, which is commonly referred to as the IPC, is based on an international multi-lateral treaty administered by WIPO. This treaty is called the Strasbourg Agreement Concerning the International Patent Classification, which was concluded in 1971 and entered into force in 1975. The Agreement is open to States party to the Paris Convention for the Protection of Industrial Property. On January 1, 2000, 45 States were party to the Strasbourg Agreement. However, the industrial property offices of more than 90 States, four regional offices and the International Bureau of WIPO under the Patent Cooperation Treaty (PCT) actually use the IPC.

The Strasbourg Agreement establishes the International Patent Classification which, in its seventh edition, divides technology into eight sections with approximately 69,000 subdivisions. Each subdivision has a symbol consisting of Arabic numerals and letters of the Latin alphabet.

The appropriate IPC symbols are indicated on each patent document (published patent applications and granted patents), of which about 1,000,000 were issued each year in the last 10 years. The IPC symbols are allotted by the national or regional industrial property office that publishes the patent document.

The Classification is indispensable for the retrieval of patent documents in the search for "prior art." Such retrieval is needed by patent-issuing authorities, potential inventors, research and development units, and others concerned with the application or development of technology. In order to keep the IPC up to date, it is continuously revised and a new edition is published every five years.

Benefit-Sharing

Creation of the Genetic Resources Recognition Fund (GRRF)

Prof. Ronald (1998) provides a succinct summary of how the Genetic Resource Recognition Fund was conceived:

> *Because there was no university precedent for germplasm compensation to source countries and because there was no prior agreement governing intellectual property rights (the material was collected in Africa before the entry into force of the United Nations Convention on Biological Diversity), UC Davis wished to define an appropriate method of recognition to the germplasm source countries. The absence of some form of recognition was deemed inappropriate and would be likely to make it more difficult in the future for the university to obtain research access to developing countries' national genetic materials. Our goals were five-fold:*
>
> *(1). To establish a mechanism to recognise and compensate for germplasm contributions from developing nations.*
>
> *(2). To provide a means for scientists to patent their inventions while maintaining productive collaborations and good relations with scientists from developing countries.*
>
> *(3). To encourage university/ developing nation/ industry links for commercialization of genetically engineered products.*
>
> *(4). To create a constructive solution that would be easy to implement and be widely accepted.*
>
> *(5). To create economic incentive for continued sharing of germplasm and conservation efforts.*

Prof. John Barton of Stanford University, a widely respected international authority in the field of law relating to international germplasm conservation and utilization, advised Prof. Ronald on implementing these goals in an effective benefit-sharing mechanism. Prof. Barton suggested that GRRF should be created and dedicated for providing scholarships to students from the donor countries. It was also realised that it would be difficult to find out as to "who exactly should receive compensation as the owner of a specific genetic resource".

In June 1996 UC Davis established the GRRF to recognize the contributions of various developing countries to the success of Xa21 cloning. The intention was that the royalties generated from commercialization of the cloned gene would be pooled in the GRRF. The GRRF will be used for providing fellowships to students from developing countries who would return to their countries to help in nation building. The fellowship would be given first to the students from countries which have donated germplasm, such as Mali, but not only to the students from these countries.

Figure 5 – *Oryza longistaminata* grows in the marshes and river banks of Mali.

It was expected that the GRRF would have USD 150,000 as future royalties from industry, UC Davis, and the inventors' contributions (Ronald, 1998). Other forms of compensation, like health care or conservation costs were expected to be incorporated into future agreements. Dr. Ronald pointed out (Ronald, 1998) that her goal was:

> *to create a practical compensation method to genetic resource contributors while allowing for the development, dissemination and commercialization of their contributions. The GRRF is a special fund set up for income derived from Xa21. However, it is hoped that the GRRF concept will be widely adopted by all the University of California campuses and in other major agricultural and medical research institutions. The setting up of similar funds at other major research institutions would provide a large and ongoing source of funds for fellowships or other types of contributions. The presence of compensation programmes would encourage source countries to conserve valuable land and genetic resources and can provide an economic incentive to do so.*

Non-commercial researchers such as public sector funded programmes were to enjoy free access to the gene, so long as they did not develop commercial products based on that genetic material. UC Davis and IRRI have agreed that IRRI would have full rights to develop new rice varieties incorporating cloned Xa21 and distribute this material as well as clone the gene freely to developing countries. This is a major conceptual and operational breakthrough in terms of North-South transactions on biodiversity. The Material Transfer Agreement draft letter available at the UC Davis website is enclosed in Annex 3.2.2.

Dr. Ronald (1998) proposed a sample text which could be used by various institutions to set up similar GRRFs:

> *(I)n addition to other royalty obligations, company x shall annually pay n% of sales of products and derivatives of gene x as defined in Article X, into a genetic resources recognition fund for n years following the end of the first year of commercialization, until it has transferred a total of X$ into that fund under this agreement. The genetic resources recognition fund shall be maintained by the university as a separate restricted fund, to be used entirely for fellowships and fellowship assistance to students and postdoctoral researchers from developing nations studying agriculture with a preference to be given to students and researchers from (name of source countries). The GRRF shall be managed by the Dean of the College of Agriculture and Environmental Science of the University of California at Davis.*

Institutional responses to GRRF:

The response to GRRF can be seen at three levels:

a. The response of UC Davis and other stakeholders such as the licensee companies, the Rockefeller Foundation and other fellow scientists using biological resources from developing countries for developing patentable technologies.

b. The response of formal research institutions in Mali and their awareness as well as preparedness to participate in GRRF.

c. The perception and response of local communities involved in the conservation and utilization of, or interaction with, *O. longistaminata*.

a. Response at UC Davis

Kate and Collis (1998) in their comprehensive study on GRRF point out that the access and benefit-sharing conditions of the CBD do not apply to *ex-situ* collections acquired by various research institutions prior to the CBD entering into force.

One view is that anybody who receives the designated germplasm from a CGIAR Center would not be able to seek plant variety protection on the unchanged material but would be entitled to seek patent or plant variety protection on inventions or new plant varieties derived from such materials. On the other hand, there was also a view that the recipients of designated germplasm from CGIAR Centers cannot claim any monopoly on the use of germplasm.

IRRI uses a "Standard Order Form" in which, Kate and Collis add, the recipient would undertake "not to claim ownership over the material received, nor to seek intellectual property rights over that germplasm or related information" and to ensure that any subsequent person or institution to whom the material was sent would be "bound by the same provision". The material is then sent to the recipient, accompanied by a "Shipment Notice" containing the same terms, which the recipient is obliged to sign. (Kate and Collins, 1998:8).

In February 1998, the CGIAR system had called for a moratorium on the grant of intellectual property rights on designated germplasm held in the Centers. While the restriction applies to all the germplasm that was transferred after 1994, the CGIAR hopes that recipients would exercise self-restraint even for the material obtained before 1994 for which Material Transfer Agreements (MTAs) were not signed. The Moratorium was called for after it was alleged that numerous grants for protection had been made in respect of designated germplasm. These allegation were never substantiated. It was acknowledged that Australian government agencies had filed applications for plant variety protection rights on two chickpea varieties obtained from International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) under a research co-operation whose origins pre-dated the institution of MTAs. However, even filing was not accepted since the applicants were unable the satisfy the Australian plant variety protection authorities that they were entitled to file an application.

During the negotiations with the companies, Kate and Collis (1988) described the proposal of UC Davis,

> *(T)he financial benefits contributed by companies should take the form of a royalty of a certain percentage of sales of the products marketed by the companies based on Xa21. However, from the companies' perspective, Xa21 would only make a small contribution to the genome and desirable traits of any new crop variety developed, so they were not comfortable with an open-ended royalty commitment. Instead, the university and the companies settled on financial benefits consisting of payment of a single lump sum by each company: US$ 52,000 in the case of the first company, and US$ 30,000 in the case of the second company. Given that only a minute proportion of research actually leads to a successful commercial product, the companies and the inventors settled on "commercialization" of a successful product, defined as the availability of the product for sale on the*

market, as the most appropriate trigger for payment of these sums. The benefit-sharing arrangement involves a single payment by each company into the Fund of the agreed sum one year after the commencement of sales by that company of the first new product that makes use of the Xa21 gene.

Dr. Ronald stressed in personal discussions as well as through subsequent correspondance that corporations pledged a sum of about USD 80,000, once the Xa21 gene was commercialized. UC Davis pledged to match the corporate contribution. It was also understood in the licensing agreement with the two companies that if the companies concerned did not commercialize or use the gene for three years, the rights would revert to UC Davis for subsequent licensing to any other party. Three years have passed and the GRRF has received no money to date. Thus, no monetary benefits could yet be shared with the germplasm donor countries. As mentioned earlier, IRRI has the right to use this gene in any variety and make it available freely to developing countries.

The draft Material Transfer Agreement (MTA)

Communication from UC Davis (February 16, 2000) states that the material concerning Xa21 which belongs to UC Davis can be used only in cooperative scientific research. The recipient would not have any right to pass "these materials, their progeny or derivatives on to any other party or use them for commercial purposes without the express written consent of The Regents of the University of California" (See Annex 3.2.2 for a copy of the MTA). Any risks in using this material will be borne by the recipient. Since exclusive patent rights have been granted, "no commercial licenses or rights are available for this material".

Personal discussions and subsequent communications with the right holders have indicated that this gene can be used freely by developing countries for incorporation in their plant varieties for conferring resistance to bacterial blight. Since the private sector may be involved in multiplying the seeds for distribution among farmers, it is not clear whether they will have rights to do so. At the moment, if material is received through IRRI, there is no constraint to its use in any way, except that intellectual property rightss cannot be obtained on this material.

Regarding the role of the Rockefeller Foundation, Dr. Ronald feels that "it would be inappropriate for them to contribute" to GRRF. However, the effectiveness of benefit-sharing frameworks and the role of intellectual property rights within such frameworks could be improved if the Rockefeller Foundation had a clear cut policy about:

(a) how royalties from resulting intellectual property rights will be shared if the genetic resources utilized in research funded by the Foundation originates in developing countries (irrespective of whether it was collected before or after entry into force of CBD),

(b) how benefits will be shared if the funded research generates commercializable technology, as appears to have been the case here, and

(c) what would be the rights of communities and countries from which the germplasm has been obtained.

In this case the effort to share potential benefits with germplasm donor countries came from the moral sense of equity of a scientist, Prof. Pamela Ronald. However, beyond the voluntary choice of the researcher, the CBD provides that Contracting Parties "shall take legislative, administrative or policy measures […] 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 utilization of genetic resources with the Contracting Party providing such resources.

Such sharing shall be upon mutually agreed terms." (Article 15.7). As mentioned earlier, no amount has yet been credited to the Fund even after three years (duration of the agreement). In the absence of any contribution from the university, the benefit-sharing mechanism seems to be dying a slow death).

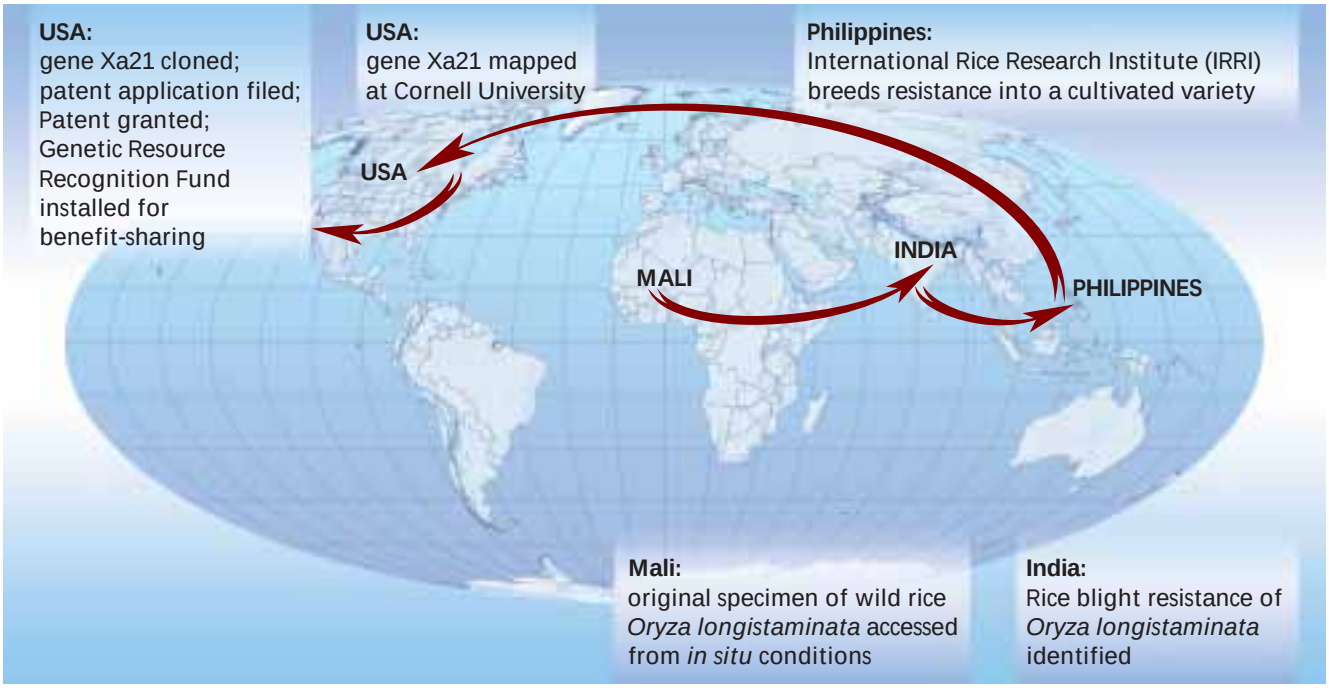


Figure 6 – The World Map Path of the *Oryza longistaminata* from Mali through India, Philippines and the USA and the sequence of Research and Development that led to the isolation, cloning and patenting of gene Xa21.

Prof. Ronald explained that she had devised in consultation with Prof. Stephen Brush a simple system in which every UC faculty member could mark a box on the "*UC Invention Disclosure Form*" suggesting that a share of the royalties from patents obtained on these inventions be credited to the Genetic Resource Recognition Fund.[5] If the two companies concerned do not license this gene by December 1999 the rights for commercialization would revert back to the university.

Prof. Coulsett, an eminent wheat breeder, noted that the concept of the GRRF was not very popular on campus, nor had it been mainstreamed. Some of the scientists felt that sharing benefits arising from the use of genetic resources in their inventions cannot be mandatory. Prof. Ronald agrees with the submission of some scientists that benefit-sharing cannot be obligatory. She considers that it should be a standardized voluntary policy. Others felt that benefits could be shared in the form of technologies, i.e., improved varieties being made available to developing countries. While there was a consensus among senior scientists at UC Davis for *ex-situ* conservation, many senior scientists did not seem convinced about the importance of *in-situ* conservation of landraces. Dr. Charles Ricks, a scientist knowledgeable in the conservation of germplasm, recognized the need for *in-situ* conservation although he admitted that no institutional arrangement existed for the purpose so far. He also noted that when the seeds were selected for acquisition by gene banks, the banks assumed that the samples were random and did not take into account the genetic structure of the population. He also felt that breeders did not spend much time on conserving biological diversity within the country. There was no downside in his view to the concept of *in-situ* conservation. For example, the University of California at Davis has more than 3000 accessions of tomato varieties, of which 1000 had been identified for donating genes, 1000 were cultivated varieties, and another 1000 could be wild races. The *ex-situ* banks have also been used to safeguard genes endangered in war. It is easier to

know the pedigree of varieties but more difficult to know which gene came from which parent. Prof. Brush argued that benefit-sharing was necessary at least for *in-situ* conservation.

Dr. Kevin M. Smith, Vice Chancellor for Research at UC Davis, mentioned that he was quite supportive of the concept surrounding Prof. Ronald's initiative.[6] In a subsequent communication, Dr. Smith observed,

> *UC systemwide has a policy regarding distribution of royalties, some going to patent/ licensing expenses, some to inventors, some to the State of California, and some to Chancellors of campuses. If inventors wish to reassign their royalties they may do so, but we cannot unilaterally mandate any actions with regard to the other funds which are outside of the control of the inventors – currently policy does not allow that. Neither does our policy allow the campus to mandate the use of the inventors' income.*[7]

Some stakeholders in developing countries may feel that the voluntary assignment of rights does not encourage full reciprocity among germplasm-contributing and -utilizing institutions and countries. Such a policy is bound to affect the pattern of liberal germplasm exchange among various countries that existed in the past. Further, such a policy also does not encourage local communities to conserve local genetic resources and their diversity. Accordingly, the optimism that had been shown by UC Davis through its press releases in 1997, has been succeeded by limited institutional and financial success.

b. Institutional response of scientists in Mali

Dr. Bino Teme, Scientific Director, Institute of Economic Research (IER), who is in charge of agricultural research in Mali, did not know about the UC Davis initiative of establishing a Genetic Resource Recognition Fund. This illustrates the importance of extensive information exchange for any benefit-sharing arrangements in which all stakeholders are to participate effectively.

Box 5: Stakeholders in *O. longiistaminata*

Mali	India	Philippines	USA
Government of Mali	Rice research program	Int'l Rice Research Institute (IRRI)	Government of USA
Scientific Research Institutions (ERI, etc)			UC Davis
local land-owning farmers			Prof. Pamela Ronald, et. al
Landless Bela community			Two private companies in agrobiotech sector
Malian agriculture students			

On the cloning and patenting of gene Xa21, the view was that as long as the scientists in Mali could get access to the cloned gene to improve quality and productivity of their own agriculture, then they did not object to the patenting and cloning. They would of course appreciate if there was collaboration between UC Davis and their organization and if the improved material was exchanged.

When informed about the framework of the Genetic Resource Recognition Fund and the cloning of the gene from Malian *Oryza longistaminata*, Dr. Teme was highly appreciative of the efforts made by UC Davis. He did not have any objection to a patent being granted on gene Xa21 and felt that scientists who do research to add value to local biological resources should be granted exclusive rights for the same. He mentioned that the proposed scholarship scheme would be highly appreciated in Mali. There was no policy for *in-situ* conservation as yet and also no Plant Variety Act in force.

Local scientific knowledge about *Oryza longistaminata*

According to the Malian agricultural scientists, there are three kinds of wild rice which sometimes grow together, namely *O. barthii* (red color), *O. glabberma* (panical wide open), and *Oryza longistaminata* (panical slightly tight and propagation vegetatively). Generally, the fields where *Oryza longistaminata* is found are supposed to be very fertile. This rice is a host to the Rice Yellow Mottel Virus though it is not affected by the virus. While *O. glabberma* is used for breeding, *Oryza longistaminata* was not being used in any of the major crosses. In 1976 all native germplasm was surveyed and about 1000 local varieties were collected.

Dr. Teme and other scientists were intimately aware of the fact that this wild rice spreads in the paddy fields, so much so that in some cases the fields have to be abandoned because of the extensive spread of *Oryza longistaminata*. Poor people collect the grains, which fall down since the grains of this landrace shatter very fast.

Mr. Dond Kone, Farming Systems Research Team leader at the Niono Research Center of IER, considered *O. longistaminata* to be a weed. He pointed out that people have developed strategies to fight it. Ten years ago there was a serious problem to control it and even the herbicide 'Round Up' failed to control its spread. Farmers tried double ploughing and many other ways to control it, including second ploughing at the beginning of the season. Farmers have also tried to uproot the rhizomes which remained buried in the water.

Figure 8 – (l-r) Mr. H. Magassa, Prof. A. Gupta (the author), Mrs. Aisse Toure, Mr. M. Diawasa and Mr. M. Roes. The author with local scientists who are undertaking agricultural socio-cultural and economic research in Mali, including research on rice varieties-based indigenous knowledge systems.

Dr. M. K. Nidia Ye, Soil Scientist, and Mr. Ydounbia, Agronomist, provided additional information about *Oryza longistaminata*. They mentioned that the older varieties were photo period sensitive, but more tasty. Only the *phulani* and *bela* people were dependent on *Oryza longistaminata* for their subsistence. *O. bhartii* is an annual wild rice, whereas *Oryza longistaminata* is perennial. The local name for *Oryza longistaminata* is '*maluf* ' (black rice) whereas *O. bhartii* and *O. glabberma* are called '*Komolo*'. Some of the cultural uses of *Oryza longistaminata* and *O. bhartii* are:

- The *Bela* people used to make masks out of *O. bhartii* to cover one's body while performing rituals. Muslims, who are not supposed to use masks and perform the rituals, have not used *O. bhartii*.

- While performing ceremonies, the stem of *Oryza longistaminata* is used to fence the place where ceremonies are performed. Sheep, goats, cows and donkies are fed on the straw and *tifa*, another weed found along side, is used for making roofs. Generally the *mopti* people collect *O. bhartii* and sell it in the market.

There are several other wild rice varieties growing in the region besides *Oryza longistaminata*. Some of the old varieties of rice have either become extinct or are not favoured at present. The relation of *O. longistaminata* to the *in-situ* utilization and conservation of related wild rice varieties include the following:

- '*bintubala*' is not found any more. It had a good taste, a long grain, and white caryopses. Its yield was about 2 tons per hectare and it matured after six months in November. This variety has died out.

- '*docu*' was a late maturing, slow growing dwarf variety (40 centimeter variety), light red in color, with a short grain size, and a yield of three tons per hectare.

- *O. bhartii* is called '*malibli*' when found in the cultivated rice fields and it is called *komolo* when found in swamps outside the fields. Farmers try to weed this rice out and landless women, particularly those belonging to *bela* community, collect it.

Mr. S. Sala, a weed scientist, acknowledged that people used this wild rice as a food in the past though it is considered a weed at present. In the North of Mali from the Mopti to the Gai regions, people collect the grains of this rice, particularly the landless people. People also eat the grains of the weed, called *Echinochola colona*, which is very difficult to distinguish from the paddy plant at the early stages of growth. This weed is much more prevalent in poorly flooded soils and in low lying rice areas it is a very competitive plant and is often very dominant.

Farmers have selected some types of *Echniochola pyramidallis*. They transplant it and use it as a feed for animals in the Mopti areas, since it does not cause a problem in frequently cultivated areas. In contrast, *Oryza longistaminata* earlier caused a lot of problems. In Matsana, a small town, sixty kilometers from Segou, farmers abandoned about 900 hectares of irrigated area because of *Oryza longistaminata*.

All the center delta regions are populated by *Oryza longistaminata*, which plays multiple roles in the local ecosystems. For example, *Oryza longistaminata* provides the host for the stem borer and the Rice Yellow Mottel Virus. However, *Oryza longistaminata* seems also to be a host of *Oncocephalus*, the predator of the stem borers. So far, no formal scientific study has been done to determine whether the resistance of *Oryza longistaminata* to the two stem borers, i.e. *Chile zaccepious* and *Maliarpha separatala*, is correlated with its ability to provide a host to *Oncocephalus*. The most serious problem of land-owning rice farmers is the virus for which *Oryza longistaminata* provides the host. But *Oryza longistaminata* itself is never affected by the Yellow Mottle Virus. Nobody has even seen a dead plant of *Oryza longistaminata* displaying the symptoms of the virus. An awareness about the likely resistance of *Oryza longistaminata* to viral and bacterial diseases thus existed among the local scientists, even though they never considered it worthwhile to be a subject of scientific research, because they considered this wild rice to be a weed only.

In the past, during magic shows the local people used to beat drums, organize a dance and a person covered by *Oryza longistaminata* stalks would appear like an animal and dance. Nobody acknowledged consuming the wild rice, except the *Bela* people who consume *Oryza longistaminata* as well as *Echinochloa colona*. *Oryza*

Figure 9 – Paddies of *Oryza longistaminata* Millet and corn being dried for local food consumption in Mali.

Figure 10 – Women of the Bela local communities use stalks of *Oryza longistaminata* for basketry production purposes and other local needs.

longistaminata is supposed to have diffused through the rivers and waterchannels in the region. *Oryza longistaminata* was found in the region before the irrigation system was established. In the olden times villagers would uproot *Oryza longistaminata* and dry its roots.

While *Oryza longistaminata* is considered a weed, there are several other varieties of rice which have been developed and are being cultivated by the land-owning farmers of the local communities. Some of these related local varieties of rice are the following:

- Banjul — Big grains, reddish, mature in six months, used as par boiled rice, there is a town named Banjal near Gambia (the capital of Gambia). This rice may have come from Gambia.
- Gambiaka — Close to Bomoko there is a village, Kokum, and researchers made selections from the local rice to develop this variety.
- Bindu bala — White grain, thin and slightly brownish red stock, matures in six months.
- Doc — Late maturing, about seven months.

