

# **BIOPIRACY: AN EMERGING DIPLOMATIC CHALLENGE**

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**PAPORI KONWAR**



**CENTRE FOR THE STUDIES IN DIPOMACY,  
INTERNATIONAL LAW AND ECONOMICS  
SCHOOL OF INTERNATIONAL STUDIES  
JAWAHARLAL NEHRU UNIVERSITY  
NEW DELHI-110067  
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CENTRE FOR STUDIES IN DIPLOMACY, INTERNATIONAL LAW AND ECONOMICS  
SCHOOL OF INTERNATIONAL STUDIES  
**JAWAHARLAL NEHRU UNIVERSITY**  
NEW DELHI - 110 067

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**CERTIFICATE**

Certified that the dissertation entitled '**Biopiracy: An Emerging Diplomatic Challenge**', submitted by Papori Konwar, Diplomatic Studies Division, Centre for Studies in Diplomacy, International Law and Economics, School of International Studies, Jawaharlal Nehru University, New Delhi-110067, India, in partial fulfillment of the requirements for the award of the Degree of Master of Philosophy, is her original research work and has not been previously submitted for any other Degree of this or any other University.

We recommend that this dissertation may be placed before the examiners for evaluation for the award of the Degree of Master of Philosophy.

Prof. Manoj Pant

**(CHAIRPERSON)**

Centre for Studies In Diplomacy  
International Law and Economics  
School of International Studies  
Jawaharlal Nehru University  
New Delhi-110067

Prof. Pushpesh Pant

**(SUPERVISOR)**

Professor  
Centre for Studies In Diplomacy  
International Law and Economics  
School of International Studies  
Jawaharlal Nehru University  
New Delhi-110067

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*Papori Konwar*  
Papori Konwar

## List of Abbreviations

ABS	access (to genetic resources) and benefit sharing
ARA	Academic research agreement
BDA	Biodiversity Act (India)
BMC	Biodiversity Management Committee (India)
CBD	Convention on Biological Diversity
CoP	Conference of the Parties
CITES	Convention on International Trade in Endangered Species of Wild Flora and Fauna
CRA	Commercial research agreement
CSIR	Council for Scientific and Industrial Research
CTE	Committee on Trade and Environment
EPO	European Patent Office
FAO	Food and Agriculture Organisation
GATT	General Agreement on Tariffs and Trade
GI	Geographical Indication
GMO	genetically modified organism
HGDP	Human Genome Diversity Project
IAC	Inter-Agency Committee
IGC	Intergovernmental Committee
IMF	International Monetary Fund
IP	intellectual property
IPC	Intellectual Property Committee
IPR	intellectual property right
LMMC	Like Minded Megadiversity Countries
LMO	living modified organism
MAT	mutually agreed terms
MEA	Multilateral Environmental Agreement
MS	Multilateral System
MTA	Multilateral Trade Agreement; multilateral transfer agreement

NBA	National Biodiversity Authority
NBSAP	National Biodiversity Strategy Action Plan
NGO	non-governmental organisation
NTFP	non timber forest products
OECD	Organisation for Economic Co-operation and Development
PBR	plant breeder's rights; People's Biodiversity Register (India)
PEO	Presidential Executive Order (Philippines)
PGRFA	plant genetic resources used for food and agriculture
PIC	prior informed consent
RAFI	Rural Advancement Foundation International (Canada)
R&D	research and development
SBB	State Biodiversity Body
TKDL	Traditional Knowledge Digital Library
TNC	transnational corporation
TRIPS	Agreement on Trade-related Aspects of Intellectual Property Rights
UN	United Nations
UNEP	United Nations Environment Programme
UPOV	Union Internationale pour la Protection des Obtentions Vegetables (International Union for Protection of New Varieties of Plants)
USPTO	United States Patent and Trademark Office
WIPO	World International Property Organisation
WTO	World Trade Organisation

## Preface

The international political and economic arena is riddled with iniquitous relationship between the developed and the developing countries that cuts across almost all spheres of their interactions. It has remained unchanged over the centuries which have witnessed tremendous developments in the fields of technology, industries, institutions etc.; infact the developments can be said to be manoeuvred by those who wanted this inequity to perpetuate by keeping the developing countries out of the development bandwagon. The only option left for the developing countries (including the least developed countries) is to struggle for their even rightful share. The one thing that has changed over the years is that the methods of plundering and exploitation have become more sophisticated and subtle.

The developing countries have an inherent right to the fruits of development because they have been historically the natural resource base for the development brigade. However the developing countries have been compelled to surrender this right in the hopeless struggle for the recognition and reward of their contribution. They are being forced by the international regimes to accept an unequal partnership with their own exploitators and to boost up others' economies at their own cost.

With unprecedented progress made in the field of biotechnology, the same old relationship applies appropriately when the tussle over biological resources and related traditional knowledge is taken into view. Form engineering micro organisms, plants and animals to the mapping of human cell lines, biotechnology has become a big business. This enormously profitable business is an absolute prerogative of the Northern (developed) countries, notwithstanding the fact that the genetic resources to for this biotechnology industry are from the immensely biodiverse and culturally

diverse Southern (developing) countries. The Southern tropical countries which are home to around 80% of the world's biological diversity and which have 95% of world's cultural diversity lying among their people, have been providing biological resources to the Northern food and pharmaceutical corporations, biotechnology companies and R&D establishments to create new types of medicines and agricultural products by manipulating the living materials. Problem arises when these institutes and corporations extract not only the resources but also the traditional knowledge about the various uses of these resources far and above the legitimate manner and without acknowledging the origin of the resources and the knowledge. In addition to these, with minor tampering with the available traditional knowledge on their various uses, the biological resources are packaged into patentable and profitable products. The Transnational companies (TNCs) have sought to establish monopolies on seed, medicines etc. under the international patent regime, thereby stealing away the right over resources from the owners. This practice is precisely termed as 'biopiracy' by many developing countries.

The developing countries are desperate because this very practice which they term illegal is largely legitimized by the WTO TRIPS Agreement (1995) which has universalized a biased and westernized patent regime by outrightly neglecting that biopiracy exist.

However taking recourse to the United Nations on the Convention on Biodiversity (CBD) of 1992, the developing countries have been negotiating in the TRIPS Council forum to make the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) compatible with the CBD, particularly to make the Intellectual Property Rights (IPR) regime more transparent and accountable while dealing genetic resources and traditional knowledge. At the same time negotiations



have been going on within the CBD framework to establish an international equitable and access and benefit sharing mechanism for biological resources and traditional knowledge.

The entire gamut of issues relating to biodiversity and traditional knowledge has now come into the diplomatic arena and has thrust enormous responsibility on international environmental diplomacy. The diplomatic clout and bargaining strategies of the concerned countries would determine the status of South's biodiversity and associated traditional knowledge vis-à-vis the international IPR regime. It has proved to be rather challenging to the developing countries to negotiate for international IPR protection to traditional knowledge because in the first place, many of the developed countries have ruled that the TRIPS Agreement cannot extend IPR protection to traditional knowledge and secondly because these countries consider that national legislations are more effective in protecting traditional knowledge. With such basic contradiction at the negotiations fora, the developing countries are quite apprehensive about a diplomatic breakthrough to deal with rampant biopiracy.

This dissertation is structured to analyse the nuances involved in the diplomatic interactions between the developed and the developing countries in the TRIPS and the CBD fora on the twin issues of biodiversity and traditional knowledge. The study aims at exploring the possible avenues of compatibility between the negotiating blocks so that the tropical Southern countries can effectively safeguard their biological resources and related traditional knowledge from the biopirates. The study would also analyse how viable the Food and Agricultural Organisation (FAO) and the World Intellectual Property Rights Organisation (WIPO) could be in protecting plant genetic resources, community rights over their resources and

traditional knowledge and farmers' rights. The TRIPS Agreement and the CBD require that the member countries establish their own *sui generis* legislations to protect plant varieties and farmers' rights and national biodiversity legislations to protect biodiversity and traditional knowledge. The study would also explore how far these options are sufficient in the absence of an international legal mechanism.