Before colonization of this area, *Oryza glabberma* rice was found here, called *Melabli* in the local language. Shattering was one of the reasons why the government did not allow cultivation of *Oryza glabberma*. Its advantage was that it matured early, and had good taste, lot of energy and did not fall prey to any diseases. It was believed that people who consumed it also did not get many diseases.

c. Community's perspective

The local communities have developed detailed taxonomies, practices and knowledge systems around the *in-situ* utilization of *O. longistaminata* and related wild rice varieties. According to the botanical taxonomy of the traditional knowledge system, both *O. longistaminata* and *O. Bharthii* are considered *komolo*. *Komolo* is a generic term for rice growing in the river. However, *O. longistaminata* (figure 1) shatters more than *O. Bharthii*.

Box 6: *O. longistaminata* in different Local Knowledge Systems in Mali.

Local landowning farmers:

- "a weed"
- no knowledge of disease resistance
- some knowledge of ecological relations
- detailed knowledge of reproduction and its avoidance

Local scientists:

- "a weed"
- no scientific knowledge of disease resistance
- no scientific knowledge of ecological relations
- some scientific knowledge of reproduction & avoidance

Oryza longistaminata

Landless local Bela community:

- "a food resource for conservation"
- detailed knowledge about disease resistance
- detailed knowledge of ecological relations
- detailed knowledge of reproduction & avoidance

O. Bharthii matures late and is non-synchronous in nature. Its panicles are tight when it matures and after maturity the spikelets spread out. *O. longistaminata* has slightly different kind of spikelets. *O. longistaminata* is also called '*diga*.' It has to be controlled very fast when it is in the field since it may make land unfit for cultivation. The grain yield is very low, namely about ten grains per plant and extremely poor people collect it.

Several aspects of the prevalent socio-cultural system are relevant to the case: people use black rice (*O. Glabberma*) during fairs, collected from the wild, and mill it. Because it is an early maturing rice in swampy areas, those who do not have anything to eat, harvest it and it is generally considered a famine food. The number of cattle, which grazes the stalks of *O. longistaminata* after the October/November period, is generally considered the sign of an individual farmer's wealth. Vegetables like Okra, which are grown around the rice fields, as well as income from the poultry belong to male farmer. Women are given small plots to do horticulture and income from these plots belongs to them. The income from farming belongs to their entire joint family.

Figure 11 – A woman Geneva Dia Ilo from the farmer's community of the Nanco village Sasrakalla, Mali, demonstrating the local use of *Oryza longistaminata*.

Figure 12 – O. Glabberma an early maturing wild rice variety closely related to *Oryza longistaminata* local grain, being milled for local food supply.

In the past, families in the Nanco village used to grow sorghum, cotton, millet, some of which are still cultivated. The community came from Sariwala about one hundred years ago and now cultivates six hectares of land. The community of the Nanco village had come from Kuchala about a hundred years ago, when the French forced them to migrate. Consequently, the community is apprehensive that if they build permanent houses, they might be moved away. They grow several grains such as *kadmi*. This white long grain susceptible to shattering yield was good and very tall, but bird attack was much more frequent. The *bindubala* variety of rice was valued much more. Mr. Okesamaki, one of the farmers had four hectare of very poor land. Earlier he and his family members used to grow cotton but when water came, the plantation of cotton was discontinued.

There were a lot of diseases and pests and ultimately the community had to abandon the land. Even aerial sprays of pesticide did not help and the pest damage in other crops were very serious. They also used to grow '*cokono malu*', i.e., rice grown in small rivers. It was black or red and was not known as a high quality variety. They used to broadcast the seed in the river and different families used small patches of swamps. The patches closer to the sorghum and millet fields were being used with particular frequency and the community had more fields than it could cultivate at that time. The farmers were fighting against *O. longistaminata*.

The Bela people and the Village Sirewual: The real stakeholder in conservation of *O. longistaminata*

The Bela people originally came from Gudan, a place near Timbuktu. They moved from the northern dry regions to Sirewual several decades ago, in hope of a better life. The Bela settlement is situated on the outskirts of the township, though very close to the research center. All the fallow land in the area where the Bela settled was taken over by the government which in turn allotted it to private owners. Some of the private owners, who did not cultivate the land themselves, allowed the impoverished Bela people to grow sorghum for the time being. They now live on the land granted to other residents of Niono, who have let them stay here and till the adjoining plots. As and when these owners/grantees of land will need it, the Bela will have to move away, maybe a few kilometers or more. The Bela have made numerous petitions to government for land, but have not been granted any.

Figure 13 – Community members of the economically marginalized Bela people in Senawal, Mali.

Figure 14 – A community member of the Bela people, preparing *Oryza longistaminata* for food consumption.

The community members pursue brick making, manual labor on others farms, and the plantation of sorghum for the market. They also grow a pearl millet variety called *sanyon joma*, a kind of white pearl millet, and a sorghum variety was called *kinki.* When asked if they could get improved seed, they declined. Their socio-economic context is comparable to the fate of the rural landless poor in other developing countries of Africa or Asia. The Bela are, in effect, a highly impoverished and economically marginalized people.

The black rice growing in the swamps and river was uncontrolled and the Bela could harvest the rice or collect the fallen rice. They collected about six hundred kg to one ton of rice from the wild. They harvested *O. longistaminata* and *O. bhartii* together and cooked it with meat. They found this rice to provide a lot of energy and strength. During discussions, they pointed out that hungry people do not have the privilege of discrimination when asked as to which rice they preferred. Consequently, they collect and conserve whatever is available.

While nobody in Mali was fully aware about the disease resistance of *O. longistaminata*, the Bela were the only community which held detailed ecological and ethnobotanical knowledge about the functions and characteristics of this rice, including its resistance to rice blight. The Bela people pointed out that *O. longistaminata* never contracts any diseases under normal conditions. Only when water is scarce have they noticed dead plants, perhaps from diseases, but in general they knew about the resistance of *O. longistaminata* to many diseases.

While everybody else referred to birds as a nuisance from which they had to protect the crop, the Belas viewed the birds very differently. Without birds, they stressed, the grains would not be distributed. Birds distribute the grain/seed and thus the community can collect rice from larger areas. A concentration of birds in the adjoining trees indicates that the rice is mature nearby and that the community can begin collection. The bird that particularly eats *O. longistaminata* and indicates places of particular rice concentration by singing around such locales, is called '*Chironi*'. For farmers, this bird increases the burden of weeding, but one person's weed is another person's food.

Based on the traditional practice of collecting wild rice and other local biological resources, the traditional knowledge system of the Bela community about the wild rice varieties, recognizes that *O. longistaminata* is a variety with a particular resistance to diseases, which exceeds the disease resistance of other varieties, including for rice blight.

This illustrates that ethnobotanical knowledge of plant genetic resources is neither tied to scientific, nor land-owning farmers, nor to criteria of 'indigenousness', but rather to the local and practical *in-situ* use of the genetic resource. This has several conclusions for benefit-sharing arrangements surrounding genetic resources and associated traditional knowledge:

- The stakeholders are not limited to formal scientific research institutions of the country of origin of the genetic resource;

- The ethnobotanical knowledge of local PGRFA is not necessarily and only held by local landowning farmers, but can also be held by local communities that are landless and subsist on mixed modes of income. This may have implications for the concept of farmers' rights in the revision of the International Undertaking.

Figure 15 – Bela woman demonstrating local utilization practices and ethnobotanical knowledge related to *Oryza longistaminata*.

Figure 16 – As in the previous figure, a demonstration of local utilization and knowledge of *Oryza longistaminata*.

- The ethnobotanical knowlegde is not limited to indigenous communities, but often is held by local communities to a larger extent than by indigenous peoplescommunities. This may have implications for the implementation of Articles 8(j), 10(c) of the CBD, which refer to the TK embodying the lifestyles of "indigenous and local communities relevant to the conservation and sustainable use of biological diversity."

There was general consensus among the community that there were no fights on who collected from where, and all counterparts referred to the principle of "first come, first serve." Anybody who reached earlier could collect the grains from a given place. The Bela harvest some grains and the rest they collect from the river after it has shattered and fallen from the stems. In some aspects, the Bela may be viewed as the continuing link between the ancient culture of food gathering from the wild and the culture of contemporary cultivation. However, the Bela people are not an unstructured and homogenious community; they themselves have distinct internal social structures and classes. The community members who move about and sing for remuneration are considered of lower social standing than the other community members. There is no inter-marriage between these subgroups. The Belas also did not let their women talk too much. When asked, the stock reply was they might not know.

When asked about their vision for the conservation of *O. longistaminata*, they replied that they didn't own the land and therefore had no agency to make suggestions on the conservation and utilization of the biological and other resources on which they subsist. However, the Bela have developed specific conservation practices for *O. longistaminata,* since they are economically dependent on this plant for their subsistence and survival. Ms. Gineba Diallo (Figure 3), the grand daughter of Aminata, mentioned that if they did not remove the husk from *O. longistaminata*, one could conserve it for over a year.

Contemporary innovations:

At the Musawere village, some families of the Belas came from different parts of Mali. They came from a region growing cotton, sorghum, pearl millet and cow pea, and they learnt about rice only after arriving in the Niono region. For them the use of rice, and the knowledge on the properties and collection of *O. longistaminata*, was a contemporary innovation to their traditional practices and one on which they depend for their survival.

Figure 17 – Malian stakeholders discussing the case of *Oryza longistaminata* and the role of intellectual property rights in the sharing of benefits arising from the use of the rice at the Center for Indigenous Knowledge, Bamako.

Feedback:

At a seminar held at the Center for Indigenous Knowledge with participation from government departments, the local university, NGOs, and international research centers like ICRISAT, discussions focused on the accountability of researchers towards those who provide knowledge and information about genetic resources in Mali. There was consensus that the disjunction between formal knowledge and the informal knowledge systems was very strong here. The awareness about intellectual property as a tool for the promotion of innovation and the sharing of benefits arising from the use of Malian genetic resources was considered very low.

However, the community members did raise concerns about the ethics of knowledge sharing and the inequity of knowledge retrieval by Western scientists. The interactions of an outsider with any community pose several methodological dilemmas, including in this case study. For instance, when I asked a lady, Aminata Coulabaly (Figure 2), in the Sarakala region about this rice, her remark was, 'white people ask too many questions?', 'we can't ask them similar questions?' After this dialogue I encouraged every respondent in individual and group meetings to ask questions about anything they wished and this led to rich insights about knowledge exchange.

Lessons Learned

The case study offers a few lessons:

Concerns raised about so-called 'bio-piracy' have led numerous scientists and companies to seek innovative ways of sharing the benefits arising from their use of plant genetic resources and traditional knowledge, and intellectual property rights play an important role in them. However, no benefits have yet been shared from efforts whichefforts, which rely on only voluntary benefit-sharing. There was no evidence at UC Davis that the initiative of Prof. Pamela Ronald had received sufficient support. Some policy fora and processes, such as the revision of the International Undertaking on Plant Genetic Resources at the FAO, have therefore considered establishing a multilateral system for facilitated access to and mandatory benefit-sharing in PGRFA.

- The administration of large universities like UC Davis is sympathetic to the idea but apparently unable to trigger a major university-wide debate on the subject of intellectual property and equitable benefit-sharing. While the Genetic Resource Recognition Fund is highly instructive about the possible roles of intellectual property rights in bilateral benefit-sharing, the fate of the GRRF does not warrant optimism about the success of voluntary bilateral benefit-sharing initiatives in PGRFA. By implication, the GRRF may also offer some lessons as to the role of intellectual property rights in a multilateral system.

- The fact that the land-owning farmers in the region where wild *O. Longistaminata* grows have no interest in its conservation and no knowledge about its rice blight resistance raises several important issues for benefit-sharing in traditional knowledge and for the concept of farmers' rights as contained in the revision of the International Undertaking.

- Should the local farming communities of the region where plant genetic resources for food and agriculture are accessed be considered as the default stakeholder? In this case, the Bela community, which is from Timbuktu in the far north of Mali, but which is dependent upon *O. Longistaminata* for its survival and knows about its characteristics and utilization, is the real stakeholder in the conservation of *O. Longistaminata*. Under conventional ABS frameworks, both bilateral and multilateral, this landless community is likely to be excluded. Policy makers concerned with benefit-sharing policies may wish to take into account such landless communities as stakeholder in the *in-situ* conservation of local biological resources.

- The case study exemplifies a limitation in the applicability of the criterium of "indigenous" knowledge, when speaking of biodiversity conservation. In this case, the ethnobotanical knowlede of *O. Longistaminata*, and in particular its resistance to rice blight, was held by impoverished local immigrant communities, rather than the 'indigenous' local farming communities. The case study indicates that the definitive criterium of traditional ecological knowledge is its connection with the local ecosystem, i.e. its *local* character.

- The policy processes at the FAO, the CGIAR and the CBD require further discussions in order to clarify whether international regulations to ensure facilitated access and equitable benefit-sharing in using biological resources are necessary. Attention will have to be given to the role of contractual arrangements as a practical tool for benefit-sharing. Given the asymmetry in technological competence among different countries, the question is whether international regulations will help in overcoming the asymmetry or further exacerbate it. The role of the Global Environment Facility in conservation or value addition in agro-biodiversity has been limited so far. It is obvious that we have to go a long way if experiments like GRFF have to be institutionalized within developed country institutions.

- The role of intellectual property rights is crucial in generating benefits from commercializable technologies which utilize the genetic resources, in this case by Mali. In the present case, UC Davis had the legal right to use the germplasm without any permission from anybody. The fact that the gene was first identified at a public funded research institution in the Philippines, namely IRRI, may raise questions about inventorship in relation to the patented gene Xa21. While the willingness of UC Davis to provide this gene freely to developing countries is highly commendable, the Material Transfer Agreement might make this goal more clear and explicit.

- A close involvement of the gene donor country, i.e. Mali, in the biotechnolocial research which utilizes the Xa21 gene was not sought in this case. This benefit might have been the easiest to be shared and such sharing might have been possible within the research funds available from the Rockefeller Foundation as well as from the two companies to whom the gene was licensed for three years. The Rockefeller Foundation did not have a policy of mandatory benefit-sharing with genetic donor countries in the research which they fund. However, the Director of Food Security of the Foundation expressed the following views regarding the role of intellectual property rights in benefit-sharing from Rockefeller-funded research:

The position of the Rockefeller Foundation is that the results of the research it funds should be made available without royalty charges for use in developing countries. However, IPR can be taken in developed countries to generate income for further research.

In the case of the Xa21 gene, UC-Davis licensed the cloned gene to IRRI and others without charge for use in developing countries. They also licensed it to companies and generated income which will, in part, support further research. The Foundation has had no involvement with the GRRF gene fund but I personally think it's a good idea.

The naturally occurring Xa21 gene can, of course, be used in conventional breeding without any restrictions since it was discovered by IRRI and there is no IPR on it.[8]

This raises several technical questions on how such a policy on intellectual property and benefit-sharing should be implemented in the exercise of intellectual property rights which were acquired to protect the results of research funded by the Foundation. These questions include, *inter alia*:

- when the Foundation enourages the acquisition of IPRs on funded research, has any consideration been given to the possible incorporation of claims of gene donor communities in licensing arrangements after IPRs on the research results have been acquired. In such an arrangement it would be possible to share with the gene donor community, benefits accruing form royalties or licensing or both of Rockefeller-funded research.

- which measures could be taken to take into account that the capacity for using proprietary technology may not exist in the gene donor country. The present case is indicative since the scientific leaders in Mali did not know about the gene patent on Xa21. This raises the question whether information sharing and scientific capacity building in gene donor country should not be part of the Rockefeller Foundation's funding policy.

The Foundation addressed these questions through the following statement, which is based on its extensive past experiences and work in agricultural research funding:

The vast majority of RF funding is committed to capacity building in developing countries. This includes hundreds of fellowships for Ph.D. training in labs such as Pam Ronald's and then support for the fellows' research after they return home. Over the past ten years over 400 fellows received training in biotechnology including some from Mali. However most fellows from Africa receive training in conventional breeding, agronomy, IPM, microeconomics and other areas that are more relevant to the needs of their home institution and country. If the RF helped to fund the GRRF we would be taking funds from these other fellowships and from research in developing countries and giving even more to UC Davis who I doubt could do as good a job as we can in selecting fellows who will return home.

We do not encourage IPRs on RF funded research, we allow it. We do not have contracts, we give grants. We cannot force our grantees to do anything. If they do not share we simply do not renew their grant because they are not meeting the objectives of our program. We do not have a policy on sharing royalties with gene donor communities because this issue is of no relevance to the vast majority of our grants.[9]

Recent debates have raised questions regarding the provision of scholarships as a means of benefit-sharing. Some commentators have raised issues with regard to alternative ways of conceptualizing benefit-sharing.[10]

> (1) Who will really benefit from the scholarship fund? The idea of providing scholarship … aims at building long term capacity in the gene donor countries as well as in the country where the germplasm was conserved. The problem arises when we try to understand as to who may actually benefit from such scholarships. Studies have shown that school dropout rates are generally highest in biodiversity-rich regions and also where agriculture is rain-fed and risk prone. It is these regions in which land races are likely to be conserved. Yet, young boys and girls (in fact, the dropout rate of girls is almost twice as high as that of boys) from these regions are unlikely to get the advantage of scholarships unless a specific stipulation is made in the rules requiring this fund.
>
> Further, it should be made mandatory for recipients of such scholarships to go back to their own countries. It will be ironical if the recipients stay behind in the USA and the fund works like a suction pump to draw out able young scholars.
>
> (2) The contribution to the conservation of land races may also require the setting up of trust funds under the leadership of local growers of land races in the gene donor countries. It must be insisted that the funds must be managed by those who grow land races. Otherwise owners of irrigated land holdings, growers of high yielding varieties, and those having more influence and power will dominate these funds.
>
> (3) Sharing royalties with students from the Philippines is fine so far as the need for that country to get such help is concerned. But this must be distinguished from giving property rights to the Philippines on every germplasm on which research is done at the International Rice Research Institute (IRRI). Otherwise it could imply, for instance, that India will become claimant for royalties from germplasm stored at ICRISAT, Columbia for CIAT's collection, the United States of America for the repository of genetic resources at Fort Collins, etc. Having the gene donor country's share in royalties depleted by such stakeholders would not conform with the CBD objective for fair and equitable benefit-sharing. A weighting criteria and priority list in this regard may need to be developed. Otherwise, better off countries and communities in Western Africa or any other region will take away the benefits of this new instrument of reciprocity between gene donors and gene beneficiaries.
>
> (4) The contributions to these funds should come not only from University royalty funds but also from corporate stakeholders who are utilizing this gene for a period of no less than 20 years (the standard minimum term of protection for patents, as set out in Article 34 of the TRIPS Agreement). To ensure that such funds become large and attractive for local communities to really conserve land races it will be necessary to generate revenues from seed companies and/or the growers of disease resistant varieties of rice having this gene. In any case all the high yielding varieties have incorporated genes from land races without exception.
>
> (5) Sharing of benefits should be seen as a mark of responsibility rather than charity. It is, however, important to mention that such a responsibility should be shown by public and private

sector agencies (seed companies, grain procurement agencies, exporters, growers and consumers of high yielding varieties, etc.) in each country. By focussing exclusively on a few stakeholders the issue of generating larger civil society responsibility in all countries towards conservation is easily lost sight of.

- The Mali case brings out the import of the issue of voluntary benefit-sharing. But it also highlights a need for increased institutional commitments to such initiatives. UC Davis or, for that matter the UC across all campuses, have not had a dialogue so far on institutionalizing a system of mandatory benefit-sharing from the patented products or processes based on genetic resources or linked traditional knowledge.

Short of having an international agreement establishing international norms for the protection of TK and improvements therein, ways and means of using existing intellectual property rights for benefit-sharing must be explored.

Surely, in cases where prior knowledge is documented and available, it can be cited to invalidate the patents as was done in the case of US Patent 5,401,504[11] over the use of turmeric in wound healing. In the present case, no knowledge was used but only a sample of wild rice was accessed prior to the CBD entering into force.

- A minimum benefit to be shared by UC Davis is to provide the gene and associated know-how to the Institute of Economic Research in Mali. At present, Chinese scientists are working with Prof. Pamela Ronald and transferring this gene into Chinese varieties. Why not do the same with Malian varieties with the help of Malian scientists? This gene is available free for non-commercial purposes to third world institutions and accordingly it is available to the scientists in Mali also. However, creating capacity among the Mali scientists to absorb this technology should have been one of the first follow up steps of this research.

- *The role of donor and funding agencies in benefit-sharing:* The Rockefeller Foundation did not respond to queries about their policy in this case. However, donor and funding agencies should have a policy on benefit-sharing arrangements in cases where intellectual property rights are acquired for research results attained through their investment. The management of UC Davis would hardly have ignored the benefit-sharing issues had there been some conditions or benchmarks from the Rockefeller Foundation.

- *Considering all stakeholders:* The conservation of wild rice from which the gene in question has been obtained can not be pursued effectively if benefits were to be channeled only to the communities from the region where this wild rice grows. The land-owning farmer community in Mali had no interest in the conservation of wild rice and the same applies to the government. For them *oryza longastaminata* is merely a weed and it must be banished. It is for the *Bela* people that this rice matters. They hold detailed ethnobotanical knowledge about this plant genetic resource, on which *in-situ* conservation of genetic resources depends. The literature and initiatives on benefit-sharing have ignored so far issues and concerns of this type of stakeholders.

- The merit of providing scholarships as a means of sharing benefits has been criticized in some recent publications on intellectual property rights and benefit-sharing.[12] The point was that in the areas in which this wild rice may be found and among those who are involved in its conservation (i.e., the *bela* community), there may not be anybody qualified to avail of PhD fellowships at UC Davis. If the fellowship were given just like that, then sons and daughters of elite scientists or bureaucrats may actually benefit – contrary to the intention of Dr. Pamela Ronald. Therefore, the choice of instruments for sharing benefit needs to be decided after much greater discussion with the communities who conserve both the knowledge system and the genetic resources.

- Sharing of research findings with the communities needs to be done in the local language.

1 Pamela C. Ronald, 1998, The Genetic Resources Recognition Fund, AgBiotech News and Information Vo.10, No.1; http://www.agbiotechnet.com/review/jan98/html/ronald.htm

2 Collection and exchange of germplasm following the adoption of the Convention on Biological Diversity (CBD) in 1992.

3 For an account of these debates, see e.g., Grunwald, R. and Vogel, F. *Patenting of Human Genes and Living Organisms*. Heidelberg: Springer, 1994.

4 The generation of resistance through expression of a gene is a complex process which requires considerable technological expertise. However, the possibility of viruses transferring such genes from crops to weeds is not unthinkable. It is a fear of this kind which has made some environmentalists quite suspicious about transgenic technologies. On the other hand, the damages due to pesticides are well known and unfortunately do not generate similar passions despite considerable adverse consequences for farm workers, particularly women and their children, and the environment.

5 Prof. Pamela Ronald, personal communication.

6 Kevin M Smith, personal communication, December 22, 1999

7 Kevin M Smith, personal communication, January 7, 2000

8 Gary Toenniessen, Director, Food Security, Rockefeller Foundation. Personal communication, February 29, 2000.

9 Gary Toenniessen, Director, Food Security, Rockefeller Foundation. Personal communication, March 3, 2000.

10 Anil K Gupta, 1997, 'Biopiracy' vis-à-vis Gene Fund: A novel experiment in benefit-sharing, Honey Bee 8(2), 16-17.

11 See, *Use of Turmeric in Wound Healing*, U.S. Patent No. 5,401,504, issued March 28, 1995

12 *Honeybee Newsletter* 8(2) 1997: p. 16-17.