The first chapter would introduce the concepts of biopiracy and bioprospecting and their interrelationship based on the hypothesis that bioprospecting facilitates biopiracy. The chapter will justify the graveness of the problem of biopiracy to the biodiversity rich developing countries with experiences from around the world and will seek to identify their core concerns as well the factors that aggravate the situation.

The second chapter will delve into the contradictions between the TRIPS Agreement and the CBD to analyse how real the conflicts are and how they can be reconciliated through diplomatic interactions. Their interactions within these frameworks to build mutual compatibility will be evaluated. The viability of involving the WIPO and the FAO in this context will be examined in this chapter. This chapter will also introduce the important concepts and their interrelationship, which will be subsequently discussed in the dissertation. The issues of biodiversity, traditional knowledge, IPRs, bioprospecting, access and benefit sharing, prior informed consent (PIC) etc. are intertwined in the whole debate about biopiracy.

The third chapter will deal with India's concerns, India's domestic and diplomatic measures for the issue of biopiracy. The chapter will study the impact of the people's movements for the protection of biological resources, community rights over resources and traditional knowledge on the governments domestic and international biodiversity policy.

The next chapter will cover select developing countries from around the world, which have developed national measures to regulate access to their biological resources and traditional knowledge. These cases would shed light to the hypothesis that national measures are not adequate to protect biodiversity and related traditional knowledge from biopiracy. The prospects of establishing an international regulatory regime for access and benefit sharing may not be promising at the moment, but it is considered very instrumental by many developing countries to check the irresponsible flow of their resources to the developed countries. The other indispensable step to combat biopiracy is the dilution of the TRIPS regime as proposed by the developing countries. But above all, any kind of legal protection or regime, be it national or international, to be considered effective, should ensure the involvement of local and indigenous people as direct beneficiaries as well as decision makers in issues that concern them.

# Chapter 1

## Introduction

The issue of **biopiracy** has come into vogue recently but is the mere extension of debates that have divided the North and the South for decades. The controversy has come into sharp focus because of the industrialised nations' interests in securing trade benefits from high technological industries and the developing nations' attempt to maintain a hold over the biological resources, which are owned by them but are used by the high technological industries to make enormous profits.

The concern of some developing countries about **biopiracy** surfaced around the same time when the world, particularly the developed countries were raising a hue and cry about the dwindling rainforests along with their biodiversity. Biological diversity is the variability among living organisms from all sources and includes diversity within species, between species and of ecosystems. Biodiversity is of extreme importance in the ecological, biological and cultural sense. When in the 1980s the unprecedented loss of biodiversity was noticed globally, many of the developing countries were also waking up to the fact that pharmaceutical, food and biotechnology companies from the developed countries were making huge profits from products developed from their plant genetic resources and were using their traditional knowledge associated with the various uses of the genetic materials, without acknowledgement and compensation. The age of biopiracy had begun.

A new but gloomy picture has begun in the long and exploitative history of the developing countries that have been the resource base for most of the industrialisation that took place in their developed counterparts. With the boom in

the biotechnology sector in recent years, once again the wave of exploitation has regained its vigour, now with all eyes and hands on South's biodiversity. Plant and animal genetic resources from Southern countries have been appropriated by the biotechnology rich Northern countries without compensation and acknowledgement. The runaway world of IPRs helps them to patent the food and pharmaceutical products made from these genetic resources, which are just manipulated modifications of the already existing traditional forms of the products. Many developing countries name this manipulation as **biopiracy**. The developed countries give it a cloak of respectability and call it **bioprospecting**. Many developing countries consider **biopiracy** as just another strategy of the developed world to rob them of their green gold, i.e. biodiversity. Biopiracy is all the more menacing because it is armoured with an IPR regime (read TRIPS) that facilitates this act.

However, international law has not defined uncompensated extraction as piracy. Therefore many developed countries view that the characterization of such acts as biopiracy serves more as a normative assertion by the developing countries that they have a right over their genetic resources. In recognized legal terms, claim of biopiracy will involve unauthorized access to genetic resources and using those resources in a manner that contravenes national biodiversity legislations. This criterion is minimalist and inadequate because it is conditional to the existence to the existence of national legislations only, whereas the emphasis should have been on an international standard. Any number of national legislations to protect biodiversity and related traditional knowledge do not suffice in the absence of international legal standards for access and benefit sharing. Therefore the claim of biopiracy should stand valid even in the absence of national biodiversity legislations. The requirement of national law is essentially to provide national

protection to biodiversity, which is by itself an important step towards controlling the flow of genetic resources from the South to the North. The second and more crucial step would be to establish a fair and equitable access and benefit sharing regime under the CBD framework which is unfortunately not forthcoming because the roots of the problem lies somewhere else.

### **Defining Biopiracy**

**Biopiracy** is an offshoot of the TRIPS regime. **Biopiracy** involves the unauthorized and uncompensated extraction of biological resources and associated traditional knowledge by Northern based biotechnology companies, seed companies, pharmaceutical corporations and Research and Development (R&D) through the process of bioprospecting. These genetic materials then undergo rapid and precise screening procedures that allow for the isolation of chemicals displaying a specifically targeted activity, be it of medicinal or agricultural value. In most instances, the traditional knowledge about the various uses of the genetic resources are also procured and based on such knowledge, the researchers produce profitable and patentable products with little innovation of their own. A patent allowing transnational corporations (TNCs) and R&D establishments to deprive the poor in the developing world from using their own biodiversity and knowledge to meet their needs for food and medicine is called **biopiracy**.<sup>1</sup>

The international IPR regime not only legalises such piracy but also effectively negates all the contributions of indigenous cultures in developing the knowledge about the uses of biological resources and in nurturing the valuable plant

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<sup>1</sup> Shiva Vandana, *Campaign Against Biopiracy*, (New Delhi, Research Foundation for Science, Technology and Ecology), 1999, p. 10.

genetic resources over the centuries. On the contrary, the IPR regime creates an order in which the original innovators, i.e. the indigenous people of stealing what they themselves had originally innovated and have been using for generations.<sup>2</sup>

Many in the developed world claim that biopiracy is an emotionally loaded accusation against bioprospecting. But it is also true that under the vast majority of current bioprospecting agreements whereby indigenous people share information or genetic materials, they effectively lose control over such resources, regardless of whether they are compensated or not.<sup>3</sup> While it is true that ideally patenting of a product do not technically stop the traditional use that biological material, the current practice proves otherwise. In many instances of patenting, such as on neem and turmeric, there is hardly any difference between the patented process and product and the traditional use of neem and turmeric, thereby making the indigenous communities vulnerable to legal action for practicing their own traditional knowledge. The patent holder enjoys all rights to produce and profit from the same traditionally used biological resources, whereas the traditional knowledge systems are not protected by any IPR system.

### **Bioprospecting and Biopiracy**

Biodiversity prospecting, **bioprospecting** in short, encompasses a wide range of commercial or potentially commercial activities including the pharmaceutical, biotechnological, seed and crop, horticulture, botanical medicines, cosmetic and

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<sup>2</sup> Ibid.