Case Study Two: India

Value addition to local Kani tribal knowledge: patenting, licensing and benefit-sharing

Overview

The subject of this case study is the role of intellectual property rights in the benefit-sharing arrangements concerning the "Jeevani" drug, which was developed by scientists at the Tropical Botanic Garden and Research Institute (TBGRI), based on the tribal medicinal knowledge of the Kani tribe in Kerala, South India. "Jeevani" is a restorative, immuno-enhancing, anti-stress and anti-fatigue agent, based on the herbal medicinal plant *arogyapaacha*, used by the Kani tribals in their traditional medicine. Within the Kani tribe the customary rights to transfer and practice certain traditional medicinal knowledge are held by tribal healers, known as *Plathis*. The knowledge was divulged by three Kani tribal members to the Indian scientists who isolated 12 active compounds from *arogyapaacha*, developed the drug "Jevaani", and filed two patent applications on the drug (and another patent based on the same plant but for different use). The technology was then licensed to the Arya Vaidya Pharmacy, Ltd., an Indian pharmaceutical manufacturer pursuing the commercialization of Ayurvedic herbal formulations. A Trust Fund was established to share the benefits arising from the commercialization of the TK-based drug "Jevaani". The operations of the Fund with the involvement of all relevant stakeholders, as well as the sustainable harvesting of the *arogyapaacha* plant, have posed certain problems which offer lessons on the role of intellectual property rights in benefit-sharing over medicinal plant genetic resources and traditional medicinal knowledge.

Policy Context

A. CBD / UNCCD / TRIPS Agreement

The objectives of the Convention on Biological Diversity (CBD) include the conservation of biodiversity, its sustainable use, and the fair and equitable sharing of the benefits resulting from such use. The CBD recognizes that the authority to determine access to genetic resources rests with national governments and is subject to national legislation, but it is silent about the ownership or property rights of these resources. Article 15(4) of the CBD requires access to resources on mutually agreed terms. Article 15(5) of the CBD requires the prior informed consent of the Contracting Parties while accessing biodiversity. Article 8(j) provides that the knowledge, innovations and practices of indigenous and local communities relevant to biodiversity conservation and utilization should be respected, preserved and maintained. It further obliges Contracting Parties to promote the wider application of such traditional knowledge with the approval and involvement of the holders and to encourage the equitable sharing of the benefits arising from the utilization of the knowledge. Article 15(6), 15(7), 16, 19(1), and 19(2), advocate fair and equitable benefit-sharing arrangements between the providers and users of relevant resources. There are other international instruments which have a bearing on the options of Contracting Parties to explore economic opportunities through the sustainable extraction of, and value addition to, biological resources.[1]

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides, *inter alia*, minimum standards for the protection of patents in all fields of technology. This includes the field of biotechnology, where biotechnological inventions utilize biological and genetic resources in new, non-obvious and industrially applicable ways. Such inventions may be conceived with or without the use of traditional knowledge associated with the genetic resources.

Parties to the CBD are obliged to take legislative, administrative and policy measures with the aim to conserve biodiversity and also to ensure the fair and equitable sharing of benefits as per the provisions of the Convention. India, as a Party to the Convention, is obliged to pass legislation pursuant to the provisions of the Convention. Ordinarily, the legislation will provide a broad framework to guide access and benefit-sharing arrangements for biological and genetic resources. Instruments such as contracts and material transfer agreements would effectively determine the basis for regulation of these arrangements.

The implementation of the provisions of the Convention is riddled with problems. Most Contracting Parties, including India, have not yet arrived at a scientific basis for estimating the limits of sustainable extraction of various species in different ecosystems. In addition to the technological hurdles and those of equitable contractual agreements, one has to address social and ethical issues in accessing biodiversity using local knowledge and innovations. Several issues arise, such as:

- how to ensure that the stakeholders know the real value of their knowledge;
- how to ensure that their consent is truly an "informed" one;
- how could one maintain a balance in the flow of benefits to the local communities and individual herbalists without harming their traditional conservation ethic.[2] (Gupta, 1991)

The major actors in the formulation and implementation of these regulations are governments, non-governmental organizations, the private sector, as well as indigenous and local communities. These actors need to come together to develop acceptable norms for conserving biodiversity and the fair and equitable sharing of benefit arising out of the utilization of biological resources and associated TK.

B. Draft Indian Biological Diversity Bill, 2000 (Bill Number 93 of 2000)

Currently, India does not have a law governing access to genetic resources, except to a limited degree the genetic resources located in national parks and sanctuaries. However, a bill has recently been been tabled in the parliament. Since this bill constitutes an important part of the policy context in which this case of access and benefit-sharing over biological resources took place, salient features of the draft bill are given below:

1. Knowledge of local people related to biodiversity shall be respected and protected as recommended by the National Biodiversity Authority to the Central Government through measures which may include registration of such knowledge at local, state and national levels, and development of and adjustment in *sui generis* system for intellectual property protection of such knowledge (section 36-4).

2. Any person who is not a citizen of India, any body or corporate association or organization which is not registered in India, or which is registered in India but has non-Indian citizen participation in equity or management, is prohibited from obtaining any biological resource occurring in India and/or associated knowledge for research, commercial utilization, or bio-survey and bio-utilization without prior approval of the National Authority (section 3(1), (2), sec. 4). This prohibition will also apply to a citizen of India who stays abroad (section 2(b)) Collaborative research projects involving transfer / exchange of biological resources and information relating to them between institutions including government sponsored institutions of India and similarly placed institutions in other countries will be exempted from the provisions of sub-paragraph (i) and (ii) above.

3. It is also proposed to prohibit transfer of any result of research with respect to any biological resources by any citizen of India or any body or corporate association, organization registered in India, without the prior approval of the National Authority (section 4). This does not restrict publication or dissemination in a seminar or conference, if such a publication is as per the guidelines issued by central government.

4. National Authority shall ensure that the terms and conditions of approval secure equitable sharing of benefits arising out of the use of biological resources and knowledge relating to them. Such benefits may include joint-ownership of intellectual property rights, transfer of technology, location of R&D, association of Indian Scientists and local people with R&D and bio-survey and bio-utilization, location of production units, setting up of Venture Capital Funds, direct monetary compensation and other non-monetary benefits as may be appropriate for the entity from where it has been accessed (section 21(2)).

5. Any person intending to apply for any form of intellectual property right in or outside India for any invention based on any research or information on a biological resource occurring in India shall be required to obtain prior permission for such application of the National Authority in the prescribed form; while granting permission the National Authority may impose benefit-sharing fee or royalty or conditions on the financial benefits arising out of the commercial utilization of such right (section 6).

6. The national authority will ensure that the amount of nenefit sharing is deposited in the National Biodiversity Fund,"provided that where biological resources or knowledge was a result of access from specific individual or group of individuals or orgnaizations, the National Biodiversity Authority may direct that the amount shall be paid directly to such individuals or groups of individuals or organizations in accordance with the terms of any agreement and in such manner as it deems fit (section 21 (3)).

7. So far as biodiversity exploration by Indian citizens or corporations is concerned, they will have to give prior intimation to State Biodiversity Board in the prescribed form (section 24 (1)). State Biodiversity Board may, on receipt of such intimation, prohibit or restrict any such activity if it is of the opinion that such activity is detrimental or contrary to the objectives of conservation and sustainable use of biodiversity or equitable sharing of benefits arising out of such activity (section 24 (2).

8. National Biodiversity Authority may, on behalf of the central government, take measures to oppose intellectual property rights granted outside India on any biological resource or associated knowledge taken out of India (section 18 (4)).

It is apparent from the above review of the proposed Biodiversity bill that Indian nationals are not subject to similar constraints as international biodiversity-prospectors. In the case of joint or collaborative projects among state institutions, prior clearances will not be needed, even though international researchers may be involved. This is relevant to the present case. The Bill provides that no research outputs can be transferred to anyone outside the country without prior approval of the competent national authority. There are a whole range of incentive measures suggested (both monetary and non monetary) for meeting the expectations of genetic resource and/or knowledge providers. The most significant feature of proposed bill is that any one desirous of applying for protection of intellectual property will have to take prior permission of the national authority. How this would affect the strategic interests of the inventors remains to be seen. To what extent it will lead to equitable sharing of benefits has to be seen in the light of various other ways in which the same goal can be met. The experience described in this case will illuminate these issues further.

Traditional Knowledge and the Jeevani Drug

Exploration of Traditional Knowledge of Kani Tribe

The subject of this case study is the benefit-sharing arrangements concerning the Jeevani drug. 'Jeevani' is a herbal medicine developed by the scientists of the Tropical Botanic Garden and Research Institute (TBGRI) as a restorative, immuno-enhancing, anti-stress and anti-fatigue agent based on the knowledge of the Kani tribe. Jeevani acts on the human system in the following ways:

- activates the body's natural defenses
- activates delayed type hypersensitivity reactions and antibody synthesis
- increases the number of polymorphonuclear granulongtes
- activates the cellular immune system
- exhibits hepato-protective and cholorectic activities
- has adaptogenic properties as evidenced by anti-peptic ulcer and anti-fatigue effects.

Anuradha (1998)[3] has described in detail some of the key activities of this case along with the institutional context of value addition and benefit-sharing. The present case study draws upon the general history of the process through which the collaboration among various stakeholders emerged. It brings in the perspective of those members of the Kani tribe who benefited directly from the collaboration as well as those who may not have benefited so far, but are likely to do so in the future. It is important to add the perspective of the Forest Department under whose jurisdiction the Agastya forest lies, where the plant in question is found. We also look at the indigenous knowledge systems of the Kanis which provide clues to the long healing tradition of this tribe.

Major players:

- All India Coordinated Research project on Ethnobotany (AICRPE)
- Ministry of Environment and Forestry, Government of India (MOEF)
- Tropical Botanic Garden and Research Institute (TBGRI)
- Forest Department
- Arya Vaidya Pharmacy (Coimbatore) Ltd.

Minor players:

- Kerala Institute of Research Training and Development of Scheduled Caste and Scheduled Tribes (KIRTADS)
- Integrated Tribal Development Program (ITDP)

Key actors:

- Kani Tribals (Living within the forests as well as outside the forests)

The **Tropical Botanic Garden and Research Institute (TBGRI)** is a registered autonomous institution under the Travancore-Cochin Literary, Scientific and Charitable Societies Registration Act, 1955. Being the largest botanical garden in Asia, TBGRI plays an important role not just in the country but also at the international level as a member of the Botanical Garden Association. The garden is spread over 300 acres, having 50,000 accessions belonging to 12,000 genetic variants of 7000 tropical plant species. It aims at studying conservation and sustainable utilization of plant diversity in tropical India. The Chairman of its Governing Body is the Chief Minister of Kerala, the Secretary of this body is the Director, TBGRI, in addition to whom there are fourteen members. The Chairman of the Science, Technology and Environment Committee (EC), Government of Kerala chairs the Executive Committee of TBGRI. The Secretary of the EC is the Director, TBGRI, and the EC has four members. Both bodies have representation from other State Departments such as the Forest Department and the Planning Board.

The main objectives of TBGRI are:

- to carry out botanical, chemical and pharmacological research for the development of scientifically validated and standardized herbal drugs[4] and other industrially important chemicals and value added products for food, cosmetics, etc.
- to study and conserve tropical plant genetic resources and develop strategies for their sustainable use.
- to develop location-oriented production technologies that utilize local resources and human skills.
- to translate the fruits of research into socio-economic advantages.
- to conduct collaborative research programmes with similar institutions in India and abroad.

The **Kerala Institute of Research Training and Development of Scheduled Caste and Scheduled Tribes (KIRTADS)** is a research institute under the Government of Kerala which was set up under directions of the

Central Government. It was established with the purpose of promoting integrated development of research and training pertaining to Scheduled Castes and Scheduled Tribes in Kerala. KIRSTADS feels that the 'Kanis' should be encouraged to directly interact with wider society and administer their medical knowledge according to terms set forth by the Kanis themselves. KIRSTADS feels that the only way tribal medicine can survive is by preserving its original form and premises, otherwise it is liable to be misused as a convenient resource base for other systems of medicine. It feels that TBGRI should consider ways and means to impart technical know-how to the Kanis to manufacture the Jeevani drug and thereby involve them further in the process.

The **Integrated Tribal Development Programme (ITDP)** was initiated by the Directorate for Tribal Welfare, government of Kerala. A pilot phase for cultivation of the plant was initiated under it in some of the Kani settlements, in areas adjoining the reserved forest during the period 1994-1996. Fifty families were given Rupees 1000 each by ITDP to cultivate the plant. Under the scheme, TBGRI agreed to buy the leaves harvested by the families. These were then supplied to Arya Vaidya Pharmacy (AVP) for the plot phase production of Jeevani.

The **All India Coordinated Research Project on Ethnobiology (AICRPE)** is a project that was set up by the Union Ministry of Environment and Forestry in 1982 with headquarters at RRL Jammu to:

a) develop a better understanding of the life, culture, customs and traditional knowledge systems of tribals,
b) to develop sustainable development alternatives which are in sync with the values and ethos of tribals, and
c) to strengthen the linkages between tribal welfare and the management of the forests.

AICRPE has 27 centres all over the country and has so far documented information about 9500 medicinal plants, 3900 edible plants, 700 plants and other materials required for cultural functions, 525 fibre and cordage plants, 400 fodder plants, 300 pesticidal and pisicidal plants, 300 gum resin and dye plants, 100 incense and perfume plants, etc. Of the 1500 wild edible species, more than 300 could be identified as source of future foods (Saslin Salim[5], 1993).

TThe **Arya Vaidya Pharmacy (AVP)** is a Coimbatore based company pursuing the commercialization of Ayurvedic and herbal formulations in a highly value based manner, upholding high quality standards. TBGRI licensed the technology for a fee of Rupees10 lakhs to produce the drug for seven years in addition to two per cent of the sales as royalty. Arya Vaidya Pharmacy has been a manufacturer of Ayurvedic drugs since 1948.

Figure 1 – JEEVANI™ is a product of the Arya Vaida Pharmacy which is an Indian company.

Figure 2 – The Augustayar forest in the Western Ghats of Kerala, where Kani tribal members identified the arogyapaahez plants to a team of scientists from All Indian Coordinated Research Project on Ethnobiology (AICRPE).

The **Forest and Forestry Department**: The forests of the Augustayar Valley are thick and provide the home to a wide variety of plants, tree, shrubs, etc. The most important species include *terminalia peniculta, terminalia tomentosa, cario harboria, psidium guajava, colophyllum ilatum, arogyapaacha (trichapus zeylanicus), ficus glomerata, phoenix pusilla, michelia champaca, pongamia pinnata, tamarindus indica, madhuca indica* and *alstonia scholaris*.

Kani Tribals: relationship with biodiversity, culture and forest bureaucracy

The Augustayar Forest is designated as a reserved rain forest. It has several small streams running across the forest and draining into the Neyyar river. In such an area all acts not permitted by the Forest Office of the State Government are prohibited. The Forest Department periodically issues a list of minor forest produce which can be extracted by the tribals living in the forest. It is significant to note that in principle the Forest Department has agreed to include *arogyapaacha* (*trichopus zeylanicus travancoricus*) under the minor forest produce list, but formal orders have not been issued (declaration awaited at time of preparation of this case study).

The **Kani tribal people** live in the forests of the Thiruvananthapuram district of Kerala in south India. Their current population is estimated to be approximately 18,000. Their settlement system is such that a few families live in a cluster interspersed with the forest. The terrain is undulated. Every Kani has a small garden in front of his/her hut and has few plants of rubber and other palms besides some fruits and flowers around their hut. They do limited cultivation of tapioca, banana, millets and cash crops such as pepper, coconut, rubber, arecanut and cashewnut etc., in small plots of land given by the Forest Department. They derive most of their livelihood from crafts, and gathering and selling of various permitted forest produce. It may seem paradoxical that the original inhabitants of this area are dependent on the state for using the natural resources conserved by them for centuries. But the forests were nationalized and despite the recent constitutional amendment making tribal people the custodians of all minor forest species in their areas, the situation at ground level has not improved much. Also the much acclaimed decentralization to panchayat (the village councils) level in Kerala does not seem to have had any major effect on the lives and choices of tribals in the area studied.

The Kanis are reported traditionally to be a nomadic community but most of them are well settled now for a long time. Their economic condition is one of extreme impoverishment. Some of them do not even have a thatched hut. The huts of others were built by the Forest Department and Tribal Department years ago without taking the design and material preferences of the tribals adequately into account.[6]

Anuradha observes, that traditional structure of the community was that of a highly coordinated unit under the control of a tribal chief, called *Muttukani*. Traditionally, the *Muttukani* combined the roles of the law giver, protector and dispenser of justice, physician and priest. However, with time the traditional system of governance among the Kanis has been eroded to a large extent and the role of the tribal chief is only a token one. (Anuradha, 1999).[7] The role of the Forest Department in determining their choices is quite evident even to a casual visitor. There are some settlements on the other side of the Neyyar river on which there is also a Neyyar Dam. One has to go to these settlements by a boat from dam site or by road from the other side. The local social structures have become weaker in proportion to the increase in their dependence on forest department for their survival. The lack of any material goods worth their name in the huts of most Kanis shows that they have been bypassed by the developmental impulses of the last fifty years of the post-independence era. There are some who have better living standards either due to their proximity to outside forces or their social status with in the local communities. The Kani society is quite stratified and the general romanticised view of homogeneous community structure is not applicable.

Figure 3 – The Kani Tribe, which was traditionally a nomadic community, is now mostly settled under conditions of extreme impoverishment.

Figure 4 – The tribal physicians of the Kani, known as *Plathi*, are the exclusive holders of the traditional medicinal knowledge of the tribe.

Tribal physicians among the Kanis are known as '**Plathi**' – 'he who is a repository of tribal medical wisdom'. They cure ailments through their traditional healing art which includes administration of various drugs or some magico-religious cures like manthras and rituals. Much of the tribal medicinal knowledge among the Kani is dispensed by the Plathis. Plathis perform various rituals and chants from birth to death with the help of an instrument named *kokara*. Only they can use this musical instrument. After seven days of the death of a person, they perform the '*dodhi chant*' to purify the soul of the diseased person. There are more than twenty kinds of chants such as the *pini*, *deeva*, *twodi*, *karthikeya* chants, etc. In the Quilon district, the Kanis change the Plathi if he is found to be inefficient and the ceremony is known as *Nallu Vachu Nokal*. Depending upon the number of possible candidates for becoming *plathi*, they would judge a new person who is qualified to be a priest. Selected people are screened by this ritual to formalize the position of Plathi. Then there is a ceremony called *Pallaga yeduppa*. They ask the God who should be selected and the selected person has to be approved by God.

An existing Plathi trains the new person for about six months. In this chain of formalization of Plathi, the last ritual is *Kakar dupa*. After the training is over, the new Plathi is allowed to play the *Kokara* musical instrument. Once he gets this instrument he is considered to be qualified to be a Plathi. For seven weeks, once every week the rituals are practiced for the new Plathi to induct him in his new role. Before giving the musical instrument *Kokara* to the new Plathi, permission is taken from all those present one by one whether he should give the *Kokara* to the new person. The Plathis of nearby settlements are also invited on the occasion to offer sanctity. The newly selected Plathi performs the *Kadalpok* chant on the *Kokara* musical instrument. The induction process helps generate commitment among the Plathi towards their society. The new Plathi leads the chanting of songs and if he goes wrong, the old Plathi or Plathis from other settlements correct him. By the morning this chant is completed. And this process continues once a week for seven weeks and after it is done the new Plathi becomes properly established. Only after seven weeks he is considered fully recognized. The health tradition of the Kani tribes inhabiting the forests of the Western Ghat region of Kerala is quite rich. The herbal lore of this tribal community of a large number of wild plants found in the flora-rich forests of the Western Ghats holds a lot of potential for the future. Conservation of biodiversity and related knowledge systems thus has to be an important objective of any benefit-sharing system apart from the improvement of local livelihood support systems.

Intellectual Property Rights

The drug Jeevani, on which a national patent application was filed, was developed from the perennial plant *Arogyapaacha* (*trichopus zeylanicus*). This plant is a small rhizomatous, perennial herb distributed in Sri Lanka, Southern India and Malaysia. In Sri Lanka it grows in lowland sandy forests near streams. In the Malay Peninsula it is found in low-lying forests. In India it is found at an altitude of around 1000 meters. The sub-species found in India is called *trichopus zeylanicus travancoricus*. Within India the plant is endemic to the region of the Western Ghats that falls in the Thrivananthapuram district of the State of Kerala and the Tirunelveli district of the State of Tamil Nadu.

Discovery and development of the drug

It was in December 1987 that Dr. Pushpangadan[8] (then with the Regional Research Laboratory in Jammu) stumbled upon the herb while leading a team from the All India Coordinated Research Project on Ethnobiology (AICRPE). During an ethnobotanical expedition to the Western Ghats, Kani tribals who accompanied the team as guides, did not feel tired whereas the scientists were feeling fatigued. They observed that the Kani guides were continously munching black fruits of some plants. They offered a fruit to the exhausted scientists during the trip. "Upon eating the fruits, AICRPE team felt immediately charged and full of energy and vitality (Pushpangadan *et al.*, 1988).[9] The tribals were initially reluctant to reveal the identity of the fruit and pleaded that it was a time-honored tribal secret and a sacred one. After a great deal of persuasion the Kani led the AICRPE team to the *arogyapaacha*.

Figure 5 – Kani tribal member identifies components of the *arogyapaacha* plant.

The scientists pursued analysis of *arogyapaacha* through a variety of chemical and pharmacological tests. It was identified as *trichopus zeylanicus*. It is likely that only the species found in Agasthyar (*Trichopus zeylanicus travancoricus*) has the claimed medicinal properties though the plant is found in Malay peninsula and Sri Lanka as well. Detailed scientific investigations including chemical screening to isolate the active principles and pharmacological tests were carried out at the Regional Research Laboratory in Jammu by Dr. Avinash K. Sharma, C. L. Chopra and Pushpangadan.

The analytical approach included both allopathic as well as Ayurvedic tests. The drug was evaluated on the basis of the Ayurvedic *dravya guna* and *rasa shastra*. *Arogyapaacha* was found to belong to the Svathahita (health promoting) group of drugs.

The anti-stress and immuno-stimulating property of the plant were first discovered by the researchers in Dr Pushpangadan's team.[10] Later they also identified other properties such as tumour control, anti-fatigue, stamina boosting properties, etc. TBGRI conducted clinical trials of "Jeevani". In India "Jeevani" has been administered orally to 100 human subjects in studies involving either healthy or non-healthy individuals. Studies were focussed to determine the ability to withstand adverse conditions (increased work load exercises), quality of work under stress, athletic performance, increase in mental alertness and work output. Results of this open clinical trials were highly significant and "Jeevani" was found to exert favorable effects in a number of situations.[11]

The research program over the past 12 years has demonstrated that the importance of this medicinal plant alone or in association with other ingredients, as combined in the Jeevani drug, could be higher than that of Ginseng without any steroid being present in it.[12] Its potential was acknowledged in prestigious journals like *Nature*[13] and magazines like *Time*[14].

Recently, the drug has been featured on the cover page of top sports and fitness magazines[15] which claimed that, "having gone through successful clinical trials, Jeevani will soon be made available in the U.S. as an energizer, adaptogen and immune stimulator" (2000). It has also been included in Chinese/Japanese medicine such as "Shosaikoto" with considerable clinical effect.[16] One company in the United States of America has also registered a trademark of "Jeevani" for sale of the same drug in the USA.[17] There is another company which is soliciting plants and/or seeds of *arogyapaacha*.[18] This drug, based as it is on traditional knowledge of the Kani tribe, seems to have tremendous potential in global markets for natural health care products and sports medicines.

TBGRI isolated five compounds in all from *arogyapaacha*, but the detailed characterization of four compounds has been delayed due to the lack of adequate technology and equipment. TBGRI has been forced to send these compounds to Copenhagen for characterization, says Dr. Pushpangadan. For the one compound for which characterization was possible at TBGRI without delay, a patent application was filed.

The patent application for the Jeevani Drug

In 1996 TGRI filed a process patent application for a process of manufacture of a herbal sport medicine, based on the compounds isolated from *arogyapaacha*. The application describes the invention as "a novel, safe herbal sports medicine, having antifatigue, antistress and stamina boosting properties." The application contains two claims, relating to a process of preparation of a herbal drug from the plant *arogyapaacha* (*trichapus zeylanicus*) and three further plants in the form of granules or suspension. The application does not specifically mention the tribal knowledge of *arogyapaacha*, but it records that "the therapeutic effect of this plant has been established by detailed pharmacological studies. (Pushpangadan *et al.* (ed) Glimpses of Indian Ethnopharmacology, pp. 137-145, TBGRI Publication 1995)" and it specifies that "The physical appearance and characters of this plant matches well with the description of 'Varahi' described in Susrutha Samitha (Pushpangadan *et al.* Ancient Science of Life, 13-16, 1988)." With respect to the second plant used in the invention, *Wiuthania somnifera* or *ashwagandha*, the application mentions that "Ashwagandha is mentioned as an important drug in the ancient Ayurvedic literature."

International Cooperation for Research and Value Addition

A collaborative research project entitled "Ethnopharmacology of Indian Medicinal Plants" is carried out between the Tropical Botanic Garden and Research Institute, Trivandrum, and the Department of Medical Chemistry at the Royal Danish School of Pharmacy, Copenhagen, Denmark, sponsored by the Danish International Development Agency (DANIDA). The project is undertaken on a mutual understanding that

- all patents and patent rights developed under this project belong to the Indian partner.
- all scientific publications resulting from this collaboration are published as joint publications between the two institutes.

Under Phase I of the project, two scholars received training in Denmark on screening 70 medicinal plants of pan-tropical Asian distribution in antibacterial, antifungal, antimalarial and anti-hypertensive agents. This would strengthen the capacity of TBGRI in the area of natural product chemistry and additionally during this period the physiochemistry and ethnopharmacology laboratories were equipped with DANIDA assistance.

The second phase of the programme was originally planned to start from July 1997. However, owing to various reasons, especially due to a series of reviews conducted on the progress of Phase I and the review of programmes to be started in Phase II, the scope of the programme was further broadened. DANIDA has now agreed to extend this project for a further period of three years from 1999-2001, with a total financial outlay of 6.6 million DKK. Out of this an amount of 2 million DKK is kept apart for strengthening the spectroscopic and other instrumentation capabilities of TBGRI, which will be received as gift to TBGRI from DANIDA. The remaining amount is utilized for offering doctoral and post-doctoral training to TBGRI staff and mutual visits by other participating scientists from TBGRI and RDSP.

A protocol was designed for clinical trials of an anti-diabetic herbal drug formulated by the Institute. Acetone, alcohol and water extracts of 40 medicinal plants were prepared and studied for their anti-cancer activity. One of the plants showed DNA scission activity and detailed investigation is ongoing.

Mr. Pushpangadan pointed out that patent applications have already been filed for 12 drugs. A sports medicine is being developed and one of the 19 wild species of pepper which was found to have anticancer properties is under valuation. Another 150 species have been identified for valuation.

Similarly, collaboration with Singapore University helped TBGRI scientists to do research using the most advanced 'through-put-analysis,' which can screen a thousand plants in one day against the traditional method that takes six months to one year to study one plant.

Tissue Culture:
Before mass production of the compound drug is possible, *arogyapaacha* has to be cultivated on a large scale. The Institute has started tissue culture for the fast propagation of the plant which is slow in natural multiplication. However, it may not be most necessary to wait for tissue cultured plants for propagation since the tribals have been able to propagate it easily. There are reports that shoot tips of the plant can be used to culture this plant for rapid propagation.[19] The Forest Department has suggested in personal discussions that TBGRI should provide the technology of tissue culture to tribals so that they did not have to collect the plant from the wild. However, the propagation of this plant in moist and shady environment is quite easy and many Kanis tribals have actually already cultivated this plant.

Acquisition of Intellectual Property Rights

It was realised by the researchers led by Dr Pushpangadan that without intellectual property protection they would not be able to generate much revenue by licensing the drug they developed. Since the CBD is an instrument applicable to plant genetic resources and traditional knowledge, they tried to follow various articles of the CBD as faithfully as they could. In 1987, when the discovery was made, scientists took this exploration as a routine ethno-botanical investigation. Early work at RRL Jammu was thus aimed at publishing the findings and in some cases filing patent applications.

It was only after Dr. Pushpangadan moved to TBGRI that he got fully involved with value addition. The collaboration with DANIDA helped in developing breakthroughs quite fast with all the intellectual property rights remaining with TBGRI. The research team was actually a natural science team and they had no experience of dealing with complex socio-political and socio-economic problems. Dr Pushpangadan had to face lot of opposition and criticism for his attempt to share benefits. If he had done what all the ethnobotanist have been doing all these years, that is record and publish the local knowledge with or without value addition or patent and enjoy the benefits oneself, perhaps he would not have had to face any criticism. It is precisely because he did not take any share out of benefits for himself or his senior colleague Dr. Rajasekharan, and that he achieved extraordinary results in such a short time period through international research, that his motives became suspect to some.

Dr. Pushpangadan faced all of that opposition till he was appointed Director of the National Botanical Research Institute. He continues his interest in the matter and tries to persuade the Forest Department to let this experiment succeed. He also realizes that too much attention on himself and his colleagues by media around the world may have contributed to the indifferent attitude of some of the Forest Department officials. The officials of the Forest Department supported in principle the idea of benefit-sharing, but they had less appreciation for their limited role in design and implementation of benefit-sharing arrangement. They did not seem to mind that patents were obtained, even though KIRTADS was extremely critical of this step.

Two of the patent applications on Jeevani were for

a) a process of Preparation of novel immunoenhancing anti-fatigue, anti-stress and hepato-protective herbal drug, (Pushpangadan P., Rajasekhran S. and George V., 1996, Patent application number 959/MAS/96 dated June 4, 1996) and

b) a process for the preparation of a Glycolipid fraction from *Trichopus zelyanicus* possessing adpatogenic activity, (Butani, K. K., Gupta, D. K., Taggi B. S., Anand K. K., Kapil R. S., Pushpangadan P., and Rajsekhran S., 1994, Patent application number 88/Del/94).

In addition there were two more patent applications in which this plant was included. One was for diabetes (957/MAS/96, dated June 4, 1996) and the second a sport medicine (958/MAS/96 dated June 4, 1996).

It is important to note that while the Kani informants had used the plant fruits for vitality and energy, the scientists had made the preparation by using the leaves of the plant. But the fact that the plant was being used for the same purpose for which local people used it underlined the logic of benefit-sharing. After all if the local communities had not conserved the biodiversity, the probability of scientists making any selection at all will be remote or nil. In cases where local communities provide the lead and the use of the biological resource in the TK is identical to the use of the resource claimed in the patent application, the case stands for:

- sharing intellectual property, i.e. shared inventorship,
- shared licensing agreement, and
- common benefit-sharing.

Such a case has not arisen in many situations so far.[20] Several small but multiple institutional changes have to take place if such a philosophy has to be institutionalised.

The Patent (second Amendment) Bill 1999 aims to make many changes in the Indian Patent Act 1970. The definition of chemical process will include "biochemical, biotechnological or microbiological process", the duration of patent protection will be extended to 20 years as per the minimum standard provided by the TRIPS Agreement, the applicant will have to "disclose the source and geographical origin of the biological material in the specification, when used in an invention" [section 8 (D)], allow product patents (on subjects not otherwise prohibited in the act), reversal of burden of proof, etc.

The most important provisions relevant to the subject of this case study are found in Art. 17:

> "(j) that the complete specification does not disclose or wrongly mention the source or geographical origin of biological material used for the invention;
> (k) that the invention so far as claimed in any claim of the complete specification is anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in any country"

The above two provisions are two additional reasons on which opposition to any patent application can be pursued. These provisions have not yet been attempted in the patent acts of other countries to the best of the author's knowledge. It still does not fully ensure that the biological resources and traditional knowledge used by an inventor in a claimed invention have been obtained lawfully and rightfully.

Licensing and the exercise of Intellectual Property Rights

The governing body of TBGRI authorized the director of TBGRI to transfer the technology for manufacturing Jeevani to interested parties on payment of adequate license fee. Negotiations for the same were conducted by a committee constituted for this purpose headed by the Chairman of the Executive Committee of TBGRI, who is also the Chairman for the State Committee on Science, Technology and Environment, Government of Kerala. The Committee recommended transfer of the right to manufacture Jeevani to the Arya Vaidya Pharmacy (Coimbatore) Ltd. for a period of seven years for a license fee of Rupees Ten Lakhs. TBGRI was to also receive two percent royalty on any future drug sales. This was done as per the guidelines of Council of Scientific and Industrial Research.

TBGRI has stated that it was the best bargain that could be arrived at by their selection committee. They emphasize that the license period is only for the purpose of a promotional venture, and that once the drug is able to establish a market for itself within the license period of 7 years, the license fee could be suitably enhanced and that it could be licensed to another company if that is more beneficial.

The rules of the Council for Scientific and Industrial Research (CSIR) are specific that technology can be transferred to other parties, including private companies for a trial run, free of cost.

TBGRI has also entered into technology transfer agreements with the Madras-based Velvette International Pharma Products for the production of a herbal health care kit consisting of 14 drugs. The herbal preparations were developed according to WHO standards at the Ethnomedicine Division of the Institute. The kit contains 14 scientifically validated drugs in granule, tablet, powder, capsule, ointment and oil forms. It is designed to tackle all the common ailments afflicting a person including fever, headache, cold, cuts and wounds, diarrhea, dysentry, inflammation and burns.

Figure 7 – The *arogyapaacha* plant from which the Jevaani drug was developed and subsequently patented by the Indian research institute TBGRI.

The first tranche of Rupees 5 lakh and royalties of Rupees 19,000 of the benefit-sharing formula were deposited in the account of Kani Samudaya Kshema Trust at Kuttichal Union Bank. The first meeting of the Trust after the transfer was held at the Kallar Mattammodhu Kani tribal settlement on March 19, 1999. In the meeting it was decided to grant Rupees 50,000 as special incentive to Mallan Kani (Rupees 20,000), Kuthy Mathan Kani (Rupees 20,000) and Eachen Kani (Rupees 10,000) who passed on the information to the scientists.

The special secretary of the SC/ST Development at state level, Mr. Subbiah feels that the Trust should float a factory and begin production after the agreement with Arya Vaidya Pharmacy expires. This is to ensure that the tribal people retain the control of production and marketing. However, scientists at TBGRI are wary of the idea. They feel that tribals could gain more by licensing the rights to private producers though they are not averse to the idea of experimentation. They realise the need for local value addition so that higher share of value chain remains in local area.

A team of experts from a Japanese pharmaceutical firm visited the capital city and initiated negotiations with the government to purchase the DNA rights of the plants. They reportedly offered Rupees 10 crores for outright purchase. The government is understood to have rejected the offer. The fears about the possible patenting of *arogyapaacha* plant by foreign entities are quite strong in the mind of local officials and leaders. In addition, they want to ensure that their right to use this plant should never be compromised. This would require that a patent would be granted in India for the plant and it is not possible under Indian Patent Act 1970 as amended.

Benefit-sharing

Establishment of the Trust

In November 1997 with the assistance of TBGRI a trust was registered, named the **Kerala Kani Samudaya Kshema Trust**. The Trust has been registered with nine members, all of whom are Kani tribals. The president and vice-president of the Trust are the two Kanis who imparted the traditional knowledge to TBGRI regarding *arogyapaacha*. The decision to form the Trust was taken in a local meeting of around 40 Kanis. The Trust deed states the objectives of the Trust to be:

- welfare and development activities for Kanis in Kerala,
- preparation of a biodiversity register to document the knowledge base of the Kanis,
- evolving and supporting methods to promote sustainable use and conservation of biological resources.

The aim of the Trust is to have all adult Kanis in Kerala as its members. Kanis in the *vithura* and *permigamala* panchayat areas are opposed to this Trust. Members of the Trust are of the view that once the Trust becomes functional they would be able to organize the Kanis better. Awareness about the Trust is very low and even those who are aware, are often sceptical about its effectiveness. There has been some criticism of the Trust and the mode of sharing benefits.

Figure 8 – Kani tribal members should benefit from the Kerala Kani Samudaya Kshema Trust, which was established to share royalties from the patent on the Jeevaani drug.

Figure 9 – Sustainable extraction of the *arogyapaacha* plant in the Augustayar forest has been of concern to the Forest Department.

John and Sindhu (1998)[21] highlighted the grievance of several Kanis about their lack of awareness about the Trust, new medicine developed, and the future program of development. The Director of KIRTADS complained that intellctual property rights were not being sought by local tribals and instead rights were being granted to private entities. There was a suggestion about enacting new laws which would grant intellectual property protection to Indigenous peoples like the Kanis instead of only to the formal scientists or outsiders. Suman Sahay, Coordinator, Gene Campaign, felt that TBGRI, by taking out a patent for Jeevani, has "effectively challenged the principle of the Common Heritage of Mankind, which considers all genetic resources the property of everybody, with no particular ownership." Many of these observers have overlooked that the patent applications by TBGRI were only for the process of making drugs, because Indian patent law did not permit product patents until now. Thus nobody's right was affected adversely by the patent applications in any real sense, because what was in the public domain will remain so before and after such patents have been granted. The formulation that TBGRI had developed was sought to be protected. But as is well known, the Indian patent office takes a long time to issue patents. Applications made in 1996 are yet to be processed.

Earlier Dr. Pushpangadan had proposed to route the funds through the Tribal Department of State Government. He contacted the author of the present case study, Prof. Gupta, and was persuaded to set up a Trust Fund rather than route the funds through a State Government body. This was supposed to provide greater flexibility and control to the Kanis. It is true that the process of trust formation could have been more participative within the settlements from which Kanis were included. TBGRI did take the help of some regional NGOs in creating trust and generating awareness, but it was not adequate. However, the fact that Kanis could dare to protest against Forest Department when they were not being given the right of collecting leaves of *arogyapaacha*, shows that capacity was built among them to participate actively and consciously in the decision making processes which affect their TK.

The Trust is currently working out a scheme to utilize the funds. A tentative project is to set up a Telephone booth which will be the first one in the Kottor area bordering the forest belt. An insurance scheme for pregnant women and another to cover accidental deaths is also being worked out.

Sustainable Extraction

During the harvest of leaves, some people uprooted the whole plant from their gardens and some others took the wild herb from the forest. This alerted the Forest Department against possible large scale "smuggling" of the herb. Scientists at TBGRI also feel that this should not be done since sustainable collection of the leaves of the plant is possible. They emphasize that only the leaves of the plant are required for the production of Jeevani. In a widely reported operation in 1996, 10,500 plants of *arogyapaacha* were confiscated, which had been collected for a private nursery at the Vithura village in Thuruvananthapuram.

The Arya Vaidya Pharmacy is disappointed that despite there being a good market for the Jeevani drug, there is no raw material to manufacture it. AVP had written to the Kerala Forest Department and the Tribal Welfare Department proposing a plan for the cultivation of *arogyapaacha*, whereby it would pay the Kanis an initial seed money for the cultivation of the plant and enter into a buy-back arrangement with the Kanis to buy the leaves harvested from the cultivated plants. It is prepared to buy five tonnes of leaves a month. However, the Forest Department rejected AVP's proposal explaining that the collection could not be permitted because it concerned an endemic plant. AVP is willing to cooperate with the State Government in arriving at a mutually beneficial and sustainable mechanism for harvesting the plant.

The Forest Department has been quite concerned about sustainable extraction and thus had not allowed this plant to be commercially exploited so far. Unless they include this plant in the list of minor forest produce, it will not be allowed to be sold.

Discussions with the Forest Department in November, 1999, suggested that TBGRI should agree that any drug which it develops from forest-based plants should be licensed for commercial use only under three conditions:

a. all the four parties, i.e., TBGRI, the Forestry Department, the local community institutions, and the licensees should be involved in the discussion.
b. A sustainable extraction plan should be submitted by the licensee to ensure that commercial utilization does not pose any threat to the ecosystem or long term sustainability of the species.
c. Research programmes on such plants should be reviewed by TBGRI and the Forest Department from time to time so that if any endemic, endangered plant provides a lead for a valuable medicine then, unless technologies are developed for *ex-situ* cultivation through tissue culture, such a technology will not be commercialized and licensed lest the plant becomes extinct.

Lessons Learned

The need for multi-stakeholder frameworks for discussing the scope of access, value addition and benefit-sharing was brought to light by this case study. If the Forest Department has jurisdiction over a territory, then the Department must be included in the stakeholder discussions while establishing benefit-sharing mechanisms.

Further, the rights of informants and that of the community need to be distinguished in the benefit-sharing arrangements. The informants were the first to receive payment from the amount deposited in the community trust. Actually they should have been paid from the resources that scientists and research institution (in this case, TBGRI) received. By not doing so, an avoidable impression was created among the Kani tribals that the trust was supposed to benefit only a few community members. The real intention of the scientists was to help the community to manage resources through their own volition and institutions. To that extent, this model of a Trust Fund was more democratic and accountable to the local community than was the Trust Fund developed in the Nigerian BDCP case. Comparison between the two cases shows that one needs to experiment with different models in different cultural, ecological and institutional contexts.

It is important to note that the Trust Fund came into existence only because patent applications were filed for the value-added processes developed from local knowledge and licensed to a commercial entrepreneur. The fact that scientists did not claim any share from the license fee goes to prove that their values and motivations, as reflected in the benefit-sharing arrangements, were focused on equity and the fair sharing of benefits.[22]

- The patent applications filed on drugs based on *arogyapaacha* were all national process patent applications, none had been granted, and yet licensing of the technology had already yielded a very good amount, fifty percent of which was shared with the community. This is an important indicator of the potential which the effective use of intellectual property rights might have to generate benefits which can be shared with the communities. As this case illustrates, the use of intellectual property rights can in some cases help to generate benefits, even before exclusive rights over the TK-based invention are granted.

- The scope of benefits to be shared could have been much wider if:
  - international patent applications had been filed under the Patent Cooperation Treaty administered by WIPO, to protect the formulation in countries other than India;
  - product patents were available in India for pharmaceutical products, not only process patents, and
  - trademarks had been registered to protect the distinctive signs distinguishing this product from those of other undertakings.

  At the same time, these intellectual property rights would not have restricted the rights of local communities.

- The case highlights the possibility of third party Trademark protection as done by NutriScience Innovations, LLC, USA which owns Jeevani Trademark in the United States of America.[23] This in turn would have generated a much higher share of funds to be shared with the Kani tribe and also to fund future research. The exposure this drug is getting internationally demonstrates the potential that lies ahead.

- The case illustrates that while intellectual property rights play a crucial role in generating benefits from biological resources and traditional knowledge, which can become subject to benefit-sharing, their role should be balanced with the conservation objective:

The increase in demand could have led to excessive extraction of the biological resource,

- if adequate awareness was not raised among all stakeholders,
- if local institutions of sustainable extraction were not supported or created, and
- property rights of individual experts and communities in the biodiversity and associated knowledge were not negotiated and defined at local level legitimised through state and national policy instruments.

Such a possibility did arise in the early stages of the case when many people started buying this plant at the rate of Rs 100 per kilogram. The Forest department had to impose restrictions when they confiscated illegally collected leaves and whole plants. The offer of the Arya Vaidya Pharmacy of giving a buy back guarantee to the Kanis along with the technology to cultivate and extract leaves in a sustainable manner was one answer to this problem.

The effective protection of intellectual property is a necessary condition for generating benefits, which will be subject to benefit-sharing, but it is not a sufficient condition. Several additional measures are needed to supplement the role of intellectual property rights in benefit-sharing over biological resources and traditional knowledge.

- The objective of the Kani Samudaya Kshema Trust to establish a biodiversity register to document the knowledge base of the Kanis must be pursued with the intellectual property implications of such a register in mind. Intellectual property questions to be resolved for the creation of such a register include who operates the register, who provides access to its contents to which parties on which terms, who conducts documentation of the knowledge, who has the right to authorize documentation on behalf of the tribes, which knowledge elements will be documented in which format, how to deal with local language documentation in relation to national and international use of the register, etc.

- The degree of involvement of various tribal settlements and groups could have been increased. The rights of informants vis-à-vis the communities requires more discussion among the communities themselves.

- The non-material contribution of benefits by way of empowerment of local communities deserves to be noted, but several more such benefits could have been considered. For instance health check-ups for the local communities were urgently needed given the very poor condition of many women, children and also some male adults.

- The role of the *Plathis* as an informal association of healers which hold rights to the use of certain traditional medicinal knowledge was not recognized by the benefit-sharing arrangements in this case. Building on existing and accepted institutions of traditional knowledge holders can be an important tool to structure their participation and ensure the acceptance of the communities for benefit-sharing arrangements.

- The Forest Department had not permitted the cultivation and collection of the *arogyapaacha* plant. This was so in spite of the fact that the plant could be easily cultivated and many tribals had actually done so. Discussions with the tribals on the subject elicited a sympathetic response. If the Forest Department had been involved from the beginning in this value chain, perhaps their attitude might have been different.

- The tribal informants were not named as co-inventors in the patent application. This option should be explored as a practical intellectual property-based benefit-sharing mechanism between TK holders and the formal research and development institutions.

1 Article 16(g) of International Convention on Combating Desertification also echoes similar concerns for dry region when it provides for exchange of information on local and traditional knowledge, "ensuring adequate protection for it and providing adequate benefit from it, to the local population concerned". See, United Nations Convention to Combat Desertification (1996).

2 The assumption is, that flow of material benefits to local conservators – communities or individuals – may impair their values and weaken their conservation ethic. Obviously, it is also assumed that our values can remain intact despite the accumulation of wealth.

3 Anuradha, R V, 1998, Sharing With Kanis: A case study from Kerala, India, New Delhi: Kalpvriksha Mimeo

4 Conforming to WHO standards, 1991.

5 Salim Saslin, 1993, "Challenging Ginseng: Arogyappacha, The health food of the 21st century," *The Week*. August 29, 1993

6 *Report of the All India Coordinated Project on Ethnobiology* – Undated.

7 Anuradha, R. V., 1998, "Sharing With Kanis: A case study from Kerala." India, New Delhi: Kalpvriksha Mimeo, 1998, and personal field work.

8 Dr. P. Pushpangadan, was the Chief Coordinator of AICRPE at that time.

9 Pushpangadan P., Rajasekhran S., Ratheesh Kumar P. K., Jawahar C. R., Velayudhan Nair V., Lakshmi N., and Sarad Amma L., 1988, "Arogyapacha (*Trichopus Zeylanicus* Gaertn.). The Ginseng of Kani Tribes of Agasthyar Hills (Kerala) for Eevergreen Health and Vitality." *Ancient Sciences of Life*, 7 1988: 13-16.

10 Pushpangadan P., Rajasekaran S., Latha P. G., Evans D. A. and Valsa Raj R., 1994, "Further Studies on the phramacology of *Trichopus zeylanicus*." *Ancient Sciences of Life*, Vol. 14xiv(3) 1995: 127-135.

11 Dr. P. Pushpangadan, Personal Communication, 1999.

12 Subramoniam A., Madhavachandran V., Rajasekharan S., Pushpangadan P., "Aphrodisiac property of Trichopus zeylanicus extract in male mice." *Journal of Ethnopharmacology*, Vol. 57(1). Issue: June 1997: 21-27. Subramoniam A., Evans D.A., Valsaraj R., Rajasekharan S., Pushpangadan P., "Inhibition of antigen-induced degranulation of sensitized mast cells by *Trichopus zeylanicus* in mice and rats." *Journal of Ethnopharmacology*, Vol. 68(1-3). Issue: December 15, 1999: 137-143.

13 Jayaraman K. S., "Indian Ginseng brings royalties for tribe." *Nature*, 381, May 16, 1996.

14 Meenakshi Ganguli, 1998, "Descendants of "God's Physician" Share Their Secrets." *Time*. Nov 9, 1998. Reprinted in Japanese languauge version, No 38, February, 1999.

15 "Jeevani: The Anti-Stress/Pro-Energy Botanical Complex", *Natural Bodybuilding and Fitness*. New York, February, 2000.

16 Amagaya S., and Ogihara Y.: *Journal of Ethnopharmacology*. 1990:28; 1990:357; and also see Hiai S. in: *Adv. Chin. Med. Mat. Res.* (year unknown), cited in Hildebert Wagner, Hildebert, 1996. "Drugs with Adaptogenic Effects for strengthening the powers of resistance," 1996, available at <http://www.healthy.net/othersites/hobbs/index.htm> or <hwinfo@healthy.net>

17 See, <http://www.nutriscienceusa.com/productinfo22.htm>, sales staff, personal communication, April 24, 2000.

18 See, <http://florawww.eeb.uconn.edu/invmenus/wishlist.html>.

19 Krishnan P.N., Sudha C.G., and Seeni S., 1995, "Rapid propagation through shoot tip culture of *Trichopus zeylanicus* Gaertn., a rare ethnomedicinal plant." *Plant-Cell-Reports*, 1995, 14(11): P 708.AB 50140708.299.