<sup>3</sup> 'Bioprospecting, Biopiracy and Indigenous People', RAFI COMMUNIQUE, Rural Advancement Foundation International, Nov/Dec, 1994.

personal care, food and beverage sector etc. The term should not be confused with activities like bulk trade in timber or cut flowers, the collection of non timber forest produces (NTFP) such as high intensity protein sweeteners for local and regional trade and mining for minerals etc. Bioprospecting also do not sales of raw plant materials for the purpose of manufacturing pharmaceutical drugs, or the continued sale of products based on genetic resources.<sup>4</sup> One of the earliest definitions of bioprospecting puts it as the exploration of biodiversity for commercially valuable genetic resources and biochemicals.<sup>5</sup> Yet another way of putting it is that 'it is the research, collection and utilization of biological and genetic resources for purposes of applying the knowledge derived therefrom to scientific and/or commercial purposes'.<sup>6</sup>

Another definition provided by a Canada based NGO RAFI (Rural Advancement Foundation International), bioprospecting is the exploration, extraction and screening of biodiversity and indigenous knowledge for commercially valuable genetic biochemical resources.<sup>7</sup> The definition provided by RAFI brings out the exploitative nature of bioprospecting. This definition asserts that along with biodiversity, bioprospecting also involves scanning of traditional knowledge about the various uses of the resources. It may be acknowledged that bioprospecting does not necessarily involve the use of traditional knowledge, but it is also clear that valuable

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<sup>4</sup> Laird, Sarah A. and Kate, Kerry ten, 'Biodiversity prospecting: the commercial use of genetic resources and best practice in benefit sharing' in Sarah A. Laird (ed), *Biodiversity and Traditional Knowledge: Equitable Partnership in Practice*, (London, Earthscan Publications Ltd.), 2002, pp. 278-79.

<sup>5</sup> Reid, W.V. et al (eds), *Biodiversity Prospecting: Using Genetic Resources for Sustainable Development*, (Washington DC, World Resources Institute), 1993, pp. 34.

<sup>6</sup> Charles Victor Barber and Antonio La Vina, 'Regulating access to genetic resources: the Phillipines Experience' in Mugabe, John et al (eds), *Access to Genetic Resources: Strategies for Sharing Benefits*, (Bonn, IUCN), 1997, p.124.

<sup>7</sup> Refer to Note 3.



commercial compounds derived from plants, animals and micro-organisms are more easily identified and are of greater commercial value when collected with the help of traditional knowledge and/or are found in territories traditionally inhabited by indigenous people.

The Northern countries, which have the biotechnology but lack in biodiversity, and the Southern biodiversity rich countries lacking in biotechnology, can ideally engage in mutually benefiting agreements. This is the logic behind bioprospecting. Fair and equitable benefit sharing arrangements with the context of a mutually agreed legal and policy framework can be in the interests of all the stakeholders involved including governments, research institutes, local communities and companies in both the provider and the user countries. But bioprospecting as advocated by the Northern countries have conveniently done away with the 'equitable benefit sharing' aspect and have plunged into full-scale commercial exploitation of South's biodiversity and traditional knowledge.

Many developing countries are concerned about the current bioprospecting activities because the international legal and policy environment do not adequately ensure prior informed consent and equitable benefit sharing. Though bilateral bioprospecting agreements are sanctioned by the CBD, in vast number of cases, commercial bioprospecting agreements can't be effectively monitored and enforced by the provider communities and countries or by the CBD. Under these circumstances, many developing countries apprehend that **bioprospecting is nothing more than legalised biopiracy.**

When the definition of bioprospecting itself is so contentious, differences among various countries about the utility of bioprospecting contracts are bound to be

grave. Most of the biotechnology hub countries whose profits burgeon with on the supply of genetic resources from the tropical countries find it convenient to propagate the ideal nature of bioprospecting. It is their most effective key to the biological riches of the South. What most developing countries are opposed to is that while access is ensured in the bioprospecting contracts, very often benefit sharing is not equitable.

The other crucial difference in their perspectives is about the role of traditional knowledge in bioprospecting. The Northern countries generally do not acknowledge the role traditional knowledge in bioprospecting. However traditional knowledge does help enormously in identifying the valuable compounds in plants and animals. One example cited by RAFI is that 86% of the plants used by the Samoan healers displayed significant biological activity when tested in the laboratory. In another instance, crude extracts of plants used by one traditional healer in Belize gave rise to four times as many positive results in the laboratory tests for anti-HIV activity than did specimens collected randomly.<sup>8</sup> Traditional knowledge about the different uses of biological resources as food and medicine are time tested and practised by indigenous people for centuries. They are also the nurturers of these resources and therefore it is but natural that the most valuable resources are found with the indigenous people. But despite owning the knowledge which forms the basis of bioprospecting activities, the knowledge of the indigenous people feature nowhere in the definitions of bioprospecting as adopted by developed countries. These differences make the debate about the relationship between **bioprospecting** and **biopiracy** more polarised.

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<sup>8</sup> Ibid.

Many developing countries find the unregulated bioprospecting agreements as inherently inequitable due to the disproportionate negotiating strengths of the TNCs and their potential for misappropriating and monopolising biological resources and traditional knowledge through the utilisation of IPR regimes. There are certain circumstances, which substantiate these fears. In the first place, there is no international legal mechanism for rewarding the indigenous people on an equitable basis for safekeeping biodiversity. There are international mechanisms, on the other hand, to promote bioprospecting without laying down specific terms and conditions for benefit sharing. The CBD itself promotes such bilateral agreements but fails to provide a strong plan of action for sharing benefits with the local communities. By not being specific about who should be parties to such agreements, the indigenous communities or the countries, there is a possibility that the CBD might pit them against one another. Bioprospecting, at its present form, facilitates the flow of biological materials from the tropical countries to the North and further in their patenting. International regulation is a prerequisite to check the misuse of bioprospecting.

### **The TRIPS Agreement and Biopiracy**

By extending IPRs to biodiversity based products as well as life forms, the TRIPS Agreement has pushed biodiversity related traditional knowledge systems to destabilisation. It facilitates monopoly control of biodiversity related products which are otherwise in the public domain (article 27 of TRIPS). This particularly affects the rural poor and the indigenous communities who depend on biodiversity for day-to-day survival. Biopiracy therefore commits a double theft. First it steals genetic

material and traditional knowledge from their owners and secondly, through monopolisation of the same, robs the dependants of their means of subsistence.

The TRIPS Agreement overlooks the contribution of traditional knowledge systems in developing and modifying valuable genetic resources and which are now being used as filter by TNCs and R&D establishments. A patent claim on products developed with minor modifications of the traditional process is cleared as an innovation, failing to acknowledge its 'prior use' traditionally.

The TRIPS Agreement has put all member countries under tremendous pressure to establish the patenting of life forms namely, microbes, genes, crops, livestock and even human cells. The real push behind this pressure is generated by the mega TNCs who want patent rights on these items to increase their profits from the global sales of food, drug and technology. Their stake mainly lies on the new markets and legal control over the basic technologies and resources of global food and health care systems. It is not surprising that the TRIPS Agreement caters to the commercial interests of the mega corporations, when in fact a coalition of twelve American corporations under the banner of Intellectual Property Committee (IPC) participated in the conception and shaping of the TRIPS framework. These TNCs are Bristol Myers, Dupont, General Electric, General Motors, Hewlett Packard, IBM, Johnson & Johnson, Merck, Monsanto, Pfizer, Rockwell and Warner.<sup>9</sup> Many among these corporations have direct stake in biological resources of the South.

Patents on life forms have been widely practised in the developed world since the mid-1980s. One of the first cases that legalised such patents was in the U.S. when

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<sup>9</sup> Note 1, pp.11-12.

the U.S. Supreme Court in the case 'Diamond vs. Chakraborty' (1980), ruled that genetically altered plants are patentable.<sup>10</sup> In 1987, US Patents and Trademarks

Office (USPTO) extended patenting to all altered or engineered animals stimulating within a few years, series of patents in the North to microbes, plants, animals and human cell lines and genes.<sup>11</sup> The TRIPS Agreement has forcefully universalised this Northern practice. On the other hand, the most crucial question revolving around a wide range of ethical, economic and political concerns is being thrown out from the backdoor, i.e. whether it is right that corporations should own the biological underpinnings of life. These questions do not find any place in the global talks.