20 In the case of SRISTI and GIAN (Gujarat Grassroots Innovation Augmentation Network), the patent applicationss have been filed only in the name of the local innovators. Though the inventors have assigned the patent to SRISTI to safeguard their interest, the entire licensing fees money haves been paid to the innovator with GIAN or SRISTI not keeping any share or brokerage at all. This is so decision was taken despite the fact that they have contributed to added value addition and SRISTI has provided initial venture risk capital also. But the implication of this generosity is that SRISTI will have to remain dependent on grant giving institutions for its functioning. Some body has to pay for reducing the transaction costs (both *ex ante* as well as *ex poste*) of linking what we call as Golden Triangle for

Rewarding Creativity by linking innovations, investment and enterprise (which has been called the Golden Triangle for Rewarding Creativity; Gupta, 1996, 1998, SRISTI and GIAN 1997). Thus it is desirable that various mediating institutions charge for their services or contribution in a reasonable manner so that they do not remain dependent on out side stakeholders or funders or even on the state. Whether the benefits should have been shared in fifty-fifty ratio as was done in the present case by TBGRI, or any other ration will depend upon the case specific circumstances of the case. The Past experiences suggest that benefits should not be shared only in the form of money or other material contributions but should also include other inputs such as non-monetary contributions through capacity building, awareness creation, education, removal of informational asymmetries, sharing of research findings, acknowledgement of knowledge providers on product packages as was suggested in the Nigerian case.

21 John J. and Sindhu Menon, 1998, "Kerala Tribe Accuses Indian Biologists of Stealing Knowledge." *PANOS-Biopiracy* IOPIRACY/1, London, August 4, 1998, London.

22 In personal discussions the Director of TBGRI appreciated that it was good that both the senior scientists involved in development of Jeevani did not take any share from institutional royalties, in order to set an example and prove that they had only foremost the public interest in mind while doing all that they did making the benefit-sharing arrangements. But he also felt that several other scientists would rather wish that they got some share out of license fees and royalties. The norms in this regard are yet to be developed.

23 NutriScience Innovations LLC, personal communication by email, April 24, 2000 on enquiry as to whether they owned the "Jeevani" trademark or had taken it on license from AVP Ltd.

Case Study Three: Nigeria

Overview

The subject of this case study is the role of intellectual property rights in the benefit-sharing arrangements surrounding the work of the Bio-resources Development and Conservation Programme (BDCP) as a part of the International Cooperative Biodiversity Group (ICBG) in the field of traditional medicine. In particular the role of patents, trade secrets and trademarks are discussed. The case examines, *inter alia*, a national patent and an 'international' patent application under the Patent Cooperation Treaty (PCT), with claims over TK-based pharmaceutical inventions related to the work of the ICBG. Copies of these patents are attached in Annexes 3.4.3 and 3.4.4. Based on these examples, the availability of patent protection is identified as a key requisite for generating benefits to be shared with local practitioners of traditional medicine from pharmaceutical research based on their knowledge. The central role of a Trust Fund established by BDCP for sharing these benefits in monetary and non-monetary form is highlighted. The case study also illustrates the difficulty of balancing the input of various local stakeholders of TK and biological resources, such as traditional healers' associations vis-à-vis local community representatives.

Policy context

After the recent ushering in of democratic processes, Nigeria is strengthening its economy, civil society, and intellectual institutions. With a population of over 120 million people, 250 ethnic groups with different languages and sometimes different cultures, with a majority living in rural areas (Nnadozie, 1989), the role of agricultural and biological resources is extremely important for current subsistence and future income growth. In Nigeria there has been a long tradition of bio-trade as well as bio-prospecting for research and commercial purposes. Two of the major efforts among this spectrum of activities have been undertaken by the National Institute for Pharmaceutical Research and Development (NIPRD) and the Bio-resources Development and Conservation Programme (BDCP), independently as well as under the auspices of the International Cooperative Biodiversity Group (ICPG), which is funded by the National Institute of Health, the National Science Foundation, the National Cancer Institute and US Aid for International Development (USAID). In addition, private sector companies such as Shaman Pharmaceuticals, Inc. have also been active in the country.

The complexity of the legal and administrative system in Nigeria is that of a federal structure where each state may legislate in certain areas while the Federal Government may legislate in other areas. In certain cases this structure poses challenges in the context of access to biological resources and associated knowledge systems. Nnadozie (1999) describes this complexity by showing that the laws dealing with patents, trademarks, industrial designs, merchandise marks, etc., are under the exclusive jurisdiction of the Federal Government, whereas land, forestry and forest resources are subject to State Law. So far as Federal reserves and national parks are concerned, forest resources therein are covered by the Federal government. He points out that the Federal authority is appreciative of the limits of its jurisdiction in the context of forest resources. Nnadozie illustrates this point by the "draft National Park (Amendment) Decree which seeks to incorporate the provisions of Article 15 of the CBD with respect to access [and] restricts its application only to National Parks and Federal reserves" (op. cit., 1999). Ajai (1996, 1997) describes the efforts which environmental lawyers have made to influence public policy on the subject. He illustrates these efforts by referring to Section 36(1) of the National Parks Decree (Decree No. 46, May 26, 1999) that prohibits any person from prospecting for genetic material from national parks without the written prior informed consent of the minister. Section 36(2) of the Decree deals with issues of prior informed consent, indigenous and community rights, and benefit-sharing, and these provisions are not restricted to the National Parks only.

The customary laws lie within the power of state governments, which can also establish customary codes. Part 4, 23 (1) of the Forestry Law [LSLN 16 of 1972. 1988.No.(5)] states that "the protection, control and management of a local government council protected forest shall be undertaken by the local government council constituting it or within whose jurisdiction it is situated, subject to the supervision and control of the state commissioner, exercised with the advice of Director-General." Further, the law states (Part 5, 24) that "any local government council at the request of any native community within the area of its jurisdiction may, with the approval of the state commissioner, declare any area occupied by such native community, a communal forestry area". Part 5, 26 states that "a communal forestry area shall be managed and controlled by the native community acting on the advice of the local government council and the forestry officer". The law empowers the government's council to make rules prescribing duties for the native communities, prohibiting or regulating the collection of forest products of any kind, their sale or modification, etc. In effect, therefore, the forest department determines broadly the framework of access and utilization of a wide spectrum of biological and genetic resources in the forest areas. The historical rights of local communities and their biodiversity-related knowledge systems have been eroded or disturbed where extensive tracts of forest lands have been granted for large scale farming (Nnadozie, 1999).

Intellectual property

Intellectual Property Act of Nigeria of 1971

The intellectual property acts of Nigeria, viz. The Patents and Designs Act of 1970, the Merchandise Marks Act of 1958, and the Trade Marks Act of 1965, and the National Office of Industrial Property Decree no 70, 1979, do not contain any specific provisions relating to traditional knowledge or community knowledge. The Patents and Designs Act of 1970 and the National Office of Industrial Property Decree no 70, 1979 do provide for the availability of process as well as product patents, with a term of protection of twenty years from the filing date. Patents cannot be obtained in respect of plant or animal varieties, or essentially biological processes for the production of plants or animals (other than microbiological processes and their products) or for inventions, the exploitation of which would be contrary to public order or morality. Further industrial property rights that are

available include those of the protection of trade secrets and trademarks. The National Agricultural Seeds Decree (1982) provides for maintaining registers of persons and/or corporations which are pursuing research on crop varieties leading to the registered release of the same for commercial production. Such registered persons or bodies can import, subject to the provisions of national phytosanitary regulations, crop varieties and/or biological materials duty free for commercial release. The Decree does not have any specific provision for landraces or farmers' varieties. The National Crop Varieties and Livestock Breeds Registration Act (1987) provides for the registration, naming, and release of old and new crop varieties or livestock breeds which meet the distinctiveness, uniformity and stability requirements. It also does not provide any specific mechanism for the protection of farmers' varieties or landraces, though it does require maintenance of a National Register for all crop varieties and livestock breeds and it requires monitoring the effects of exotic plants and animals on them. Nnadozie (1989) describes the implications of the amended Federal Environment Protection Agency Decree No.58 of 1988 which confers the Federal Environmental Protection Agency with the overall responsibility for the conservation of the environment and biodiversity and the sustainable utilization of Nigeria's natural resources. The Agency is developing the country's Biodiversity Action Plan.

African Union's Model Legislation for the Recognition and Protection of the Rights of Local Communities, Farmers, Breeders, and for the Regulation of Access to Biological Resources

The African Union (AU) has recently drafted "Model Legislation for the Recognition and Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources," based on a Decision by the Ministerial Council of the AU (Addis Ababa, March 20-23, 1998). It provides, among other things, a direction for implementing Article 15 and Article 8(j) of the CBD. Under Article 5, the Model Legislation requires prior informed consent of not just the State, but also that of the local communities which would be granting access to biological resources. Under Article 6, it provides for a Public Registry, so that any person may consult and comment on the application for access to specific biological resources or knowledge about them. Under Article 8, the Model Legislation requires "guarantee to deposit duplicates of each specimen of the biological resource, or the records of community innovation, practice, knowledge or technology collected with the duly designated governmental agencies and, if so required, with local community organizations". It requires that the national competent authority and the concerned community be informed of all the findings that result from research and development of the resource.

As far as intellectual property rights are concerned, the Model Legislation requires a commitment to be undertaken by the collector of resources to:

> *not apply for a patent over the biological resource or its derivatives and not to apply for a patent or any other intellectual property rights protection system over community innovation, practice, knowledge or technology without the consent of the original providers; compensate the state and/or concerned local community or communities for their contribution in the generation and conservation of the biological resource, and the maintenance of the innovation, practice, knowledge or technology to which access is sought; submit to the National Competent Authority a regular status report of research and development on the resource concerned and where the biological resource is to be collected in large quantities on the ecological state of the area; and abide by the relevant laws of the country particularly those regarding sanitary control, bio-safety and the protection of the environment as well as by the cultural practices, traditional values and customs of the local communities.*

Under Articles 21 through 24, the AU model law provides that:

> *Local communities shall have the right to withdraw consent or place restrictions on the activities relating to access where such activities are likely to be detrimental to their socio-economic life, or their natural or cultural heritage.*
>
> *(1) Local communities shall exercise their inalienable right to access, use, exchange or share their biological resources in sustaining their livelihood systems as regulated by their customary practices and laws.*
>
> *(2) No legal barriers shall be placed on the traditional exchange system of the local communities in the exercise of their rights as provided for in paragraph (1) above and in other rights that may be provided by the customary practices and laws of the concerned local communities.*
>
> *23. (1) The state shall ensure that at least fifty per cent of benefits obtained from the commercial use of a biological resource and/or community innovation, practice, knowledge or technology are channeled to the concerned local community or communities.*
>
> *(2) The state and collector shall enter into a written contract that ensures the benefits referred to in paragraph (1) above are to be derived on behalf of the local community or communities concerned.*
>
> *(3) Any written contract referred to above shall be entered into by the state and the collector, with the full participation and approval of the concerned local community or communities.*
>
> *24. (1) The Community Intellectual Rights of the local communities shall be recognized at all times, and shall be further protected under the mechanism established by this legislation.*
>
> *(2) An item of community innovation, practice, knowledge or technology, or a particular use of a biological or any other natural resource shall be identified, interpreted and ascertained by the local concerned communities themselves under their customary practice and law, whether such law is written or not.*
>
> *(3) Non-registration of any community innovation, practice, knowledge or technology is not to mean that these are not protected by Community Intellectual Rights.*

The AU Model Legislation further suggests an institutional arrangement providing for the development of a system of *registration* of items protected by community intellectual rights and farmers' rights according to their customary practices and law (Article 29.6). Other provisions pertain to the development of a national information system (Article 36.1-3) to compile and document information on local knowledge and innovation practices of the community and their access to biological resources. The Model Legislation further provides for maintaining an up-to-date information system about the research and development on these resources and the knowledge about them. The cost of setting up new systems afresh is very high and each country need not develop its own system. Existing IP information systems, such as JOPAL, ESPACENET, WIPONET, etc., could provide efficient vehicles for such an information system, if properly utilized and evolved by all stakeholders. The accessibility of international intellectual property information systems to local communities and small inventors and innovators at low cost, in local language and with sufficient ease will remain an important issue to be resolved. Many European countries and the United States of America have already made their patent databases for the last 20 or more years available to the general public on the Internet. The Model Legislation also provides for tracking biopiracy cases and disseminating information about the same to all the concerned bodies. The Model Legislation further provides for a Community Gene Fund, "for the benefit of farming communities whose farmer varieties have been the basis for breeding of the breeders' variety". A royalty fixed

by the National Competent Authority out of the protected seeds shall be credited to this Fund. The Fund will be used to finance projects developed by the local communities with or without the participation of external experts. It is worth noting that the Model Legislation makes a specific recommendation *not* to meet salaries and administrative expenses relating to the establishment and administration of the Community Gene Fund from the Fund so that the entire proceeds go to the communities. So far no African (or other) country have enacted laws which make such provisions. The Indian Plant Variety and Farmers' Right Bill as well as the Biodiversity Bill (referred to in Case Study 2) do include provisions of this kind.

Prof. C. O. N. Wambebe, Director General of the National Institute for Pharmaceutical Research and Development (NIPRD) at Abuja, Nigeria, provided the agreement which NIPRD enters into with the herbalist whose knowledge they use to develop drugs (see Annex 3.4.2). The agreement provides a very clear and comprehensive framework for obtaining the informed consent of the local herbalist for using his or her knowledge to develop commercial products. The NIPRD is obliged to inform the herbalists if the information provided by the herbalists already exists within the Institute or has been provided by other experts. The Institute is also obliged to furnish to the herbalist in writing, the results of every scientific test or analysis carried out on the material received from the herbalist.

Regarding intellectual property rights, Article 8 of the agreement states that:

> *The INSTITUTE shall apply for and obtain or cause to be granted and obtained the letters of patent on the products IN THE NAME OF THE INSTITUTE after the same has been developed and processed PROVIDED THAT THE CONSULTANT HERBALIST'S NAME BE INCLUDED IN THE PATENT subject to the conditions hereinafter set forth.*

Such a use of patents for the direct sharing of benefits arising from the use of biological resources and associated knowledge has not been found in any other public or private sector institutions as yet. The registration of trademarks and/or designs in any product supplied by the herbalist to the Institute are supposed to vest with the Institute from the date of delivery of the product by the consultant herbalist. However,

> *the discovery of the herbal products by the consultant herbalists shall be acknowledged as such in the correspondence and literature, publications of the product as much as practicable.*

The Institute would provide to the herbalists at least ten per cent of the net profit as royalty. In the case of the Bio-resources Development and Conservation Programme (BDCP), such explicit agreements have not yet been developed, although in spirit they have tried to follow these concepts and have been pleading for reciprocity and accountability in such transactions for almost twenty years.

Indigenous Traditional Knowledge and Biodiversity Conservation

The creator of the Bio-resources Development and Conservation Programme (BDCP), Dr. Maurice Iwu, has pioneered benefit-sharing arrangements and pursued the subject of traditional medicine with great rigor. In an early study on traditional Igbo medicine (Report of a project sponsored by the Institute of African Studies, University of Nigeria, Nsukka (1978), Iwu describes the philosophical as well as empirical context of an investigation involving approximately 600 medicinal plants. Some of the problems encountered during the study include:

- about half of the 600 plants were collected in fragments that could not be used by the taxonomists for identifying the identity of the genetic resource;
- compatibility between names in different dialects for similar or identical Igbo plants was difficult to achieve;
- there were conflicts between the same or similar names being used for different plants (a problem common to many other parts of the world);
- in a few cases, the language of the central Igbo region, i.e., *orlu – okigwe*, was used;
- differing therapeutic claims about the same use of the same plants from different locations posed contradictions in these claims;
- differing therapeutic claims about similar uses of the same plants in the context of different healing rituals posed complications to the claims;
- the multiple interpretations of different diseases posed another dilemma for the researcher. For instance, '*ogwu afo osisa*' could mean the treatment of diarrhoea for some healers or the treatment of constipation for others. Since it is not uncommon for a drug to have one activity at lower dose and the totally opposite effect at higher doses, the role of food in the healing process was considered counter-intuitive by the researcher.

Such problems of translation between different knowledge systems become complicated when some influential traditional beliefs seem incompatible with the scientific knowledge or training of the scientists. The importance of the aforementioned study lies precisely in the fact that it did not ignore such complications in the translation between different knowledge systems. Iwu included many subjective interpretations of the events, therapy, and the phenomena that he observed, because he felt that when in doubt "record and report" rather than "ignore and omit".[1] This is one interpretation of the intellectual dilemma when working between different knowledge systems (formal and informal, modern and traditional).

Iwu also finds some commonalties in the medical thinking of ancient Western philosophers and the Igbo world view. For instance, he finds similarity in the scepticism about the corpuscular theory (relying too much on the empirical understanding of the way parts of the body work) and the Igbo's rejection of the explanation of diseases or health based on some microscopic constituents of material objects.

Iwu points out an important feature of Igbo indigenous knowledge which is often ignored in Western medical research. He points out that Western definitions of certain diseases and their treatment are focused on the major outstanding symptom/s, while ignoring sometimes the "subtle-but-chronic" and debilitating symptoms of the disease. He takes the example of malaria and shows that Western medicine considers the key symptom of malaria as cyclic chills, fever and headache. Various malarial drugs such as *chloroquin*, *quinine* and related compounds abolish these symptoms by counteracting the effective plasmodium species in the blood. Western medicine, he submits, does not appreciate the importance of any anti-malarial drugs which are addressed to the more serious but non-dramatic effects of malaria, such as spleno-hepatomegaly, jaundice, anaemia and hemoglobinuria. Therefore, indigenous medicines which fortify the liver or spleen are ignored in Western medicinal knowledge systems. Iwu (1978) highlights that the Igbo herbalists believe "it is only a liver weakened by malaria or exogenous chemicals that could be liable to viral attack." In the Igbo knowledge system, malaria, diabetes, or any other disease-condition refer to a variety of complex pathological states and not to any specific isolated symptoms, as they are viewed by orthodox Western medicinal knowledge.

Iwu believes that there is no knowledge without moral responsibility and therefore he omitted some practices that he considered "dangerous or bordering on occultism". He questions the assertion by some that Igbo medicine is not scientific. He says that the deficiency in the African healing system (in areas where such deficiencies do exist) is not the result of unscientific thinking, but of inadequate information. Before the need for such efforts was generally recognized, Iwu called "to update the information and the data bank of the traditional native healer." Iwu (1978) had earlier questioned the futility of comparing the Western and the indigenous systems of science emerging from different observations and cultural contacts. However, the case study will demonstrate that it has been possible to build bridges between the two systems of knowledge by comparing, contrasting, and in some places creatively complementing one by the other.

While Iwu stresses that traditional medicine emphasizes not only the physical properties of the herb, but also the natural life-force within the plant and the role of ancestors and the gods in the healing process, he does recognize the possibility of dealing with this knowledge in a reductionist manner. As an example, he describes the role of a traditional healer viz., '*Dibia*,' who is not just a herbalist but also the custodian of the religious life of the community. There are several methods by which one learns to be a healer. It could be through a long-term apprenticeship with an older *Dibia*, or through a divine selection after trance, dream, or even prolonged illness. Some individuals are supposed to be born as *Dibias*.

The National Traditional Medicine Policy, which is being discussed in the country, emphasizes "obvious hazards of traditional medicine practice, which should, therefore, be regulated". The National Traditional Medicine Board primarily aims at monitoring, controlling, and standardizing the facilities and services for the practice of traditional medicine in Nigeria. There is also a proposal to develop a Code of Ethics for the Practice of Traditional Medicine, which would regulate the relationship of traditional medicine practitioners with patients, the public, and each other. Traditional medicine practitioners are expected to keep records and follow all the procedures generally followed by the orthodox medical system. During 1997 a work plan was developed to have a long-term strategy for strengthening the traditional medicine system. However, a great deal of informality still exists, i.e. the traditional herbal medical practitioners follow very informal and highly varied protocols in this regard.

History of Traditional Medicine Regulation in Nigeria

Historically, it is reported that the Federal Ministry of Health approved research into the medical properties of local herbs in 1966 at the University of Ibadan. In 1973, the International Scientific Congress on Traditional Medical Therapy was held at the University of Lagos. In 1977, a delegation of four experts was sent to India and China to examine the systems of traditional medicine in these countries. In 1979, a nationwide seminar was organized and followed by the establishment of a Board of Traditional Medicine by the Lagos State Government in 1980. In 1984, after the report of the National Investigative Committee on Traditional and Alternative Medicine, it was suggested that every state in the country should have a Board of Traditional Medicine. This recommendation was repeated in 1984 when all the State Ministries of Health were mandated to set up Boards of Traditional Medicine.

It is obvious that the traditional medicine system has been evolving through a variety of formal and informal processes aimed at bringing about reliability, professional discipline, authenticity and a kind of accreditation system. In a recent publication, the *Handbook of African Medicinal Plants* (1997), Iwu traces the history of the healing arts in Africa to 3200 BC. Some of the African healing herbs which are recognized in the modern

Figure 1 – Ajohia. A sacred site where leftover tapir used for treating arrow heads are buried.

Pharmacopias are *calabarb* (*Physostigma venenosum*), *strophanthus*, arecanuts, kino, salix, kola, the African periwinkle, and the devils claw (*Harpagophytum procumbens*). In some cases, the African *Rauwolfia vomitoria* has been found to contain a higher content of anti-hypertensive alkaloid reserpine and the anti-helminthic drug *ajmaline*, compared to the better known species of the plant. Another outstanding example of the strength of traditional medicinal herbs is the *willow* plant, *Salix capensis*, which has been used for centuries as a pain killer and antipyretic in Africa. It contains esters of salicylic acid, which is the basis for developing a universal analgesic Aspirin.

While this wealth of medicinal plants abounds in the African region, Africa has at the same time the highest rate of deforestation in the world. In particular, Nigeria has about five per cent per year as against the global rate of 0.6 per cent. It is obvious, therefore, that the conservation of biological resources and associated knowledge systems becomes a crucial policy objective.

Institutional Context of International Cooperative Drug Development and Conservation of Biodiversity

As a part of the International Cooperative Biodiversity Group (ICBG), sponsored by the National Institute of Health, the National Science Foundation, and the US Agency for International Development, a programme for conservation and sustained economic development through drug discovery was taken up. Schuster *et al.* (1999) emphasize that

> *One of the unique features of this ICBG is that the emphasis is on discovery and development of compounds for tropical diseases such as malaria, leishmaniasis and other parasitic infections rather than only for the treatment of diseases of global importance such as cancer, AIDS and metabolic disorders. The program is committed to the development of low-cost phytomedicines, in addition to the isolation of lead compounds for drug discovery. … the ICBG – Drug Development and Conservation of Biodiversity in West and Central Africa aims to demonstrate that sustainable drug development is a viable alternative to the common destructive activities such as timber harvesting, as a source of forest income for local communities.*

The programme has used a combination of four approaches, namely:

- the development of drugs which address the priority health needs of the United States and the participating countries,
- the inventorization of native species and indigenous knowledge,
- capacity building to achieve the goals of the research programme, and
- strengthening the scientific infrastructure in the host developing country.

The programme is administered by the Fogarty International Center at the US National Institute of Health. Unlike most other projects, in this programme most of the processing and biological testing of the plant material is performed within the Group rather than in the institutions outside the Group. The idea was to build a team of scientists who will discover lead plants and develop active molecules into drugs. Selected plant products will then be developed to the pre-clinical stage before starting negotiations with commercial partners. However, the sharing of benefits is not delayed until the development of drugs and their commercialization is completed. The access fee, capacity building training and institutional development, conservation plots, strengthening of infrastructure for traditional healers, etc., are started right from the beginning without waiting for actual leads to be generated. Shaman Pharmaceuticals Ltd. had agreed to share royalties with local communities participating in the program even if no drug was actually developed from the lead provided by a specific local community. And the drugs might have been developed from the leads from elsewhere. The first newsletter of BDCP (1996) recognized this dilemma by describing the practical thresholds of instituting effective benefit-sharing arrangements:

> *While the process benefits are guaranteed, and in many ways more fruitful, product of this type of collaboration (really are)… the fine-workings of the flow of cash that is used as a measure of fairness and responsibility, and which creates the most interest. As a result, there is a popular fixation on documents themselves, to the detriment, in some cases, of the relationships upon which they are based. It took, for example, more than a year and many contentious meetings to draft an intellectual property rights agreement for the ICBG project. This was due largely to the wildly disparate institutions and outlooks involved in the program", and the lack of shared expectations in the beginning.*

The central office for the BDCP programme is located at the Walter Reed Army Institute of Research and the key institutions and organizations collaborating during the first phase of this bold initiative include the Division of Experimental Therapeutics of the Walter Reed Army Institute of Research, the Bioresources Development and Conservation Programme (BDCP), the Smithsonian Institution, the University of Ibadan (Nigeria), the University of Yaounde (Cameroon), the University of Dschang (Cameroon), the Biodiversity Support Program (a consortium of the World Wildlife Fund, the Nature Conservancy and the World Resource Institute), the Pace University, New York, the Southern Research Institute of Alabama, the University of Utah and Shaman Pharmaceuticals, Inc. During the second phase of the African ICBG the composition of the Group has changed.

The BDCP planned to follow various approaches to the selection of plants, such as random screening, selection based on ethno-medical uses, reliance on leads from literature reviews and chemical analysis approach. Efficiency of the identification approach could be gauged from the fact that there was a correlation of more than 85 per cent between indigenous knowledge and the modern therapeutic effects. Some aspects of the plant selection plan were based on the information provided by Shaman Pharmaceuticals, Inc., and as a part of its corporate contribution to the BDCP programme, the company also provided a high level of ethno-medical support to the project team. The compliance of Shaman Pharmaceuticals, Inc. with the selected articles of the Convention on Biological Diversity (CBD), as stated by them, is given in Annex 3.4.1.

Intellectual Property Rights

Patents US 5019580 and WO 91/09018

The intellectual property rights acquired over value-added biological resources and associated knowledge are expected to generate profits from which benefits would be shared with the Trust. These intellectual property rights include not only patents but also the trademark of the new company, the copyright of the descriptions and citations about the validity of herbal drugs, etc. However, this case study will focus on two patent applications filed for inventions related to the work of Shaman Pharmaceuticals and the ICBG Programme. The two patents, namely US 5019580 and WO 91/09018, are contained in Annexes 3.4.3 and 3.4.4.

On December 19, 1989, Shaman Pharmaceuticals, Inc. filed a patent application (no. 452,902) for "Dioscoretine and its Use as a Hypoglycemic Agent". The patent application contains 13 claims and 4 Drawing Sheets. The inventor named in the application is Prof. Maurice M. Iwu, the Director of the Bio-resources Development and Conservation Programme (BDCP). The statement of the technical field in which the invention lies states that,

> *This invention relates to a novel biologically active compound, more particularly dioscoretine, isolated originally from tubers of* Dioscorea dumetorum*. The novel compound of the invention is useful as a hypoglycemic agent and thus provides a new and useful agent and pharmaceutical composition for the treatment of diabetes mellitus.*

The application cites 4 references, all of which are publications of non-patent literature, published in the USA or Europe. While the non-patent literature references of the application do not include traditional medicinal knowledge of Nigeria, the second section of the patent application, which describes the Background of the Invention recognizes that:

> *The common yellow yam Dioscorea dumetorum has been used by herbalists and practitioners of West African folk medicine for treatment of diabetes, as a topical anesthetic as well as an arrow poison and as a bait for monkeys [see generally, Corley* et al. *1985, Tetrahedron Lett. 26 (13):1615-1618]. Additionally, D. dumetorum tubers are used as famine food, although it is well-known that the yams must be carefully prepared by soaking for several days in running or salt water and boiling overnight. In fact, several cases of serious poisoning have resulted from ingestion of improperly prepared tubers (Undie* et al*., 1986, J. Ethnopharm. 15:133-144).*
>
> *For use in herbal medicine for treatment of diabetes, a decoction is prepared by steeping the peeled tuber in native gin, distilled from fermented palm wine containing about 30-70% ethanol (termed 'kai-kai.') for about three days. The decoction is boiled until the color changes from yellow to brown and is then administered to patients in small cupfuls. Undie* et al. (supra).
>
> *In a preliminary investigation, Undie* et al. (supra), *have shown that crude extracts of D. dumetorum possess hypoglycemic activity when administered to experimental animals. The authors stated, however, that several constituents were present in the extracts and nothing could be known with respect to what constituent was responsible for the observed hypoglycemic effects.*

In this section of a patent application, "Background of the Invention", the patent applicant normally sets out any existing problems or difficulties which the invention overcomes. Previous solutions to the problem are described, preferably in a way which clearly sets out the difference between the present and previous solutions. In this case the previous solutions included the traditional medicinal practices of herbalists and healers of Nigeria. The application specifies that *D. dumetorum* was also used in traditional medicine for the treatment of diabetes.

This patent application does indicate the country of origin of the plant genetic resource which was utilized in the invention. Section 6, "Extraction and Isolation of Discoretine" states that:

> *Tubers of Dioscorea dumetorum were collected at Ankpa Local Government Area in the Benue State of Nigeria. The authenticity of the material was confirmed by Dr. J. C. Okafor of the Forestry Division Anambra State Ministry of Agriculture, Enugu. A voucher specimen has been deposited at the Pharmacy Herbarium University of Nigeria, Nsukka. Tubers of D. dumetorum were sliced into chips and sun dried for 4 days.*

The patent was granted by the United States Patent and Trademark Office (USPTO) on May 28, 1991. The patent is classified according to the International Patent Classification (IPC) under Maingroup 221.00 of the IPC Subclass C 07 D.

On December 18, 1990, Shaman Pharmaceuticals, Inc. filed an "international application" under the Patent Cooperation Treaty, administered by WIPO, for "Dioscoretine and its Use as a Hypoglycemic Agent". In this international application the states designated for which protection was sought included Austria, Belgium, Canada, Switzerland, Germany, Denmark, Spain, France, Great Britain, Greece, Italy, Japan, Luxembourg, the Netherlands and Sweden. For more detailed information on the Patent Cooperation Treaty see Box 7.

Text Box 7:
The Patent Cooperation Treaty – An Overview

The Patent Cooperation Treaty is administered by the World Intellectual Property Organization (WIPO) and makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing an "international" patent application.

The Treaty regulates in detail the formal requirements that any international application must comply with. Among all the contracting States, the applicant indicates those in which he wishes his international application to have effect ("designated States"). The effect of the international application in each designated State is the same as if a national patent application had been filed with the national patent office of that State.

The international application is then subjected to what is called an "international search." That search is carried out by one of the major patent offices. The search results are provided in an "international search report," that is, a listing of the citations of such published documents that might affect the patentability of the invention claimed in the international application. The international search report is communicated to the applicant who may decide to withdraw his application, in particular where the said report makes the granting of patents unlikely.

If the international application is not withdrawn, it is, together with the international search report, published by the International Bureau of WIPO and communicated to each designated Office. If the applicant decides to continue with the international application with a view to obtaining national (or regional) patents, he can wait until the end of the 20th month after the filing of the international application or, where that application claims the priority of an earlier application, until the end of the 20th month after the filing of that earlier application, to commence the national procedure before each designated Office by furnishing a translation (where necessary) of the application into the official language of that Office and paying to it the usual fees.

The procedure under the PCT has great advantages for the applicant, the patent offices and the general public:

(i) the applicant has eight or 18 months more than he has in a procedure outside the PCT to reflect on the desirability of seeking protection in foreign countries; he is assured that, if his international application is in the form prescribed by the PCT, it cannot be rejected on formal grounds by any designated Office during the national phase of the processing of the application; on the basis of the international search report, he can evaluate with reasonable probability the chances of his invention being patented;

(ii) the search and examination work of the patent offices of designated States can be considerably reduced or virtually eliminated thanks to the international search report and, where applicable, the international preliminary examination report that accompany the international application;

(iii) since each international application is published together with an international search report, third parties are in a better position to formulate a well-founded opinion about the patentability of the claimed invention.

The development of the PCT system is shown by the fact that, in 1979, 2,625 international applications were received by the International Bureau, while the corresponding numbers were 67,0007 in 1998.

It is to be noted that the patents cited were granted prior to entry into force of the CBD. They were governed by the research agreement with Shaman which provided for a benefit-sharing plan. The ICBG Programme has not resulted in the grant of any patents so far, although four applications have been filed or are under preparation. The second patent is related to the antiparasitic activity of indole alkaloids of *Picralima nitida* and related compounds.

A share of the royalties generated from commercializing the technology and licensing the exclusive rights granted by the patent will be contributed by Shaman Pharmaceuticals, Inc., to the Trust Fund established for benefit-sharing with the traditional healers and local communities in Nigeria and other countries that have been working with the ICBG Programme.

Intellectual Property and Benefit-sharing Plans

The key principles of the benefit-sharing plan are that:

- benefit-sharing should start not after the product is developed but right from the stage of the access agreement;
- while cash may be provided where necessary to individuals, communities, and other stakeholders, non-material compensation will also be given sufficient attention;
- the revenues generated from the project will be exclusively used for the goals of the ICBG, i.e. the conservation of biodiversity, drug development, and economic development of rural communities;
- local communities, through various institutions, including healers' associations, would be empowered to make decisions regarding method and extent of compensation and choice of projects;
- the African members of ICBG will be involved at every stage of drug development, so as to equip them with the capacity to pursue drug development on their own.

It was hoped that the research would not only lead to the isolation of chemicals but also to the standardization of indigenous phytomedicines. The knowledge base of local healers would be enhanced and the capacity of the local scientists to conserve biodiversity would be supported. All the stakeholders who have contributed in the identification and processing of medicinal plants and subsequent drug development will be compensated as appropriate, including traditional healers. Every contribution will be acknowledged in the patents and publications arising out of the work. The existing intellectual property rights systems might not be adequate for the purposes of the ICBG. The group also "recognizes that the need to label ideas, access to instruments of protection, and monitoring for possible infringement, expert witness, and legal assistance are necessary factors in the equitable distribution of the benefits of this project" (Bio Resources News Letter, 1. 1996. BDCP).

The right of individuals to their private land as well as to the community resources would be respected in the allocation of benefits, but ICBG also took note of the fact that information provided by the individual informant or healer might not be his/her exclusive property but might belong to the cultural resources of the community or the village at large. This led to several ethical issues. In the first issue of the Bio Resource newsletter (1996), the editor stated,

> *As has been pointed out by several investigators, exploration of chemical leads in tropical countries poses enormous ethical and political issues which must be addressed in any program that aims to use ethnobotany as a major plant selection criteria… A … concern which has been broached by Gollin (1992) deals with the modern fundamental issue of ownership patterns in different parts of the world and especially in traditional societies were most of biodiversity belongs to what could be appropriately classified as public domain.*

Given this ethical dilemma the programme has provided for channeling the benefits to the host countries and the local communities near the project site. In the absence of a universally applicable model, the group decided to experiment with various kinds of reciprocities and norms of equitable benefit-sharing. The proposed types of compensation for the short-term and immediate compensation include:

- collection fees to individuals and communities,
- long-term benefits in the form of royalties, and
- training and capacity building.

Shaman followed the approach of obtaining the clear prior informed consent of various host countries and institutions. Different kinds of short-, medium- and long-term benefits were disclosed and ethnobotanical research was not started until an agreement had been reached. A team of physicians and ethnobotanists from Shaman collaborated with a team of scientists from the University of Nigeria at Nsukka and the BDCP. This team worked closely within the Nigerian Union of Medical Herbal Practitioners. Copies of all the ethnomedical and botanical collection forms along with the voucher specimens of the medicinal plants were deposited both at the University of Nigeria and the BDCP Office at Nsukka. The scientific papers published from the research include Nigerian scientists as well as traditional healers. It was made clear that technology and resource transfer for capacity building initiated in 1990, when collaboration began, would continue throughout the duration of collaboration, even if no commercializable product was developed from Nigerian plants. From 1990 to 1996 an amount of USD 210,000 has been provided to Nigerian stakeholders. Part of this money has enabled significant capacity building at BDCP, the augmentation of the Phytotherapy Research Laboratory of the University of Nigeria at Nsukka, the Traditional Healer Organization and the rural communities. These benefits have been provided even before any drug had been developed.

Katy Moran (1998) in her case study of the BDCP, describes various factors involved in the evolution of benefit-sharing arrangements. Carlson, *et al.* (1997) describe the steps taken to establish prior informed consent and outline one of the unique features of Shaman's policy, which is to share, "a percentage of its profits (with) all the indigenous communities and countries with which it has worked, regardless of where the actual plant sample or traditional knowledge originated" (1997: 33).

King, *et al.* (1999) reviewed the ongoing global concern with so-called biopiracy. He highlights that annual retail sales of over-the-counter herbal remedies in Germany in 1996 alone were about US 3.5 billion dollars (Blumenthal, *et al*., 1998) and the same source was quoted to suggest that total sales in Germany, France, Italy, Spain, U.K., and Netherland were USD 7 billion. This volume of sale could have significant impact on the plants, the environment, the countries, and the cultures from whom the knowledge and these biological resources are obtained. King, *et al.* (1999) regret the fact that the international conservation community has neglected the huge impact of the botanical medicine industry on tropical people, plants, and eco-systems.

The Community Perspective

There are two primary communities with whom BDCP works closely in this project. The first one is the community of traditional healers through their national union as well as state-level associations. The second one includes the communities at the village level where conservation, biodiversity monitoring, sustainable extraction and other rural development activities are being planned. BDCP gave considerable thought to the definition of the term "community" and resolved to follow a very practical approach. The reliance was placed to existing traditional institutions of leadership, authority and cultural and social cohesion.

The trust fund, i.e., The Fund for Integrated Rural Development and Traditional Medicine, is aimed at enhancing the capacity of traditional practitioners. The trust fund is expected to support local projects, help build herbal clinics, botanical gardens and mo+nitor various activities. There is a view that it should not focus on helping only individuals but also help communities.

The First Trustees were: Chief (Dr.) A. A. Omotosho, Dr. Ohyu Azija, Professor I. Abdu-Aguye, Cosmos Obialor, Professor E. N. Sokomba, and Professor M. Iwu. Prof. Sokombo is the trustee as well as Secretary to the Board

of Management which includes ten members. The members include His Royal Highness Eze E. E. Njemanze; Chief Omotosho, President of the National Union of Traditional Medical Practitioners (NUTMP); Dr. (Mrs.) Ohyu Azijah; Chief Ozonnamalu, Alhaji Baba Alhassan Bangbara, Prof. Ibrahim Abdu-Aguye, Prof. Robert Boroffice, Mr. Cosmos Obialor, Dr. Tolu Fakeye and Prof. Sokombo. BDCP had developed contact with these people through its earlier work in the field of drug development. Mr. Kent Nnadozie, Consultant Lawyer, helped in setting up the trust and constituting the board of management. Various officials of established unions and associations of healers were involved. BDCP has also had a very close coordination with the government in the formulation of national policies.

Traditional Knowledge of Healing

Traditional healers draw upon a knowledge base of several generations, apart from constantly making their own innovations. They believe in the super-natural powers of deities like "*Ifa*," who is worshipped and has the power to heal. It is understood that the blessings of "*Ifa*" are available only when one follows a code of conduct properly, does not eat forbidden food, and treats the relevant diseases according to the directions.

Many diseases are not considered natural. For example, it was natural to have stress, but one could be affected by stress caused by bad forces, witchcraft, or other disturbances in one's life. The same disease may be caused by different factors in different people and hence the treatment is individualized. The factors which Chief Omotosho takes into account include how long a person has been suffering, since chronic diseases cannot be solved the same way as newly caused diseases. Once every year, the Nigerian Union organizes a training for local healers. Unlike modern medicine where a disease tends to come back, in traditional medicine it may go slowly but does not tend to come back again.

Nowadays, the traditional healers take notes and write up their diagnosis, whereas earlier they did not do that. The knowledge was treated as a common property and shared widely, though there are healers who keep it secret. Chief Omotosho almost articulated the rationale for modern intellectual property rights when he said, "*if I share, you can improve upon it, make my knowledge more useful, if I keep it to myself, my know-how cannot be improved upon*". He did feel, however, that unauthorized access to a healer's knowledge is not acceptable. If a firm develops a medicine based on a healer's knowledge, it should share the technology of making that medicine with the healer. Generally, the orthodox system of medicine and traditional medicine do not work together. For example, modern medicine does not have any treatment for blood pressure. It merely keeps it in check. Traditional medicine claims to have a treatment for the purpose.

Some healers pursue farming, healing and other occupations together, while other focus only on healing. The son of Chief Omotosho has studied modern medicine and may be able to modernize traditional medicine. Usually it takes at least two years for a person to understand the basics of traditional medicine and become a traditional medical practitioner. The healer also has to have an in-depth knowledge of taxonomy so that he can identify the plants and their components properly. Sometimes one has to spend at least two and a half years to develop this capability of identifying leaves and plants.

The State has not supported traditional medicine very much and there are not many hospitals practicing traditional medicine exclusively. There is no center for medical research in Nigeria managed and owned by traditional healers (except the one set up by BDCP). Consequently, the traditional practitioners have to do individual research and experiments to find out the relative efficacy of mechanical grinding versus manual grinding, appropriateness of different packaging instruments, methods of increasing shelf life, etc. Unless a

Figure 2 – Mr. Alanemu Dusu, traditional healer, explaining one of his remedies.

Figure 3 – Children watch as local plants are prepared for use in traditional medicine.

school of traditional medicine is established, the blending between the two systems of medicine, as achieved in China, may not be achieved in Nigeria.

Some examples of traditional medicine were also given to illustrate the way the knowledge systems work. For example, *Oruwo* leaves are washed, squeezed in water, and then drunk and fever will disappear within fifteen to twenty minutes. The same leaves are also used in Chinese Traditional Medicine. There are about 4000 medicines of this kind in Nigeria.

With respect to benefit-sharing, Chief Omotosho pointed out that the fundamental value which should guide one's professional conduct is basic ethics. The basic duty in medical practice to help others should not be compromised. His preference was that only the respondents who provided the leads for developing modern medicine based on traditional medicine should get the benefits. When asked about the role of the community which conserves the plants, the interviewed healers confirmed that the community should receive a share of the benefits derived from the application of their knowledge. However, according to Chief Omotosho, the individuals who get the benefits should share it with the community.

Mrs. Azijah, who heads the Jos branch of the Nigerian Union Medical Herbal Practitioners and was recommended to the post of Lecturer in Traditional Medicine at the University of Jos, shared the view of Chief Omotosho about benefit-sharing. Mrs. Azijah has been authorized to check the documents of any medical healer or seller in her region and register him or her with her association. In her region in northern Nigeria there was not much erosion of biodiversity, but those who are responsible should try to conserve the plants. Her association in Jos, a region in northern Nigeria, has developed a norm that without the knowledge of their healers' association nobody can collect the plants. They also put some members of the Association on surveillance duty. Chief Omotosho was from the tropical forest region, whereas Mrs. Azijah is from the Savannah region. Both of them felt that there should be information transfer agreements which create legal certainty around the transfer of their knowledge. At the same time, Mrs. Azijah[2] pointed out that if someone was too protective about their knowledge, then he or she was considered greedy by the community. She felt, "knowledge is provided by God, I cannot exclude others from it. You take it to do better things. If I don't get millions, and thus I decide not to give it, then it is bad behaviour." She also felt that if she did not tell others, they would not know that she had shared the knowledge with outsiders. Therefore, she should not be expected to share the identity of people with whom she shares her knowledge. She did want that her name

should appear, no matter how small, on any medicine made from her knowledge. *Monetary compensation alone was not the major consideration, rather recognition should be there as the most important thing*.

There were several suggestions made by both Chief Omotosho and Mrs. Azijah about the way traditional healing systems could be strengthened. The Federal Government could take steps to develop model information transfer agreements, in consultation with the Healers' Union.

The union or association should be responsible for sustainable extraction of biological resources from the local ecosystems. Outsiders would not know the individuals and they should seek to establish their contacts through the Healers' Associations. One should also think of a system for the registration of knowledge in "Local Knowledge Registeries". There should be a system of empowering associations to document the knowledge according to given rules and regulations and the individuals providing knowledge should be compensated. The healers felt that different groups might have different norms about how knowledge should be collected, pooled, shared (with or without price), acknowledged, and valorized. It is necessary that outsiders realize the ability of local healers to make informed choices about various knowledge transactions, given sufficient opportunity to understand the complexity at their own pace.

BDCP's work with traditional healers also involved setting up a Clinic in 1992 which is owned and managed by the local healers themselves. The National Union of Herbal Medical Practitioners has no control over this facility, though some of the members of the local healers' associations are affiliated with the National Union. Shaman Pharmaceuticals have invested both in kind and in cash in this programme. The healers and modern medical doctors sometimes jointly diagnose the patients or even a board is set up to enable the diagnosis of cases which are difficult and where a group of traditional healers need to work together.

A Community Knowledge System

The Umowere village provides an example to understand the way local communities deal with biodiversity and associated knowledge systems. The village has a highly diverse eco-system with undulated topography and various food, trees and crops like maize and sorghum.

The villagers primarily consume yams and cassava. Originally the forest around the village was a teak forest, but now it is being transformed into a multi-species forest and has 41 different species. BDCP has set up a monitoring plot and also a conservation plot. The level of economic development in the village is low. The people are extremely hard working and enterprising. The women pursue several processing activities other than household chores, such as food processing, extracting oil, processing yams, cassava, edible and non-edible seeds and other minor forest produce.

There are several traditional technologies, contemporary innovations and important traditional institutions in the village, which pertain to the conservation and sustainable utilization of medicinal plant genetic resources. These include, *inter alia*,

- certain *sand harvesting structures*: given the undulated topography, farmers use a whole variety of soil and water conservation structures to prevent soil erosion. The soil in the vicinity of the village is sandy loam and silty clay. Farmers build small structures with the help of poles or logs to impound the sand at the time of rain. The lighter particles of soil overflow, whereas sand fills up the small ditches so made. This sand is collected and used for construction activities. While processing grated cassava the villagers keep a strainer

Figure 4 – Members of the Umowere community returning from a collection tour of local medicinal plants.

Figure 5 – Traditional healer collecting local plants and hunting for small animals.

vessel (with holes all around) having grated cassava in the flowing water of a stream. The water passes through the cassava (through the holes) over night and in the process the anti-nutritive factors are supposed to be washed or drained away. Women taste the cassava so washed to make sure that it is safe and then serve it to their family members. Such traditional technologies relate both to the conservation of medicinal plant diversity and to the traditional knowledge provisions of the UN Convention to Combat Desertification.

- the so-called *Azohia*: there is a traditional institution, namely *Azohia*, which consists of a small grove near an old tree where the dead bodies of either rule breaking people are buried or of those who died of some serious illness. When an old healer dies, the residual medicines, of which the children often do not know the use, are thrown into that place. This is a place in which nobody is supposed to go and of course by implication it helps in conserving a wide variety of medicinal plant diversity. The *Azohia* is situated around an old *achi* tree (*Brachystegia eurycoma*). Apart from residual medicines, the herbal poisons, used for fighting by poisoning the tips of the arrow, were also reportedly thrown away in the *Azohia* bushes.

A similar institution exists in the form of a stream in which no fish is collected. The institution demonstrates that there is a strong tradition of conservation of plant species as well as aquatic systems. The streams are considered sacred in general and the life of the stream and the life of fish are supposed to be related. Different streams are supposed to have different custodian gods. The concept of the sacredness of some streams in which fish is not caught is generally captured in the native belief of "*ndu nmiri ndu azu*", i.e., "life in the stream and life in the fish." Perhaps, these streams may have had many spawning sites for the fish and therefore people did not want fish to be caught when they were full, as is the case when they are spawning. (Kent, 1999, personal communication).

Tradition under Transition

There are numerous pressures of modernization and transition at work in the village. The introduction of intellectual property rights and benefit-sharing arrangements for local biological resources and knowledge systems would themselves constitute a part of these transformative factors. It is therefore essential to understand how traditions, lifestyles and institutions that have sustained traditional knowledge formations and genetic resource *in-situ* are currently changing. Numerous examples express the villagers' changing

understandings of traditional medicine, biodiversity conservation, the role of the community, and the value of its knowledge and plants.