### Patents on human and animal genes

***MO cell line:*** In 1976, a leukaemia patient, John Moore had undergone surgery at the University of California Medical College to remove a cancerous spleen. The University was granted patent for a cell line called the MO removed from the spleen which could be used to produce valuable proteins worth an estimated \$1 billion. Moore demanded the return of the cell lines and control over his body parts, but the California Court ruled that he had no entitlement to any rights to own his cells after they have been removed from his body.

***The Human Genome Diversity Project:*** The HGDP launched by scientists of North America and Europe has come under condemnation by many

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<sup>10</sup> Somasekhar, M, "Indian drug firms focus on micro-organisms", <http://www.thehindubusinessline.com/2005/03/15/stories/2005031502640200.htm>

<sup>11</sup> Warner, Keith Douglas, "Are Life Patents ethical? Conflicts between Catholic Social Teaching and Agricultural Biotechnology's Patent Regime", *Journal of Agricultural and environmental Ethics*, Vol.14 (2001), p.301-319.

indigenous communities. The HGDP has been collecting blood, tissue and hair samples from hundreds of 'endangered' and 'unique' communities to be used to create 'transformed' cell lines of each community.

***Umblical Cord:*** Biocyte, a pharmaceutical corporation has been granted patents in the U.S. and Europe that give it right to the blood cells extracted from umblical cords of new born babies.

***The Oncomouse:*** The mouse genetically transformed to be susceptible to cancer was first animal to be patented in 1987 in the U.S. to DuPont Co. DuPont's European patent applies to all such animals and their descendants. The corporation also claimed patent protection on anticancer products ever derived from the mice.

### Patents on Plant Genes and Seed Varieties

***Bt Gene:*** A naturally occurring soil bacterium called the *Bacillus thuringiensis* (Bt) produces a protein that kills a range of common insects once it is ingested. Biotechnologists have isolated the Bt gene and inserted into a range of crops including rice, cotton, maize, soybean, tomato, potato etc. enabling these crops to produce their own insecticides. More than 400 Bt related patents have been granted to biotechnology companies worldwide, with 60% of them being owned by just top ten industrialised countries. This is an example of not only how a naturally occurring substance is patented by misappropriation of the patent regime but also how biotechnology is heavily concentrated in a few hands.

*Soybean:* Agracetus, now owned by Monsanto Co. was granted an European patent in 1994 which claims 'a soybean seed which will yield upon cultivation a soybean plant comprising in its genome a foreign gene effective to cause the expression of a foreign gene product'. This patent thus covers all transgenic soybeans.

*Rice:* Till 1998 there were some 160 biotechnological patents on rice in the world and the figure has been continuously rising up. The top 13 rice patents holders are TNCs in the US and the Japan, which cover more than half the rice patents.<sup>12</sup> These companies have produced herbicide tolerant rice varieties which infact make farmers use a particular type of herbicide, which the same seed companies or their partners manufacture. Another trend in corporatising rice is the development of hybrid rice. The 'Terminator Technology' developed by Delta Land and Pine (now owned by Monsanto) with the help of US Department of Agriculture, developed a gene that simply prevents genes from germinating.<sup>13</sup> The patent claims the gene's use in any plant including rice. Genetically engineered crops as such are developed primarily to stop the resowing of saved seeds by farmers. RAFI estimates that this practices threaten food security over one billion farmers in the developing world. Another form of gross violation of the IPR regime is the patenting of Basmati rice of the Indian subcontinent and the Jasmine rice of Thailand by the Texan TNC Rice Tec Inc. This Texan firm derived the varieties from the International Rice Research

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<sup>12</sup> 'Biopiracy: TRIPS and patenting of Asia's Rice Bowl', <http://www.geocities.com/RainForest/7813/0921/rice.htm>.

<sup>13</sup> Ibid.

Institute (IRRI) claiming that it has modified the varieties through breeding

**Quinoa:** It is a high protein cereal, which forms an important part of the diet of millions of people in the Andean countries especially of the indigenous people. Two researchers from the University of Colorado received a US patent in 1994, which gives them exclusive monopoly control of male sterile plants of the traditional 'Apelawa' variety. They claim that they were the first to identify and use a reliable system of cytoplasmic male sterility in quinoa for the production of hybrids. These scientists have merely isolated a naturally occurring property in quinoa, thereby violating the demarcation between innovation and discovery, which is crucial to the debate on patents on life forms.

Certain provisions in the U.S. IPR law facilitate such distortions in the interpretation of 'prior art'. It permits patents to be filed on discoveries made in the U.S. whether or not identical ones already exist and are in use in other countries (Section 102 of U.S. Patent law). Unless this section is amended, biopiracy will continue to occur.<sup>14</sup> The TRIPS Agreement endorses and incorporates into itself such laws, which directly promote biopiracy.

**Brazzein:** is the name of a protein found in a West African berry, 'Pentadilapandra brazzeana'. Researchers at the University of Wisconsin have received a European patent from the protein isolated from the berry. Subsequent work has focused on making transgenic organisms to produce

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<sup>14</sup> Shiva, Vandana, *Stolen Harvest: The Hijacking of the Global Food Security*, (Cambridge, South End Press), 2000, p.89.



brazzein in the laboratory, thereby eliminating the need for it to be collected or grown commercially in West Africa. This is a clear example of how patent systems completely disregard local knowledge and innovation of local people by allowing biotechnologists to claim that something was invented which is actually isolated and reproduced in their labs.

*(Source: 'Patenting, Piracy and Perverted Promises')*

*[www.grain.org/publications/reports/piracy](http://www.grain.org/publications/reports/piracy)*

Species patents on plants and plant parts such as these show how the patent system is biased against the millions of farmers and local communities and expedites corporate greed. In cases of patented crop varieties, farmers have to follow stringent rules when using these varieties in the countries where these patents are recognized. The TRIPS Agreement has made it mandatory that patents given in one member country of the World Trade Organisation (WTO) will have to be recognized by all other member countries; so there is not much option left for farmers. The patent regime while assisting the seed companies to usurp global markets, hits at the root of sustainable agriculture that is crucial to 70% of the world's farmers who are in the developing countries.<sup>15</sup> Patents take away their right to save and exchange seeds, a right which is vital for their subsistence. The enormous agricultural diversity of today can be singularly attributed to the farmers over the millennia who domesticated wild varieties, selected and nurtured the useful ones and bred disease resistant, drought resistant varieties. The monopolisation of seeds in the name of patenting 'invented' plant varieties alienates the farmers from their own seeds. On

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<sup>15</sup> Ibid.

the other hand the crop varieties improved and developed by traditional farmers to the international seed industry is estimated to be US\$ 15 billion annually.<sup>16</sup> There is therefore a strong ethical and economic cause to fight for the 'stolen harvest' of the farmers.

## **Biodiversity, Traditional Knowledge and the Stakeholders**

### *Biodiversity: Its Importance*

Biological diversity means the variability among living organisms from all sources including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and ecosystems.<sup>17</sup> This planet is home to around 30 million species out of which only 1.4 million species are described or named. Of the total species around 80% are in the Southern countries alone, making these countries biodiversity hubs for various commercial interests of the developed countries. The more astounding fact, however, is the scale at which this rich biodiversity of species is diminishing. We are losing 10,000 to 20,000 species every year. This is alarming because biodiversity is integral to the sustenance of human life on earth, catering to our food, agricultural and medicinal needs so much so that 80% of the population of the Southern countries relies on traditional or non allopathic medicines mainly based on plants and animal parts. Local and indigenous communities of this part of the world have direct dependence on biodiversity for food and livelihood.

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<sup>16</sup> Nijar, Gurdial Singh, *In Defence of Local Community Knowledge and Biodiversity: A Conceptual Framework and the Essential Elements of Rights Regime*, (Penang, Third world Network), 1996, pp.233-234.

## *Traditional Knowledge: Its Importance*

The term traditional knowledge (also referred to as indigenous knowledge) has been understood in variety of meanings. One working definition that has been formulated states, 'the term indigenous knowledge is used synonymously with 'traditional' or 'local' knowledge to differentiate the knowledge developed by a given community from the international knowledge system also often called the 'western' system, generated through universities, governmentalist research centres and private industry. Indigenous knowledge refers to the knowledge of the indigenous peoples as well as any other defined community'.<sup>18</sup> This definition is not comprehensive because the differentiation cannot be made merely on the basis of 'local' as opposed to 'international' or 'western'.

Traditional knowledge systems as defined by Indigenous and Development Monitor states, 'Indigenous knowledge systems relates to the ways members of a given community define and classify phenomena in the physical/natural, social and ideational elements. Examples are local classifications of soils, knowledge of which crop varieties grow in difficult environments, and traditional ways of treating human and animal diseases'.<sup>19</sup> A more comprehensive definition is given by M. Johnson, who defines traditional knowledge systems as 'a body of knowledge built by a group of people through generations living in close contact with nature. It includes a

<sup>17</sup> Article 2, UN Convention on Biological Diversity, UNEP, 1992.

<sup>18</sup> Ramanna, Anitha, *Patents, biotechnology and US agribusiness in India: a study of Indo-US conflict on IPRs*, PhD Thesis submitted at JNU, 1999, p.172.

<sup>19</sup> Dutfield, Graham, 'Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation', Issue Paper No.1, UNCTAD-ICTSD Project on IPRs and Sustainable Development, (Geneva, ICTSD), 2003, p. 17-18.



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system of classification, a set of empirical observations about local environment and local system of self-management that governs resource use'.<sup>20</sup>

As often believed, traditional knowledge is not necessarily local and informal. While traditional knowledge holders tend to inhabit rural areas, members of such peoples and communities live in may live in urban areas and yet continue to hold such knowledge. Traditional knowledge holding individuals, groups and communities then, may be culturally distinct tribal groups as well as traditional rural communities that are not necessarily removed from the cultural mainstream of the country. Empirical evidence also breaks the myth that traditional knowledge is age-old knowledge only. Russel Barsh says, 'what is traditional about traditional knowledge is not its antiquity, but the way it is acquired and used. In other words, the social process of learning and sharing of knowledge, which is unique to each indigenous culture, lies at the heart of its traditionality. Much of this knowledge is actually quite new, but it has a social meaning and legal character, entirely unlike the knowledge indigenous people acquired from settlers and industrialised societies'.<sup>21</sup> This means traditional knowledge augmented with each generations adding to the knowledge.

The use of the term 'indigenous people' also needs clarification because it is often used unfittingly. The presentation of indigenous people in Article 8(j) of the CBD as 'indigenous and local communities embodying traditional lifestyles' fails to consider the existence of local communities in the mainstream society and gives the impression that it applies only indigenous people who are isolated in a never changing present.

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<sup>20</sup> Ibid.

## *The Stakeholders*

***Local Indigenous People and Farmers:*** The CBD recognizes that traditional knowledge, innovations and practices are very crucial to the conservation of biodiversity and that indigenous and local communities have a close and traditional dependence on biological resources. Their livelihood and lifestyles often depend on it and is shaped by it. This is not to exaggerate the extent of dependence of local and indigenous people on biodiversity, but to highlight that these people have direct stake on conservation of biodiversity. Traditional knowledge is understood something that is in consonance with nature. Biodiversity is central to all traditional knowledge systems because of their symbiotic relationship. The knowledge of the properties, characteristics and uses of biodiversity is held by local communities in their diverse cultural and epistemological frameworks.<sup>22</sup> Local communities have not only used biological resources as food and medicine but they have also domesticated, nurtured and developed the useful species of crop, thereby contributing to the rich agricultural biodiversity. The utilisation of biodiversity in people's lives as well in the economy is guided and enhanced by a plurality of traditional knowledge systems.

***Corporate Interests:*** The other major stakeholder in biodiversity and traditional knowledge systems is the corporate sector. Biodiversity and traditional knowledge form the backbone enormously profitable corporate sectors, including pharmaceuticals, food and seed, cosmetics and biotechnology, which is by itself so ubiquitous that it is difficult to identify it as a separate sector. Sales in botanical

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<sup>21</sup> Quoted in Graham Dutfield, Note 17.

<sup>22</sup> Shiva, Vandana, *Protecting Our Biological and Intellectual Heritage in the Age of Biopiracy*, (New Delhi, Research Foundation for Science, Technology and Natural Resource Policy), 1996, p.2.

medicine industry are a good US\$16-\$19 billion yearly.<sup>23</sup> The cosmetic and personal care industry has annual sales between US\$50-\$75 billion.<sup>24</sup> In pharmaceutical industries, natural products contribute somewhere between 25%-60% of the total sales.<sup>25</sup>

In a study by Grifo and others in 1997, where they analyzed the top 150 proprietary drugs from the US National Prescription Audit for the period of Jan-Sept, 1993, found out that 57% of the prescriptions filled contained at least one major active compound 'now or once derived or patterned after compounds from biological diversity'.<sup>26</sup>

The advent of biotechnology has added a new dimension to all these sectors, with biopharmaceuticals and agricultural biotechnology penetrating the world market profusely. The global market for biopharmaceuticals is at present more than US\$300 billion a year and for agricultural produce it is in excess of this figure. Biopharmaceuticals currently contribute 11% of the sales of the top twenty-five blockbuster drugs and is likely to grow significantly.<sup>27</sup> Agricultural biotechnology is the second largest biotechnology sector. In 1998, the total commercial planting of biotechnological crops by Monsanto alone comprised more than 22.3 million hectares worldwide.<sup>28</sup>

The lure of biological resources has attracted a growing number of pharmaceutical, food, seed and biotechnological companies to the forests, fields and

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<sup>23</sup> Laird, Sarah A. (ed), *Biodiversity and Traditional Knowledge: Equitable Partnership in Practice*, (London, Earthscan Publications Ltd.), 2002, pp. 280-88.

<sup>24</sup> Ibid.

<sup>25</sup> Ibid.

<sup>26</sup> Ibid.

<sup>27</sup> Ibid.

waters of the tropical countries. The problem is not from their interests in these resources but with the way they are extracted and used without acknowledgement of the role of traditional knowledge involved in the production of highly profitable products. There are direct links between many commercial products and knowledge systems dating back to centuries. A study conducted by Farnsworth and some other researchers way back in 1985 found that of the 120 pharmaceutical products that they studied, 75% had been discovered through the study of their traditional medicinal use.<sup>29</sup> The study by Grifo and others (1997) mentioned above also demonstrated that for the base compound in most of the top 150 plant derived prescription drugs in the U.S., commercial use correlated with traditional medical use.<sup>30</sup> Traditional knowledge is a trusted tool used by bioprospectors when they stalk the South's rainforests for high value biological resources but is unfortunate that this very process results in the alienation of the locals from their resources and knowledge.

Any measure at national and international levels to protect and conserve biodiversity and traditional knowledge should give prime importance to the local and indigenous communities. To be more precise, the efforts to construct a fair 'access and benefit sharing' regime should ensure the involvement of traditional knowledge holding communities with decisive rights in the determination of terms of access and benefit sharing. Not much have progressed in the efforts to establish a global regime because of the critical differences in the interests of the stakeholders. At the global level, incompatibility in the global trade and environmental treaties and in the stands taken by the respective governments representing their concerns is the single largest obstacle in abating biopiracy. The developing countries have a lot of stake at the

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<sup>28</sup> Ibid.