There are farmers like David Dike who buy modern English medicine for headaches. He claimed that local herbalist did not share their knowledge sufficiently. On the other hand, there were healers, like Mr. Letusogu, who felt that sharing the knowledge was useful because it might help in the development of modern medicine, since this would benefit the world at large. So far as their own benefit was concerned, they would appreciate if a road could be built and electricity provided. The issue arises whether those who conserve and share their knowledge freely must remain poor just because they have different ethics, which from the conservation point of view may be considered superior.

Another villager, Mr. Alaneme Duru, and his family were suffering from severe poverty. There were some trees in Mr. Duru's garden land which were mature but could not be cut (since the area was in a protected area). However, mature bamboos were cut and sold earlier, but could no longer be sold. Incidentally, this impoverished man is the one who donated his land and forest for the purposes of community forest conservation as a part of BDCP project. The case of Mr. Duru is an example illustrating the conservation ethic of local communities which is often tied with generosity in poverty. He and his brother felt that their contribution would perhaps be remembered in posterity and that is all they had expected out of the donation of land. He pointed out that his children did not want to remain in the forest and did not bother much about traditional medicine.

A young lady, Mrs. Osebi Lillian, felt that the local community should be approached before anybody took their knowledge from one or the other member of the community. She also acknowledged that not everybody had the talent to be a herbalist. When asked about her future ambitions, she said that she wanted to learn English medicine and did not have much interest in native medicines. Some of those who were present mentioned that Christianity might have led to a decline of native medicine. An example was given of the *achi* tree which was revered by the family in whose land it was located. However, when a couple of cases of infant mortality took place in the family, the local priest asked the young people in that family to burn the sacred *achi* tree so that their supposed faith in the local deity might not prevent them from using modern medicine. The elder person of the family was not very happy with the decision of the children. There is a tension in the local culture between the traditional institutions and the influx of modern values. This dilemma raises questions about the future of a knowledge system in which culture, biodiversity and medicinal plant knowledge are closely intertwined.

The dialogues given above indicate that a community, traditional as it might be, does not represent a homogenous view point. The tension exist between:

- traditional medicine and modern medicine,
- proprietary information vs. community-wide sharing of information,
- changing aspirations of young people who want to become modern doctors vs. continuing the profession of traditional medicine practitioners.

The transition of traditions under the pressures of religions, markets and modernization may be relevant for devising incentives that make the role of the traditional healer more recognized and respected.[3] Unless this happens, young people might not like to learn and improve the traditional knowledge systems and erosion of the knowledge systems will inevitably follow. Intellectual property rights and benefit-sharing arrangements

Figure 6 – Young community members of the Umowere village on a hunting expedition. Will they take an interest in traditional medicine?

Figure 7 – Transmission of Traditional Knowledge: Mr. Cosmos, who works with traditional medicine, explains his views in the course of a discussion with community members of the Umowere village.

should provide incentives and benefits that stem this erosion.

Benefit-sharing

In the context of the BDCP, there are primarily seven kinds of benefits that have been provided so far:

(a) Biodiversity conservation plots and herbal medical gardens
(b) Support to the individuals (herb collectors, traditional healers, etc.)
(c) Support to the Herbalist Medical Practitioner Union
(d) Research and development through local research centers, herbal clinics and processing units
(e) Support to universities
(f) Support to the government
(g) Support by the commercial partner to the Trust Fund and other collaborative activities

a) Biodiversity conservation plots and herbal medical gardens

There were four conservation sites at Imo, Cross River, Ebonyi and Rivers states. A monitoring plot of one hectare each had been identified at each of these sites. In addition, there was a three-hectare plot at Umukabia village, including one hectare as a monitoring plot, one hectare for community biodiversity conservation, and one hectare for a community herbal garden. Two local farmers, namely Mr. Johnson Lereneous and Mr. Alaneme Duru, reportedly donated the land for this community forest area although they are both extremely poor. Data has been collected on the conservation plot for all plants above a particular girth size. People can collect the medicinal plants for their own use as well as for sale from the herbal gardens.

b) Support to individuals (herb collectors, local expert healers)

1(a) Healers have been given cash for their services at the rate of 5000 Nira per interview.

1(b) For each plant which is selected for screening an amount of 5000 Nira is paid for the collection of the plant.

2 If the larger quantity of particular plant material is required for laboratory analysis, BDCP goes to the same healer from whom the information was collected and pays 200 Nira per kilo gram of the plant material. In some cases the material is also collected from traditional plant gatherers.

c) Support to the Herbalist Medical Practitioners Union

Support to the Herbalist Medical Practitioners Unions (HMPU) was provided in several states: Niger, Taraba, Lagos, Enumbra, Imo, Snegu, Jos, Benve, Oyo, Edo, Cross River State, and Ebony. There are two kinds of support to the HMPUs. One is in cash and the second is in kind, in the form of technical assistance, botanical assistance, collaboration with allopathic physicians and joint diagnosis of complex sicknesses. At the University of Jos, assistance has included purchase of land to set up a traditional medical hospital, a herbal garden to grow species under threat, and technical assistance to the existing clinics to be upgraded eventually.

In addition, the Fund for Integrated Rural Development and Traditional Medicine (FIRD-TM), i.e. the trust fund described below, also has provided support to individual traditional medical practitioner as well as the unions.

d) Research and development through local research centers, herbal clinics, and processing units

A clinic has been set up at Ninth Mile Corner in addition to the research and development center. Research on the standardization of traditional medicines, safety, increasing shelf life, screening of various plant leads for pharmaceutical properties, joint diagnosis, record keeping, etc., are pursued at this research center. Intermediate or final processing of several herbs for developing products which are marketed by Axxon Biopharma also takes place. In addition, an international center has been set up to certify herbal products for their safety and therapeutic efficiency.

e) Support to universities

Several universities have been supported, such as the University of Nigeria at Nenugu, the University of Jos, the University of Abu, etc. At the University of Jos support has been given for a herbal medical garden, collaborative research with traditional medical practitioners, equipment and training, etc. Children's libraries have also been supported.

f) Support to the government

Policy formulation and analysis, workshops, computer support for database development for traditional medicine, research, etc., have been supported at national as well as regional levels.

The criteria of support by BDCP are the following:

While no formal agreement is entered into, previous experience in collecting information is taken into account. Whosoever collaborates is compensated and a token money is given to primary collaborators who were

interviewed. A community will also benefit as a part of ongoing activities through the trust fund or otherwise, although the primary responsibility for compensation is towards the providers of information. However, community interests are looked after through clinical facilities, trust funds, and other such initiatives including support for conservation activities.

In the interview sheet the name of the provider is recorded in writing so that one can go to the same healer who provided the lead for bulk collection. The healer or provider of the genetic resource or knowledge is informed that drug development from the local lead might take a long time. If the drug is developed and marketed, royalties will be shared. However, even if no drug is developed based on the lead provided, the knowledge providers would still get a share of benefits as and when the same are generated.

A Trust Fund for Benefit-sharing:
The Fund for Integrated Rural Development and Traditional Medicine (FIRD-TM).

Various stakeholders in the benefit-sharing chain are:

- Individual healers who provide knowledge,
- communities which may provide leads and/or conserve the biodiversity,
- the association of healers which help in maintaining professional quality and responsibility,
- scientists in Nigeria and
- scientists in the USA (in BDCP as well as in Shaman Pharmaceuticals or Walter Reed Army Medical Research Center).

In the years 1994 and 1995, when Shaman Pharmaceuticals got involved, it was quite excited by the level of interactions between local healers and the BDCP. At that time, a decision was taken to contribute financially to the trust fund to help traditional healers improve their practice.

In October 1997, Shaman gave USD 40,000 to BDCP. A management committee was constituted with the help of the Healing Forest Conservancy, a charity organization set up by Shaman Pharmaceuticals. Mr. Kent Nnadozie, consultant lawyer, helped in setting up the trust and constituting the board of management. BDCP does not impose any decisions on the management committee and BDCP can only make recommendations. In 1998 various herbalist associations and unions were invited for the inaugural meeting and aims and objectives of the trust fund were explained. The chairman of the Board of Directors, which works quite autonomously, is His Royal Majesty Eze E. E. Njemanze.

The general principle for allocating financial resources from the Trust Fund is the following:

- Sixty per cent was kept in fixed deposit of which only the interest will be used.
- Above 40 per cent of the fund i.e., 40,000 USD, was set aside to be used during 1999-2000. Of the 40 per cent:
  - 20 per cent was to be used for the Biodiversity Conservation Act of the National Institute,
  - 10 per cent for educational purposes,
  - 30 per cent for the Traditional Healers' Association for group projects or micro-credit funding,
  - 30 per cent for community development associations for village projects,
  - 5 per cent for women, especially widows,
  - 5 per cent for childrens' welfare.

There have been some tensions on the issue of the allocation of funds to the communities vis-à-vis the healers' union. The decisions so far have favoured the healers unions partly because they are better organized and are also well represented on the Board. The community projects have been deferred until the income from the interest gets accrued in the second year. In addition, the Board has also been concerned about the sustainability of project investments. Generally, the requirements for a community project are that it should have some kind of organization, bank account, list of the key members, nature of activities and duration, apart from the local contribution towards employment and development. The project format also requires information about the guarantor. Basically the form is organized for formal organizations and rural organization, and healers' organizations, informal as they are, may generally not be able to fulfill all the requirements. The BDCP has only one representative on the Board of Directors and therefore it cannot interfere too much with the decisions.

Sharing by the commercial partner

Shaman Pharmaceuticals has as a matter of its policy decided to share parts of its profit with all the communities with whom it works, even if the commercialized product has no relationship with the knowledge provided by a particular community. This ensures that the benefits are more widely shared than would have been the case if there was a strict one to one correspondence between product development and benefit-sharing. The trust fund was actually started in 1999 and so far all the money, i.e. 41,600 Nira have been given to traditional healers.

Out of the total funds, 50 per cent were given to the trust fund, the remaining 50 per cent, i.e. USD 40,000, were given in a ration of 2:3 to providers of know-how as well as scientists and the research programme for tropical diseases. The company set up to commercialize the herbal products, i.e. Axxon Biopharma, would pay royalties from the sales to the trust fund and other research programmes. It may also sell equity to raise resources. So far about 85,000 USD have been contributed by Dr. Iwu as a personal loan to Axxon Biopharma. Axxon Biopharma has developed herbal products using public domain knowledge.

Dr. Bankole Sodipo, Head of the Association of IPR Attorneys, felt that Nigeria had to go a long way in recognizing and supporting the rights of local communities, folk artists and small inventors and innovators. He felt that there was a great potential for Nigerian society to become inventive and innovative. He gave the example of a patent on a medicine developed in Nigeria for checking internal bleeding. This invention had received the WIPO Gold Medal and fortunately, in this case, the Nigerian army supported the research. But in most cases, policy or institutional support is lacking.

In his view, the clans, taboos, cults, etc., were various ways in which intellectual property rights were exercised in traditional Nigerian societies. He gave an interesting example of indigenous IPR as practiced in the Benin Kingdom. Only one family could record the activities of the court in bronze caste. Nobody else was allowed to do so. Even the one family which did it had to be initiated into the cult.

Lessons Learned

The case study demonstrates the potential that the development of biological resources, particularly for pharmaceutical purposes, have for generating surplus and sharing benefits. Several intellectual property rights have been used in this case. Trade secrets have been used by Axxon Biopharm to manufacture herbal medicines/food supplements, based on the traditional medicinal knowledge prospected under BDCP. Axxon Biopharm is a company set up in the US to sell food supplement drugs, based on the research in the BDCP clinic, and has a registered a trademark to distinguish its goods and services from those of other undertakings. Shaman Pharmaceuticals, which has screened a large number of plants for various ailments thus contributed support for local healers, communities, and R&D centers without receiving any commercial returns from a product based on Nigerian biological resources and associated traditional knowledge. The local community which collects the plant material is paid in cash and in kind.

In the initial years the trust fund set up by BDCP provided benefits to the traditional medical practitioners only. The local communities would receive support in the later years. Various other interventions such as procurement of herbal materials and setting up of herbal gardens have helped the communities apart from the payment of small amounts to individual respondents. Such tensions are very difficult to resolve by BDCP because of the autonomy it has given to the trust. Perhaps a few community representatives on the trust could have helped in changing the priorities.

The process of developing a commercializable drug is indeed very costly and even advanced companies have to decide whether to license the lead to a large multinational pharmaceutical company or to go for several stages of clinical trials followed by manufacture of the drug. The local communities are generous in sharing their knowledge and yet hardly any publications were found in which inventors were given joint authorship.

The case study highlights the extent to which monetary and non-monetary benefits can be shared among the strategic partners in biodiversity conservation through drug development. Several questions remain unanswered, such as striking an appropriate balance between the interest of organized groups like traditional healers and that of unorganized groups like local communities and unregistered healers. The case also demonstrates the declining respect for local knowledge within local communities and the doubt among the elders about long term viability of their knowledge systems. It is becoming evident that the current pattern of reciprocity, admirable as it is, may not be sufficient in making the local knowledge systems dynamic, such that the younger generation may want to grow up as herbal medical practitioners.

The local institutions for conservation of biodiversity and natural resources provide the context of local technical knowledge. The sacred institutions for conserving trees, rivers, and plants are all part of this institutional context, as are customary legal systems. Unless the benefit-sharing system looks at these institutions as an organic whole of the traditional knowledge system, it may not suffice in arresting the serious threat of TK erosion.[4]

The traditional life style also accommodates within itself some contemporary innovations. Unless a robust system of recognition, respect and reward is in place, these institutions may start floundering. Small innovations, when recognized, do not merely help one individual creative person. The message goes to the peers in the local community that innovations matter and that one does not have to adapt and adjust with inefficiency (which may exist in various farms or household operations). The case of a simple cooker developed by local women using old empty condensed milk containers is a good example.

The efficiency of the traditional knowledge system can also be enhanced by blending the same with modern science and technology, as the BDCP is attempting. But for such a blend to take place in a sustainable manner, much greater discussion is required among the respective experts. Such a dialogue is taking place in Jos and also Enugu to some extent.

Systematic documentation and a registration system of local herbal knowledge when properly disseminated among potential investors and entrepreneurs might generate more widespread benefits even at a smaller scale to revitalize the traditional knowledge systems.

This case highlights the role which academic researchers, particularly ethnobotanists, can play in valorizing local knowledge and in generating and sharing benefits with local communities, healers and other stakeholders. It has been realised that short term benefits may do more harm than good unless a long term sustainability is built into the benefit-sharing framework. The concept of Trust Funds is useful in this regard, although in this scheme the voice of traditional herbal healers has received greater recognition than the voice of local communities and their leaders.

The case study highlights several issues with regard to the sharing of information in local languages, participation of the communities in benefit-sharing, and participative research by informal and formal experts.

- The sharing of benefits by Shaman Pharmaceuticals through BDCP even before any drug was developed is considered to be a good practice.

- The commitment to share benefits with all the communities from whom Shaman has sourced any material at any time, even if the final products emerged from only one lead provided by only one community, is a novel idea and is worth implementing more widely within benefit-sharing frameworks.

- The creation of an autonomous Trust Fund is a positive step but as it stands at present it is biased against effective participation by the communities and their representatives. The sequence in which various investments have been made from initial monies shows the problem. It might be useful to keep in mind that the relatively greatest investment in conservation was made by the poor tribal people in the villages near Owere, when they donated a piece of land for a community garden and conservation plots. Some distinctive recognition, award or benefit may be designed for them.

- The dynamics of local social and economic conditions do not forebode a very optimistic future for TK. The young people in the community, curious as they are, do not see the TK-based knowledge systems as a means of livelihood in the future. It is here that benefit-sharing systems need considerable strengthening.

- The institutional structure for protection of TK is weak and thus large scale unauthorized use and reproduction of TK is going on. Customary systems of governance and law have not been adequately recognised and given an adequate role in benefit-sharing systems. The rights of local communities and informal experts as well as the scope of protectable subject matter need to be clearly defined, based on legal standards provided by existing international instruments, such as the TRIPS Agreement and the CBD. Intergovernmental institutions and specialized agencies for intellectual property, such as WIPO, may develop non-binding guidelines to provide guidance for professional and coporate genetic resource users in implementing benefits sharing arrangements which fully respect the intellectual

property rights they have acquired for their massive investments. Such arrangements would take into account that local communities and individual healers and herbalists have made no less valuable investments in creating and maintaining local genetic resources and related knowledge systems which commercial users today find so meaningful and relevant.

- The sharing of benefits by BDCP even in the case where they have used public domain traditional knowledge is a good precedence. However, further steps will be needed when local knowledge is collected and local language communication with the communities both orally as well as in written form is essential.

- The protection of the brand name of new herbal products through trademarks and certification marks is useful for generating market recognition and identity, as shown in the case of Axxon Biopharm, Inc. In turn, it helps in generation of revenue and consequent benefit-sharing. The protection of distinctive signs related to certain products of local communities could be explored since these products are based primarily on the local knowledge and practices of these communities. This could help them license the use of these distinctive signs to future users of their knowledge and it may avoid use of such signs which may lead to confusion in the minds of the public.

- The benefit-sharing frameworks by other institutions in Nigeria offer equally interesting lessons about the acknowledgement of local healers in inventions, the development of formal contracts with knowledge providers, and an elaborate benefit-sharing system. The National Institute for Pharmaceutical Research and Development (NIPRD) has provided an interesting model for acknowledging local contributions to its research and for implementing reciprocity towards traditional knowledge holders.

In this case, inventorship was not shared with the local healers or TK experts, because the specific knowledge used in the invention was common among local communities. This is an issue which requires considerable further study and exploration. When a patent application is filed for an invention utilizing genetic resources or related traditional knowledge, should the TK be cited as prior art under non-patent literature references or should there be requirements which provide for the disclosure of ownership interests in such knowledge, similar to the required statements for certain other ownership interests in the invention (e.g., requirements to state rights to inventions made under government sponsored research and development, etc.). In the present case study, the use of the plant for diabetes was known to the local community, while the community did not know the exact compound or mode of action of the active ingredient. Some associations of traditional knowledge holders have maintained that the acknowledgement of contributions of local knowledge providers and innovators should be required for TK-based patent applications. They have maintained that such disclosure requirements are a form of acknowledgement of traditional knowledge which would promote the conservation of TK systems, because through such acknowledgement of TK communities would learn more about the value of their own knowledge and thus may have increased incentives to conserve.

1 This is the author's interpretation of Dr Iwu's work.

2 The fact that both healers agreed on the need for sharing their information with others, indicates the common ethics underlying their knowledge systems.

3 It is for this reason that associations of grassroot inventors, such as the Society for Research Into Sustainable Technologies and Institutions (SRISTI, 1993, Gupta 1990, 1995, 1997, 1999), have suggested that incentives for biodiversity conservation and sharing of local knowledge should not include only monetary but also non-monetary form of rewards and compensation for individuals as well as communities. The portfolio approach to devising appropriate sets of incentive mixes for various social and cultural setting is likely to generate more sustainable alternatives than reliance on any one instrument.

4 The case of local traditional ecological institutions is crucial for the conservation of biodiversity as well as associated knowledge systems. Future discourse on the subject should include the mechanisms for conservation and augmentation of such institutions. In some cases, these insititutions will need to be reinvented in order to include more secular and consensual objectives.

PART THREE: OVERVIEW

The Role of Intellectual Property in Evolving Benefit-Sharing Frameworks for Genetic and Biological Resources and Associated Knowledge Systems

Intellectual property (IP), such as patents, provide a means whereby inventors and innovators may exclude others for a given period of time from utilization of an invention, without proper authorization. In the case of genetic resources, the situation is complicated, due to the fact that many seed varieties, wild relatives of cultivated plants, traditional varieties, as well as improved varieties developed at national or international level through research by the Consultative Group on International Agricultural Research (CGIAR), are already in the public domain. Genetic resources pooled in international gene banks prior to the coming in force of the Convention on Biological Diversity (CBD) in December 1993 are outside the suggested framework of obligatory benefit-sharing under the CBD. Various international consultations[87] do suggest that access and benefit-sharing norms should also apply to the genetic resource accessed from collections made prior to the CBD coming into force. However, most countries have yet to enact national legislation to implement the CBD. So far as the products of genetic or biological resources are concerned, the conventional product and process patents requirements are applicable. However, even here, many developing countries have taken the benefit of the time period available under TRIPS for bringing their IP laws in conformity with the provisions of TRIPS. In most developing countries the product patent for pharmaceutical and agricultural purposes, whether based on biological resources or otherwise, will be in place by 2005.

In this study, I have drawn upon three case studies in Mali, India and Nigeria to consider the role of the existing IP system in providing benefit-sharing mechanisms for local communities and individual innovators:

- The case study carried out in Mali deals with a voluntary initiative for sharing benefits through the licensing, and possible commercialization, of a cloned gene derived from a wild rice variety obtained from Mali, via international and national research centers. In this case, the proposed benefit-sharing model failed to work because of lack of commercial returns, and also because a benefit-sharing policy did not exist at that time in the University of California, Davis Campus. However, there are positive lessons one can learn from this experience.

- The second case study deals with an Indian experience, where a National Research Centre stumbled upon a lead for a drug based on the traditional knowledge of a tribe in South India. Subsequently, process patents were filed and a drug was developed. A trust fund was established, through which 50% of the license fee obtained from commercialization of the drug, as well as a share in the royalty, were shared with the community providing the knowledge. This is one of the rare cases where benefits were shared by public sector research institutions with local communities, again voluntarily because no national law in India is yet in force requiring sharing of benefits in such a manner.

- The third case study deals with an effort by a Nigerian Non-Governmental Organization, as well as a U.S.A. based herbal drug company, to share benefits with the local communities providing leads for the drug. The benefits have been shared with more than one community and are not just monetary in nature, but also include capacity building. A western herbal drug company has also been involved in developing benefit-sharing protocols involving all communities from which information had been obtained, regardless of whether specific information led to the development of commercial drug. This is an interesting precedent and may have implications for future discourse on the subject.

I address, below, the lessons and conclusions that can be drawn from each of the above case studies on the subject of access to genetic and biological resources and associated traditional knowledge (TK) and the fair and equitable sharing of benefits with the providers of the biodiversity and associated TK.

Innovations in Benefit-Sharing models: Lessons and Conclusions from each case study

It is obvious that each of the examples of benefit-sharing in each case study leaves considerable scope for further innovation.

Mali: The case of cloning Xa21 gene – voluntary benefit-sharing

The University of California, Davis (UC Davis) case brings out the importance of the issue of voluntary benefit-sharing. But it also highlights how weak the institutional commitment to such initiatives can be. UC Davis has, to date, failed to establish an internal system or policy to enable the sharing of benefits from patented products or processes based on biodiversity, or associated TK. In the present case, no TK was used; simply a sample of wild rice obtained before the CBD came into force. Legally speaking, UC Davis might not have a duty to share benefits derived from that wild rice, but what about moral responsibilities? How can institutions of higher learning profess the noble values of ethical conduct and professional accountability, if they duck such precise issues as shown in this case? The minimum that UC Davis could have done would have been to provide the specific cloned gene, and know-how, to IER, in Mali. At present, Chinese scientists are working with Prof. Ronald and transferring this gene to Chinese varieties. Why not do the same with Malian varieties with the help of Malian scientists?

The Rockefeller Foundation, which partly financed the research of Prof. Ronald, also felt helpless in the matter. They thought that they had helped the Malian researchers through other instruments, and thus did not have to insist on any sharing of benefits in research supported by them. I do however, feel that they should have a benefit-sharing policy in those cases where, as a result of their funding, an opportunity to apply for IP has arisen.

Furthermore, the conservation of the wild rice, from which the gene in question was obtained, cannot be pursued effectively if any benefits realized are returned only to the communities in the region where this wild rice grows. These communities have no interest in its conservation; neither does the Government of Mali. For them it is a weed, and it must be banished. It is for the poor *Bela* people that this wild rice matters. They would be willing to conserve it but they do not own any land. This raises the challenge of knowing with whom benefits should be shared.

I have already commented on the inapplicability of providing scholarships, as a means of sharing benefits, in a situation such as the Malian case-study.[88] The point is, that in the areas in which this wild rice was found, and in the Bela community which conserved the rice, there was no one suitably qualified to take up a Ph.D. fellowship at UC Davis. This raises the point that the choice of instruments for sharing benefit should only be decided after much greater discussion with the communities who originally conserved the resource in question.