<sup>29</sup> Ibid.

different global fora where negotiations are ongoing to balance the conflicting interests of the stakeholders.

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<sup>30</sup> Ibid.



## Chapter 2

### **The CBD and the TRIPS: Compatibility vs. Conflict**

The Convention on Biological Diversity and the TRIPS Agreement were being negotiated at around the same time but with very different objectives and purposes, one to be a multilateral environmental agreement (MEA) and the other to be a multilateral trade agreement (MTA). The CBD incidentally was adopted in 1992 at the Rio Earth Summit and the WTO TRIPS Agreement was adopted in 1995 after the Uruguay round of negotiations. Although the CBD and the TRIPS have different agendas there are crucial junctures at which they intersect, which bring out more inconsistency than compatibility. Their compatibility needs to be examined in the context of two compelling reasons.<sup>31</sup> In the first place, both the TRIPS and the CBD are products of the multilateral system and therefore any points of inconsistency that may arise in the two would have to be addressed in order that the signatory countries are able to meet the requirements for complying with both.

The second reason closely arises in the context of the functioning of the WTO Committee on Trade and Environment (CTE), which is mandated to bringing the objectives of the Uruguay Round agreements and those of the Uruguay Round agreements and those of the MEAs including the CBD on an even keel.

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<sup>31</sup> Dhar, Biswajit, 'The CBD and the TRIPS Agreement: compatibility or conflict?', in Christopher Bellmann et al (eds), *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability*, (London, Earthscan), 2003, pp. 77.

## Conflicting issues between the CBD and the TRIPS Agreement

<i>Sl.Nos.</i>	<i>Provisions of the CBD</i>	<i>Provisions of the TRIPS Agreement</i>
1.	Key objectives are the conservation and sustainable use of biodiversity.	Prime motive is the realization of the objectives of free trade with intellectual property protection.
2.	States have sovereign rights over biological resources	Biotechnological inventions have intellectual property protection irrespective of the source of origin of the genetic material
3.	Rights of local communities have to be recognized for their contribution to the conservation and sustainable use of biodiversity	Only corporates and individuals are assigned IPRs. No scope for granting collective rights to local and indigenous communities
4.	The use or exploitation of biological resources must give rise to equitable benefit sharing	There is no mechanism of benefit sharing between a patent holder in one country and the donor of material in another country
5.	The use or exploitation of traditional knowledge, innovation and practices should give rise to equitable benefit sharing	No such mechanism
6.	Access to biological resources requires prior informed consent of the country. Also requires approval and involvement of local consent	Patent holder may not disclose the source of the genetic material on which the patent is granted
7.	Developing countries supplying genetic material must be involved in the biotechnological research	No reference to this. It considers only the post research phase
8.	Transfer of technology to the genetic material provider country to be determined by mutual consent	'Economic value of the 'license' would be the criteria for transfer of technology

*The table has been compiled on the basis of analysis provided by Biswajit Dhar*

*(Refer to Note 24).*

The inconsistencies between the two agreements have attracted much concern between the developing and the developed countries and a level of understanding has been reached about the urgency of building compatibility. However the commitment of the developed countries towards this end is unforthcoming.

### *The Convention on Biological Diversity*

The adoption of the CBD was the first emphatic step taken by the international community towards conservation and sustainable use of biodiversity. The Convention however, could be formulated only after rows of intense negotiations between the developed and developing countries on the basic features and objectives of the Convention. On one hand, the developed countries argued that unfettered exchange of genetic resources among countries was essential for the benefit of humanity and therefore pressurized the relatively biodiversity rich developing countries to conserve their resources for the use of all. On the other hand, developing countries, having realized that direct benefits arising from the use of their genetic resources were accrued solely by the developed countries, challenged the 'common heritage of mankind' principle being applied to biodiversity by the developed countries. The continued application of this principle would mean their exploitation in perpetuity. The Convention was a landmark achievement for the Southern countries because they succeeded in winning sovereignty over their biological resources, which essentially meant the right to use their resources sustainably.

The CBD is significant for the developing countries also because it recognises the importance of traditional knowledge from the point of view of conservation and

sustainable use of biodiversity.<sup>32</sup> More significantly, the CBD frames out a strategy for the practical realization of the sovereignty and sustainable use principles through the requirement of fair and equitable sharing of benefits arising from the utilisation of biological resources, traditional knowledge and innovations.<sup>33</sup> This requirement embodies the essence of the Convention and has become the guiding principle for the developing countries to claim their rightful share of benefits arising from the commercial use of these resources and the traditional knowledge associated with them by developed countries' TNCs.

The very first article is the recognition of all these; it says 'the objective of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biodiversity, the sustainable use of its components and the fair and equitable sharing of benefits arising out of the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into view all rights over those resources and to technologies, and by appropriate funding'. The conservation and sustainable use were the common concerns of almost all the countries. But the developing countries emphasised that the CBD should establish international legal obligations that would ensure the equitable sharing of benefits.

Recognizing the interrelationship between indigenous people and biodiversity and recognizing community rights to wild and domesticated biodiversity, the CBD seeks to ensure that these indigenous communities are compensated in a fair and equitable manner for the use of their resources and knowledge by national and transnational commercial interests. Therefore, the institutionalization of an international ABS regime lies at the heart of realizing the *raison de'tre* of the CBD.

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<sup>32</sup> Article 8 (j) and Preamble, UN CBD, 1992.

This is also perceived as the most effective shield against biopiracy by many of the developing countries.

### **Traditional Knowledge and the CBD**

Traditional knowledge is the most critical link to CBD's provisions on access and benefit sharing. There is a broad recognition of the close and traditional dependence of indigenous and local communities on biodiversity in the preambular section of the Convention. Article 8(j) of the CBD requires the state parties to, 'respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of benefits arising from the utilisation of such knowledge, innovations and practices.'<sup>34</sup>

However, local and indigenous people holding such knowledge are often vulnerable both at the national and international domains when their knowledge is commercially utilized. There is indiscriminate exploitation of their knowledge inspite of the CBD mainly because the IPR regime that runs parallel to the CBD fails to accommodate the intellectual rights of traditional knowledge holders. The TRIPS Agreement is absolutely silent on traditional knowledge, thereby encouraging the TNCs to obtain patents on products that are developed with traditional knowledge as the basis. This makes it all the more imperative that the CBD institutionalise an ABS regime that prioritises and empowers the traditional knowledge holders while determining terms of access and benefit sharing.

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<sup>33</sup> Article 1, Article 8 (j) and Article 15, UN CBD, 1992.

The CBD itself, while on one hand recognises sovereign right of countries over their natural resources and the right to determine access to its biological resources, does not, on the other hand, define effective mechanism for recognizing and rewarding the contributions of local and indigenous people. The Convention falls short of giving decisive rights to traditional knowledge holders in commercial contracts of bioprospecting, which the CBD itself passively endorses. This ambiguity, if unresolved may put the communities and their governments in a mutual competitiveness, which anyways is likely to favour the governments for obvious reasons. Even when the indigenous people understand the value of their ethnobiological knowledge, 'the overwhelming power, expertise and skills of pharmaceutical companies and governments (overseas and host countries) is generally sufficient to convince indigenous people to cooperate on their terms'.<sup>35</sup>

Another shortcoming of the CBD is that it has kept implementation of Article 8(j) 'subject to national legislation'. This could be effectively used by a state to ignore the clause if its national legislation does not address the issue and could consequently annul the implementation of Article 8(j) in many countries. More discouraging is the prefix to this clause because it is not binding upon the contracting parties to implement the subsequent clauses. By making implementation conditional to the ability and will of the contracting parties, CBD nullifies the urgency of Article 8(j) and other traditional knowledge related provisions.