Finally, it is not without significance that the Bela community, a poor and deprived community living in swampy areas, was dependent in past on this wild rice to meet its food needs. This community had evolved a rich folkloric and daily knowledge in dealing with this rice. They, of course, knew that no disease or pest ever

attacked this rice. The scientists who collected this germplasm could have benefited much more had they involved this community in research on the use of this wild rice. But there was little dialogue among the scientists and this community, even in Mali.

India: The Case of the Kani – Trust Fund for sharing benefits

The need for a multi-stakeholder dialogue when addressing access and benefit-sharing was clearly brought out during this case study. Since the Forest Department had the legal control of a particular territory, they should clearly have been part of the dialogue and should not have been ignored when establishing an appropriate benefit-sharing mechanism. Furthermore, the degree of involvement of various tribal settlements and groups could have been increased. The rights of informants vis-à-vis the communities needed more discussion among the communities themselves. Sharing of research findings with the communities needed to be done in the local language(s).

The non-material contribution of benefits by way of empowerment of local communities deserves to be noted, but several more such benefits could have been considered; for instance, local communities urgently needed health check-ups, in particular the women and children, and such check-ups could have been considered as an additional non-monetary benefit.

Nigeria: The case for sharing benefits before drug development

The sharing of benefits by Shaman Pharmaceuticals, through the Bio-resources Development and Conservation Programme (BCDP), as a part of the International Cooperative Biodivesrity Group (ICBG) in the field of traditional medicine, even before any drug was developed, is praiseworthy practice. Not only that, but their commitment to share benefits with all the communities from whom they had source material, regardless of whether the final products emerged only from one lead from only one community, is a novel idea and is worth emulating.

Benefit-Sharing: an overall view

The dynamics of local social and economic conditions do not suggest a very optimistic future for TK. The young people in the community, curious as they are, do not see the TK based knowledge systems as a means of livelihood in future. It is here that benefit-sharing systems need considerable strengthening. All those who critique bioprospecting approach to use biodiversity, share benefits and thus provide incentives for conservation must confront this reality, which is evident all over the tropical world.

Some of the issues to be considered in the context of benefit-sharing are as follows:

- To what extent has the generation of awareness about rights of traditional communities and grassroots innovators among various stakeholders been effective in changing the way business is done? It seems that professionals, like scientists and academics, have been far more proactive than the corporations in this regard, with Shaman Pharmaceuticals being one of the few exceptions in this area. Most mainstream companies have so far shied away from making any bold attempt to tilt the scales in favor of local communities;
- Have the norms of benefit-sharing acquired the status of a professional value? For instance, before accepting a Ph.D. thesis, a certificate is generally taken from the student that s/he has acknowledged all the contributions in the research work. A similar declaration should be

mandatory for the researchers and commercial users of indigenous knowledge; i.e., that they have made due acknowledgements and reciprocal arrangements with the innovators. The norm of acknowledgement of local knowledge should become a professional value among germplasm collectors as well as ethno-biologists;

- What combination of monetary and non-monetary incentive would be optimal for which kind of knowledge systems and innovations and under what institutional arrangements? Unless such a contingent framework is developed, it is unlikely that most users of biodiversity will be able to initiate benefit-sharing experiments;
- We do not know what level of IP protection will make local knowledge systems vibrant and buoyant. Is it possible that fears about the erosion of local knowledge increasing due to its valorization are unfounded?
- What are possible reasons for such a dearth of information on experiments around benefit-sharing? Why are so few people trying to pursue these experiments? Why aren't consumers of value-added products in Europe and other Western countries as conscious of the rights of local communities and grassroots innovators, as they are about other kinds of human rights?
- What is preventing Non-Governmental Organizations (NGOs) and Governments in developing countries from initiating benefit-sharing measures at a national level, among the various institutions within the country? Why should domestic arrangements of benefit-sharing as attempted by Tropical Botanical Gardens Research Institute (TBGRI) and the Honey Bee Network not take place in many countries, rather than await the resolution of North-South conflicts?
- The consumers of herbal and other biodiversity-related products have never demanded fairer contracts with the local community. This indifference stands in contrast to the boycott of beef burgers in the U.S.A. some time ago to discourage environment-unfriendly rearing of beef in Latin America;
- What is the perception of local communities and innovators themselves on the issues of benefit-sharing?

Intellectual Property Rights: Using Existing Tools for Benefit-Sharing

Patents

Knowledge, which is already in the public domain, is generally considered not patentable. In the case studies carried out in India and Nigeria, the knowledge of the herbs used to produce drugs was not in the public domain. Further, the process, as well as the product, made out of the use of TK was new, non-obvious and involved value addition through further research in formal scientific laboratories involving considerable human inventive effort. Therefore these were patentable. The issue still remains that given the current definition of pubic domain in many developed countries, disputes could genuinely arise on this issue. The fact that this is a contentious issue requires an extensive reconsideration of public domain. When knowledge exists with a spatially bound community, though the know-how of its actual practice may exist only with a few local experts, and is not reasonably accessible to outsiders, and has not been catalogued in publicly accessible catalogues, it should not be considered the knowledge in the public domain.

Without the protection sought and obtained in the second and third case studies, the technology would not have been licensed for potential commercial exploitation and thus benefits would not have been obtained and shared. To this extent, the use of existing patent laws enabled the generation and sharing of benefits. In the Nigerian example, a trade name was also utilized to create a market niche for the product.

The benefit-sharing in all the three cases was voluntary and patent laws *per se* did not have any bearing on the same. It may have been quite possible, as has been the case in most other products based on genetic resources and associated TK, that the recipients of that those resources and that TK could have retained the entire commercial profits without violating any legal framework. The ethical violations would of course be obvious.

The scope of benefit-sharing with knowledge producers, reproducers and providers (individuals or communities) on the basis of existing IP systems is quite large for certain kind of innovations, but unfortunately has not been explored adequately. At the same time, there is a need for making substantial improvements in the current IP system to ensure that the benefit-sharing takes place in a fair and equitable manner. Also, it should not be just voluntarily, but should be a mandatory requirement in all cases of access to, exploration and utilization of TK, contemporary creativity and related biodiversity and other resources. While ethics cannot be mandated, justice can be.

Below, I will describe some of the issues that have emerged from the three case studies, and from experiences of the Honey Bee network.

Disclosure of Intellectual Property Applications

Domestic, as well as international agencies, have used a variety of ways to access biodiversity and TK. It appears that many of these agencies, together with other users of TK and associated biodiversity, have not yet recognized the need to disclose their attempts to seek IP on the knowledge obtained to the communities themselves. The Indian case study, and the Nigerian case study, to a lesser extent, are exceptions to this statements, as, of course, is the Honey Bee experience.

Whether this disclosure, and proof of prior informed consent, can be incorporated as a requirement in patent applications is an important issue. Some legal experts' view is that contracts concluded on the basis of insufficient disclosure of information cannot be legally questioned only on that account. For instance, information asymmetries have been exploited to extract rent from time immemorial. The issues are whether new legal regimes have to be created in the aftermath of the CBD, through revision of Art.27.3b of TRIPS, so that some of these questions can now be clarified. The ethical and moral basis of contracts, which are often asymmetrical in terms of knowledge, information and power, requires modification in the property right definitions. For instance, if a State accords property rights to a patent applicant on the basis of a disclosed invention, that State may well be within its rights to require that the applicant declares in an affidavit that the knowledge and materials used to create the invention have been obtained lawfully and rightfully. This will require enactment of laws in each country and at the same time, modification of laws in developed countries. This does not adequately take care of the issue of whether the claim is "rightful". I strongly believe that ethical responsibility of the patentee cannot be denied in such cases. While ethics cannot be legislated, it is useful to generate discussion on the subject, and thereby to slowly transform the consciousness of the dominant IP players.

Furthermore, it is the case that industry is invariably apprehensive about competitors coming to know about their sourcing strategies. Accordingly, they try to deal with such matters confidentially. Some of the draft access legislation requires a public notice about access agreements to ensure that everybody is aware of the impending contract. This is an issue, which will need to be further explored with country governments and the private sector, so that a consensus can be reached and best practices in such matters can evolve.

The Pew Ethical Guidelines raises an issue relating to the capacity of the host country or community to negotiate. Many times in the absence of this capacity, even if sufficient information is provided, the community and/or host country institutions may not have the capacity to process this information. Should this capacity building be considered a non-material benefit, which will always hold the community in good stead? Furthermore, those drawing up the Pew Guidelines did not come across any case where IP was shared between local healers and the scientists. This is so despite more than 75% correlation found between local knowledge and modern scientific information in some of the cases (Farnsworth, 1981). This is clearly an issue which needs considerable additional debate and discussion among scientific bodies.

Disclosure to local communities and the national authorities will be of different kinds. The initial disclosure can be distinguished from the subsequent sharing of information relating to the R&D carried out on the genetic resources and TK. This is an expectation, which has been articulated by many local healer individuals, and communities. The emphasis by some of the healers on the need for recognition of their contribution, while developing modern medicine or other products indicated the potential that exists for evolving best practices in material as well as non-material incentives for sharing local knowledge. Access by the communities to existing IP on products and services with which they are familiar will help in expanding their repertoire, and in generating pressure for further inventive efforts. However, so far no group has made the effort to disseminate patent information in the local language to a local community and individuals and in an easy way and comprehensible manner. It will be necessary to evolve institutional mechanisms, so that every provider of knowledge is entitled to receive state of the art information on the subject of his/her expertise. This is a challenging task, but is a goal worth pursuing.

The tendency of researchers, particularly ethno-botanists, to document and publish TK, generally without any acknowledgement of the local information providers must be censured unequivocally. Publication with acknowledgement also poses a dilemma. In the absence of publication, particularly in local language (scientists seldom do that), other communities may not be able to learn from each other. But with publication, their IP rights get preempted. In the absence of a registration system, which provides a low transaction cost system for quick protection, less and less knowledge may be shared, and still less knowledge may be published, a situation contrary to the fundamental objective of IP.

Duration of Intellectual Property Protection

For how long should the rights of communities or individuals drawing upon TK be protected? One view is that such rights should exist in perpetuity. The problem, of course, is that those who license this knowledge may not have a right of more than 20 years, as applicable in modern patents. However, if TK rights are considered valid for 99 years, then the licensees can also claim longer rights, as is the case in the trademarks and copyrights. The rationale for 99 years may be that at least four generations have no ambiguity about their rights in the knowledge, and thus can think long term while dealing with it.

Utility model/Petty patents

It has been suggested that for incremental inventions, or innovations where the inventive threshold is lower, one could use utility models to provide protection to innovators. However, the experience of the Australian IP office reveals that, even in a developed country,[89] a system of petty patents does not necessarily serve the purpose of making a small sector competitive and innovative, either through licensing external innovations, or through the internal development of innovation.[90] This is because the inventive threshold was too similar to the one required in the standard patent system. Accordingly, the Australian IP office recommended an innovation patent system, which would overcome some of the deficiencies of the utility model. It suggested that a inventor could get protection for 8 years, within 3 months of an application, and the payment of a small fee. The prior art requirement would be same as in a standard patent application, and a formality examination would also be undertaken on all applications. A substantive examination would, however, only be undertaken at the request of the applicant or a third party. Publication of the innovation patent application would occur 3 months after filing. Dual protection by both a standard and an innovation patent would be possible.[91]

My suggestions would be to further improve the Australian innovation system, so as to include a term of protection of at least 10 years, a lower inventive threshold, and availability of a product or use patent. Thus, an indigenous herbal drug developed by a local healer could receive a product patent for 10 years. During this period, potential manufacturers may get in touch with the inventor and may negotiate the right to file a standard patent for breakthrough follow-on innovation, if large scale manufacture was considered desirable and profitable. The fees should be negligible, but publication of the application within one year should be obligatory, and the granting of patent should not take more than one year or 18 months.

Such a provision of product and process patents through an innovation patent system might stimulate efforts on the part of local communities and healers, as well as other innovators, to seek quick short term protection for their non obvious knowledge. It is hoped that potential stakeholders in such innovations might enter into collaboration with the inventive community or individuals and, if successful, file for a standard patent with appropriate benefit-sharing clauses. However, it is also possible that such a thing may not happen unless public policy triggers a partnership between private and public sector laboratories and innovative communities are willing to bring their knowledge to the public domain through disclosure in the patent application. National and international registry systems have been proposed to incorporate elements of an innovation patent system, so as to provide incentives to local communities, herbalists and developers of plant varieties to share their knowledge, without forgoing the benefits possible through IP protection. The issue still remains as to whether knowledge produced over a long period of time through cumulative of contribution of communities in a given region should only receive short-term protection, with limited claims.

Developing low transaction cost system for small innovators

The cost of filing a patent varies considerably from country to country, but be very high. A survey carried out by Helfgott (1993) in 32 countries assessed the cost at between US$355 to US$4,772. However, a U.S.A patent application in the 1990s could be as much as US$20,000, whilst a patent application in the European Union could cost twice that amount. We need to devise ways of reducing these costs for small innovators and traditional communities. The proposal on INSTAR (International Network on Sustainable Technologies Applications and Registration) aims to provide limited period protection to local communities as well as herbalists, and might offer one way of reducing transaction costs for small innovators.

The rights of communities v individuals

The rights of communities to their collective knowledge may place constraints on individuals about what should be shared and with whom. It is true that local communities do process certain types of information collectively, through cultural processes and institutions generating a local common good. At the same time, certain individuals within a community demonstrate enormous creativity, and eventually become knowledge experts. Should the IP rights of these individuals be equal to the rights of local communities?

The protection of collective rights should not curtail or conceal the rights of individuals. It is all the more important, because there are local experts who may specialize in certain specific kinds of knowledge. Protection of their rights might provide incentives for such experts to emerge and be respected. We need to have mechanisms for protection of collective rights, just as we have for individual rights.

Distinctive signs (Geographical Indications, Certification Marks and Collective Marks)

TK, as well as biological and genetic resources produced and processed in a characteristic manner typical of a given region, and embodied in local life styles and linked with culture, could be protected through a distinctive sign, such as a geographical indications. Likewise, the certification mark, as attempted in the Nigerian case study, where certification by an international laboratory set up by the Bio-resources Development and Conservation Programme (BCDP), was used on the label of the drug to provide quality assurance, could provide consumers with an assurance about authenticity, and thereby improve the market prospects, and the consequent generation of benefits for the innovators and other stakeholders. Collective marks could also be utilized by associations of healers, seed producers and others to provide guarantees about quality, as well as authenticity of claims, and accordingly improve the prospect of market returns and consequent benefit-sharing.

Such provisions could go a long way in safeguarding traditional habitats and lifestyles, without constraining these by way of impoverishment and poverty. It is obvious that, if a particular production process and output does not derive any specific advantage from a given region, that production might move to a cheaper and more profitable location. In order to remain in work, local producers might be obliged to emigrate to that new location, or may become unskilled laborers in the previous productive region. Lot of TK and TK-related products have disappeared precisely through such erosion of opportunities associated with geographical regions. Most developing countries have not yet taken steps to provide protection to their locally distinct and characteristic products and process, based on value-addition by local knowledge and biodiversity. An international registry proposed to be negotiated under TRIPS for wines and spirits, could easily be expanded to include other biodiversity-related products.

Certification marks are also very important, for which national and international agencies will have to take the lead to provide recognition of distinct varieties of crops or horticultural plants or associated products, when grown in a given region. For instance, basmati rice would be a good case to protect through geographical indications, as well as certification marks, because the characteristics of the varieties are associated with a specific geographical region in South Asia.

Traditional Knowledge Documentation

Documentation and Prior Art

Documentation of TK about genetic and biological resources is extremely important to prevent its erosion over time, to enable its accessibility to subsequent generations of the same community, as well as other communities, to attempt value-addition and possible benefit-sharing among various stakeholders, and finally to link innovation, investment and enterprise. It is obvious that, in the absence of documentation, potential investors and entrepreneurs would have to bear a very high transaction cost in order to seek information about potentially viable and useful IP produced by local communities and individual innovators. The transaction cost for a community to scout potential partners for value addition would even be higher. In such a situation, a single TK documentation focal point, based on international and national campaigns for documentation, could be extremely useful.

The National Innovation Foundation (NIF) set up by the Indian Department of Science and Technology in March 2000 has attempted a solution to this problem. It has been mandated to build a national register of grassroots innovations and inventions and outstanding TK and, in effect, to act as a clearing house for Indian TK. The documented knowledge would be shared only in accordance with the directions of the provider of knowledge. Unless authorized by the provider of knowledge, it will not be shared with anyone for any purpose and will kept in the register as a confidential entry. However, broad categories of the knowledge or innovation or practice will be shared, so that interested seekers of this knowledge can be put in touch with the providers. In 2001, NIF ran its first annual campaign for scouting innovations and TK and received more than 1,800 entries from all over the country.

It is possible that same claims may be filed by more than one community. In such cases, NIF would include other claimants as co-innovators, or co-inventors, of the knowledge. In all cases where documented knowledge has not been revealed in any publicly accessible databases, it would be considered new. Just because a particular knowledge is well known among a small community, it cannot be considered as a part of prior art because it is not reasonably accessible to an outside researcher.

There is a need for international agreement on the issue of the documentation of TK and prior art. The WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore should be encouraged to continue its valuable work on this issue as a matter of priority.

Essential Disclosure by an Applicant

SRISTI has also been pleading for several years that databases of community, as well as grassroots knowledge, whether or not electronically available, should be accessed by patent offices to avoid issuance of trivial or improper patents. Specific steps required to encourage patent offices to consider such sources of information are as follows:

- Published data on ethnobiology, indigenous knowledge and other innovations should be converted into electronic databases, so that each patent office can screen these before issuing any patent. The cost of building up of these databases will have to be raised from multilateral sources. In some cases, translation from local languages will also be necessary;
- There should be incentives for groups documenting local knowledge to share such knowledge with patent offices;

- Patent offices, which do not disclose patent applications before granting the patent, should be obliged to make the applications public after a reasonable period of time of application, so that objections can be filed by any interested groups;
- There is a tremendous amount of knowledge which is available only in oral form and has not yet been documented. There have been cases when such knowledge communicated in good faith by local people has been used without acknowledgement or reciprocity to claim IP on the same. There should be severe penalty for such attempts, so that these act as a deterrent. At the same time, mechanisms should be put in place for a world-wide campaign for documentation and registration of these knowledge systems;
- Just as a discussion is taking place in the United States of America on linking the application cost of patents with the number of claims, there should be similar incentives for disclosing extensive prior art. This will encourage applicants to make extra efforts to disclose as much prior art as possible and, accordingly, pay a reduced application fee. This is particularly applicable for patent applications based on biodiversity-related knowledge and resources;
- Not every localized knowledge, which is not yet documented, should be considered public domain, unless it is easily accessible. Therefore, oral TK in which some improvements may have been made should be eligible for being considered patentable. This will help communities to decide whether they would like their knowledge to be public domain, and thus become part of prior art, or whether they would like it to come in public domain after getting protection for a given period of time.

New Systems of Protection: A Balancing Act

Any new system of protection will have to balance the long-term needs of a community to have a vested interest in the conservation of their knowledge systems, and yet provide incentives for those who may add value to share the benefits of using that knowledge for a limited period of time. In my view, any new system should discriminate between rights of communities in the knowledge systems *per se*, vis-à-vis the rights in a specific knowledge output. The rights in the systems should be perpetual. For instance, the classical health systems such as Ayurvedic, Unani or Sidhdha have recipes which are being granted patents in a rather indiscrete manner. This is improper. However, modifications in these recipes should be permissible for patenting, with the understanding that a share of the benefit will go into a global pool of funds for augmenting indigenous systems of medicines. This is similar to a system for plant varieties, in which improved varieties based on land races should contribute a share to a global and/or regional fund for *in-situ* conservation. Since every such benefit is shared ultimately at the consumer's costs, it is only natural that consumers should pay for the conservation of diversity.

Filing an objection in cases where IP has been obtained on TK could pose two problems:

- If local community knowledge is considered prior art, then it might facilitate challenges of existing patents, but it also might prevent local communities seeking new IP on knowledge that it known within the community, on the basis that it is already in the public domain;
- It may be difficult to prove that a plant found in many places originated from a particular area or particular TK.

These issues are very complex. My own preference is that communities have more to gain by accepting that much of the local knowledge is considered outside the prior art definitions, unless it is well known, and is in

public domain through widespread practice. For all other cases, where knowledge is restricted only among a small localized community otherwise inaccessible to outside scholars or corporations, it should be considered a patentable subject matter.

Intellectual Property Information System

The ability of local communities to use existing IP instruments depends considerably on their ability to access existing IP information displayed in their own language, close to their place of residence, in a user-friendly manner. The situation could be considerably improved by the establishment of pilot projects by the educational research community, local non-governmental organizations, and public service legal agencies, who could provide support to local communities in searching and interpreting existing IP on biodiversity, genetic resources and associated local and TK system. Such an information system would have to have a national or international hub that would permit national and international IP support organizations to play a role in educating, as well as empowering local communities. One idea would be the establishment of IP help-desks, capable of handling queries from local communities in local language(s). It is obvious that the current capacity of WIPO, and of national IP systems, is insufficient compared to the need of large number of communities all around the world, and consideration should be given to increase their capacity in this regard. In addition, many communities, which do not support the concept of IP on their community knowledge, would also like to make sure that others do not seek private individual IP rights on their knowledge. The proposed IP Information System, which could be administered by WIPO, should take care of the needs of these communities, as well.

Conclusions

It is always necessary in any policy research to use available experiences to illustrate and guide what may be possible in the future. The three case-studies have demonstrated the potential that exists for using existing IP instruments for the protection of local knowledge and, in some cases, for the protection of genetic resources, so as to share benefits in an equitable and fair manner. At the same time, my analysis has shown the limits of what can be done within the framework of existing IP systems. It is for this reason that I have made various suggestions going beyond the implications of the case-studies themselves.

In particular, it has been my contention to articulate the need for a stronger IP regime to support the rights of local communities and individuals in the preservation of their knowledge, innovations and practices. It is obvious that to do so will require change at a local, national, regional and international level. Unless each country takes a lead, at a domestic level, to provide protection for its own peoples' knowledge and its own genetic resources, the ability to enforce these rights internationally may be inadequate. At the same time, developed countries will have to recognize that the capacity of most least developed countries and many developing countries is unlikely to increase significantly in the short term and must be prepared to build capacity in this area.

Does this imply that the asymmetrical access and use of local and TK by corporations and institutions of developed countries will continue unabated? It is hoped that steps will be taken by patent offices in developed countries to create a precedence of more ethical and responsible behavior. One such example involved a request by a developed country patent office to access to an electronic database of TK from a particular developing country, so that the developed country patent office could avoid issuing patents on TK, already in public domain. This led to the development of the Indian Traditional Knowledge Digital Library (TKDL) initiative. This is just one example of what can be done to create the right environment for some of the initiatives that may eventually take place at a global level.

Increased erosion of biodiversity and associated TK will clearly not be halted by documentation. This is particularly true for genetic resources, which co-evolve with human societies over a long period of time. The *in-situ* conservation of wild, as well as agro-biodiversity suddenly becomes important. In the absence of various incentives, it is unlikely to take place. My suggestion is that IP provide an important means for strengthening the range of incentives that local communities need for conserving genetic resources and associate TK. In fact, IP can also provide incentives for augmenting this knowledge and resource base. The Honey Bee Network has documented many examples of plant varieties being developed by local farmers, using traditional methods and knowledge systems. In the absence of adequate mechanisms to provide protection for such efforts, proper incentives are not yet available to encourage more people to pursue such innovations. The ultimate test of any incentive system is whether it can nurture and augment the spirit of experimentation, exploration and sharing, so evident in traditional communities over the years. We need to find ways of ensuring that the value system of many of these communities does not become a reason for their remaining poor, and thus, ultimately, eroding their vitally important knowledge and resource base.

87 For instance, the Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit-Sharing: a pilot project on implementation of the CBD by and for botanic gardens and herbaria.

88 Honey Bee 8(2) 16-17, 1997.

89 The case of providing such protection to communities, of course, remains within the realm of speculation, since the same has not been tried.

90 On average 300 Petty Patent applications were filed, with 50% to 60% granted as patents. Foreign applicants were rare. Individuals, rather than companies, made the majority of the Petty Patent applications. By comparison, Australia received 20,000 applications for standard patents, out of which only 10% were made by Australians.

91 Review of the Petty Patent System, Advisory council of industrial property, AIPO Canberra, 1995.