Many indigenous communities are concerned that the creation of protected areas for '*in situ* conservation' of biodiversity may deprive them of their land and access to wild biodiversity. In spite of tall claims by the CBD to preserve and respect

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<sup>34</sup> Article 8(j), UN CBD, 1992.

<sup>35</sup> Mathur, Ajit, "Who owns traditional knowledge?" *Economic and Political Weekly*, Vol.38, No.42, 2003(18-24 Oct), p.4476.

traditional knowledge of local and indigenous people, in the absence of ownership rights over and access to biological resources, even the most elaborate and sophisticated system to protect traditional knowledge is bound to fail. Even 'ex situ conservation' in the country of origin may be used by national governments to take away indigenous genetic resources in the 'national interest' on the basis that they are threatened and compensation to the locals may be just avoided. Thus indigenous people are in the fear of losing rights over biological resources even from their national governments.

### **Access and Benefit Sharing Provisions in the CBD**

The CBD's provisions on access are premised on five fundamental concepts:

- 1) Sovereignty over genetic resources,
- 2) Facilitating access to genetic resources between parties,
- 3) Access subject to mutually agreed terms,
- 4) Access subject to prior informed consent,
- 5) Equitable sharing of benefits arising from the utilisation of genetic resources.

### **Sovereignty over Genetic Resources**

This is recognised by Article 15(1) that states, 'Recognising the sovereign rights of states over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation'.<sup>36</sup> This recognition is however not a property right granted to the states. Indeed ownership of genetic resources is not addressed at all by the CBD and the 'rights' issue is left for resolution through national legislation. Ownership issue is the

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<sup>36</sup> Article 15.1, UN CBD, 1992.

critical linkage that makes the communities entitled to benefits. Most current legislations do not determine ownership of genetic resources (as opposed to biological resources)<sup>37</sup>, making it very difficult to determine whether indigenous groups and local farmers have a right to participate in ABS. While some developing countries may respect the rights of the indigenous people, there is a long history of indifference, neglect and hostility between national governments and these communities. If in the name of sovereignty, state governments become the usurper, talking of equitable benefit would make no sense.

### **Facilitating Access**

By virtue of sovereignty over biological resources, governments have a leeway in how they may determine and regulate access to such resources. However absolute discretion is curbed by Article 15(2) that states, 'Each contracting party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other contracting parties and not to impose restrictions that run counter to the objectives of this Convention'.<sup>38</sup> A state can restrict access only until such time as it could establish an effective system for ABS. However the CBD lacks the provision for declaring a moratorium on further access agreements if a source country decides so. CBD's sanctions for bilateral contracts may endanger vital resource and information of the developing countries. By emphasising so much on bilateral access agreements, CBD seems to undermine future

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<sup>37</sup> Barber, Charles V et al, 'Developing and implementing national measures for genetic resources access regulation and benefit sharing' in Sarah A. Laird (ed), *Biodiversity and Traditional Knowledge: Equitable Partnership in Practice*, (London, Earthscan Publications Ltd.), 2002, p.365.

<sup>38</sup> Article 15.2, UN CBD, 1992.



option of multilateral South-South cooperation to benefit from free exchange of genetic resources.

### **Mutually Agreed Terms**

Article 15(4) of the CBD states that access, where granted, will be on 'mutually agreed terms' between the party providing genetic resources and a potential user.<sup>39</sup> The parties involved in a contract or in a Material transfer agreement (MTA) or any such agreement should mutually decide the terms and conditions to authorize access to genetic resources; to control their subsequent uses; and to establish the terms and procedures for sharing the benefits.

The issue of ownership right over genetic resources is critical here too because a country's national legislation would determine who is the provider party and who should enter into mutual agreements with the potential user. In many cases, indigenous and local communities do not precisely know as to with whom they are negotiating or to whom they are providing information and genetic materials. Clear identification of the parties into bioprospecting contracts becomes difficult because most Northern based TNCs work through intermediaries, thereby making the connections more complicated. Intermediaries may be private companies who are in the business of collecting and selling bio-specimens, public sector institutions, research institutes, botanical gardens, conservation groups or ethnobotanists employed by corporations.<sup>40</sup> With myriads of sources through which genetic materials reach the TNCs, indigenous people are bound to lose out somewhere in the process their due share of compensation. 'Mutually agreed terms' to be genuinely mutual should be

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<sup>39</sup> Article 15.4, UN CBD, 1992.

<sup>40</sup> *RAFI COMMUNIQUE*, "Bioprospecting, biopiracy and indigenous people", 1994(Nov-Dec).

based on identification of the parties involved. The state's responsibilities should lie in monitoring such access agreements. The state may, alternatively, conclude a separate contract with potential users specifying terms and conditions or may be a third party in a tripartite contract.<sup>41</sup>

### **Prior Informed Consent**

Article 15(5) established that, 'access to genetic resources shall be subject to prior informed consent of the contracting party providing such resources'.<sup>42</sup> Here too, national governments are left to determine what constitutes PIC and procedures for ensuring that PIC has been obtained. Though it requires that only national governments give PIC, other CBD provisions (Article 10(c)) as well the national laws of many countries imply that PIC should be obtained from the local or indigenous communities from whose territories genetic resources are obtained; and when their knowledge, innovations and practices are to be commercially utilised (Article 8(j)). A community's PIC is essential if their customary practices are to be respected and protected. Their most right is their right to say 'no' to bioprospectors showing no intention of consenting at all. It is preconditioned to strict legal protection of traditional knowledge in the source country, which should be internationally recognised.

### **Benefit Sharing**

Sharing of benefits in fairly and equitably is one of the principle objectives of the CBD. Article 15(7) requires each contracting party to take '.....legislative, administrative or policy measures....with the aim of sharing in a fair and equitable

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<sup>41</sup> Refer to Note 4.

way the results of research and development and benefits arising from the commercial and other utilisation of genetic resources with the Contracting Party providing such resources'. The benefits may be in the form of participation in scientific research, a share in the commercial benefits, access to and transfer of technology etc. However, regulating benefit sharing is by far the most challenging task especially in the absence of an international regime that binds countries to make equitable benefit sharing possible. The 6<sup>th</sup> Conference of Parties to the CBD adopted a set of guidelines called the 'Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization'. But these are still short of an international regime.

The present bioprospecting agreements that exist are largely unregulated and are disproportionately in favour of the user parties. It should also be noted that most benefits from the utilisation of genetic resources are generated by the private sector, while the CBD benefit sharing provisions apply only between its contracting parties, i.e. national governments. Individual governments have to develop their own approaches to conduct their negotiations with the private sector to ensure benefit sharing. In some agreements royalties paid are as low as 0.1% or as good as 50%. To check such irregularities, an international ABS regime is vitally essential.

### **The CBD's Implications on IPRs**

The CBD's interface with IPR arises basically from its very objectives, which delineate two sets of rights in respect to genetic resources.<sup>43</sup> The first set of rights comprises those that can be exercised over the genetic resources and concerns the countries that are potential providers. The second set of rights relates to the

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<sup>42</sup> Article 15.5, UN CBD, 1992.

technologies which have been developed using the genetic material and these rights concern the corporate interests that are engaged in developing biotechnological products. A third dimension of the CBD that cross cuts both these sets of rights deals with the rights of the local and indigenous communities who are the custodians of genetic resources and holders of traditional knowledge.<sup>44</sup> The international IPR regime gives protection to the second set of rights, many a times disregarding the other two sets of rights. In this context, the essence of CBD's approach to the issue of IPR has been to ensure that the other two sets of rights are equally complied with.

The CBD's strategy is to identify the various stakeholders who have been involved in the conservation and sustainable use of biodiversity and to make it mandatory for the governments to develop instruments through which the benefits can be shared in a fair and equitable manner. In essence, provisions relating to ABS and traditional knowledge have the maximum impact on the IPR regime and vice-versa. The scope of exclusive rights created by IPR defines who can use the information contained in genetic resources and so influence the distribution of the benefits flowing from their use. In this way and others, IPRs will affect the nature of benefit sharing. An implicit recognition in the CBD that user countries misappropriate resources and associated traditional knowledge, has given primacy to the interests of the source countries over the commercial interests of the corporations and their parent countries. Article 16(5) of the CBD asserts that 'the Contracting Parties, recognising that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to a national legislation and

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<sup>43</sup> Refer to Note 24, p.78-79.

<sup>44</sup> Ibid.

international law in order to ensure that such rights are supportive of and do not run counter to its objectives.<sup>45</sup>

## Deliberations on IPRs

The relationship between the CBD and IPRs has been most frequently and intensely discussed in the Conference of Parties (CoPs) to the CBD in deliberations on such topics as access to genetic resources, benefit sharing and traditional knowledge. The implementation of Article 15 has been hindered because of the incompatibility with the TRIPS. The Northern countries have shown least interest to resolve the issue, as they would gain more from a strong IPR regime that protects their biotechnology and biotechnological products and gives them leeway to patent life forms. The developing countries face their biggest challenge from the U.S., which does not recognise that there exists any serious difference between the two treaties and it is therefore reluctant to take any measure to build compatibility between the two.

The group of the Northern countries led by the US was not ready to deliberate on the issue of IPRs even when the CBD was being drafted. It was one of the most contentious issues during the biodiversity negotiations and the North and the South failed to agree on the relationship between IPRs vis-à-vis genetic resources, community rights and traditional knowledge systems during those negotiations.<sup>46</sup> Incompatibility with IPRs remains the single largest obstacle to implement the objectives of the CBD.

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<sup>45</sup> Article 16.5, UN CBD, 1992.

<sup>46</sup> Rajan, Mukund Govind, *Global Environmental Politics: India and the North-South Politics of Global Environmental Issues*, (Delhi: Oxford University Press), 1997, pp.202-228.

North-South differences are very acute on IPRs. There have been intense negotiations in the CoPs to the CBD on IPRs. The first few CoPs were entirely dominated by the developed countries, which strongly opposed any dilution of IPRs. The developing countries appeared to gain some influence in the deliberations for the first time after the CBD's adoption in the third CoP. Countries agreed for the first time that there were internal conflicts between the IPR system and traditional knowledge systems. India, backed by Brazil, Tanzania and Malaysia, called for a further study on 'patent application disclosure policy' under which patent applications would call for the source of the information as well as the raw materials used in the making of the product.<sup>47</sup> A group of developing countries, including India further carried the proposal of mandatory 'disclosure of origin', *inter alia*, to the TRIPS Council negotiations to review the TRIPS Agreement and is now subject to critical negotiations that aims at protection of genetic resources and related traditional knowledge. The developing countries shifted their attention to the TRIPS Council review process that had started since 1999 to build mutual supportiveness between the two treaties.

### ***The TRIPS Agreement and Biopiracy***

The TRIPS Agreement requires WTO Members to allow patents to 'be available for any inventions, whether products or processes, in all fields of technology, provided they are **new, involve an inventive step and are capable of industrial application...**'(Article 27.1). However, article 27.3(b) allows members to exclude from patentability the following: 'plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals

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<sup>47</sup> Ibid.

other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The TRIPS Agreement in this form has been universalised on 1<sup>st</sup> January 2005.

However, three closely related issues have focused critical attention on the patent system. These are, a) the extension of patents to substances discovered in nature, b) the problem of patents being granted that would not be if the novelty and inventive step criteria were properly applied and c) the opportunity that the system provides for business and researchers to acquire sole patent rights for inventions that could not have been achieved without their having first accessed traditional knowledge.<sup>48</sup> Whether naturally occurring substances are to be considered 'new' and 'invention' is a point of conflict between the Northern and Southern patent systems. European and North American patent laws allow patenting of apparently natural substances. It is well established in the patent laws of Europe and North America that while you cannot claim as an invention something as it occurs in nature, it is possible to do so if you extract it from nature and thereby makes it available for industrial utilisation for the first time. The substance is made patentable by changing it in some way such as by adding something to it (e.g. a gene), subtracting something from it (e.g. purifying it), mixing it with something else to create a new or synergetic effect, or structurally modifying it so that it differs in an identifiable manner from what it was before.<sup>49</sup> The American Court decisions on what is a product of nature are also very fact specific, making way for convenient decisions.

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<sup>48</sup> Dutfield, Graham, 'Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation', Issue Paper No.1, UNCTAD-ICTSD Project on IPRs and Sustainable Development, (Geneva, ICTSD), 2003, p.30.

<sup>49</sup> Ibid.

The Western patent systems also had different interpretation of 'prior art'. 'Prior art' is one of the means available to ascertain novelty of a patentable invention. According to this, if the claim asserted in the patent specification already existed in the public domain, whether in written form or oral, then it is taken as prior art and the supposed invention fails to satisfy the novelty criterion. However, the US Patent and Trademark Office (USPTO) does not recognise oral forms of prior art that are prevalent in territories other than their own. For instance, the medicinal plant *Phyllanthus niruri* (Jar amla) has been an ancient and well-recorded innovation in the Indian systems of medicine to cure jaundice. The USPTO granted a patent to the extract of the plant on the ground that it serves the utility requirement through its efficacy to treat Hepatitis B. The US Patents Act recognises the 'prior art' of foreign countries only in a recorded (written form).

The TRIPS regime has globalised this industrial model of innovation and property protection. It says nothing about 'prior art' and 'traditional knowledge' although it requires that patents be granted to only 'non-obvious' inventions. It guarantees ownership rights to products made in the laboratories of the North from the knowledge of the indigenous and local communities. The knowledge systems of these communities; their innovations; the societal and informal context in which they innovate and transfer information to other generations etc. are denied recognition. TRIPS fail to recognise the collective system of innovation and knowledge of local and indigenous communities. Traditional knowledge, being considered as lying in the public domain, is absolutely unprotected from being used by industries for making such products which can be patented by using the 'novelty, inventive and industrial application' principle with merely trifle changes from their traditional use. Often such patents make no reference to the relevant traditional knowledge or merely mention it



in a cursory manner as if it is of little importance. Under these circumstances, it is not surprising that biopiracy is rampant. This also suggests that the solution to the problem largely lies in the TRIPS itself. Developing countries are making recommendations to the TRIPS Council basically to resolve the differences between the TRIPS and the CBD.

### Review of the TRIPS Agreement

Even if the TRIPS Agreement is silent on traditional knowledge and makes no reference to the CBD, this has not prevented developing countries from referring to the relationship between the TRIPS and the CBD and portraying their mutual incompatibilities. When the TRIPS Council commenced the reviewing process of Article 27.3(b) in 1999 as required by the Agreement, the developing countries found the right forum to demand changes in the regime that has facilitated biopiracy. Broadly speaking, this subparagraph allows governments to exclude some kinds of inventions from patenting, i.e. plants, animals and 'essentially' biological processes (but micro-organisms and non-biological and microbiological processes have to be eligible for patents). However, plant varieties have to be eligible for protection or a system created specifically for the purpose (*sui generis*) or a combination of the two. The review of this subparagraph was required to further discuss the criteria of patentability. The Doha Declaration of 2001 broadened the discussion to include traditional knowledge and biodiversity. It says that work in the TRIPS Council on the review of Article 27.3(b) or the whole of the TRIPS Agreement under Article 71.1 and other implementation issues (both inside and outside the WTO) should also look at: a) the relationship between the TRIPS and the CBD; b) the protection of traditional knowledge and folklore and; c) other relevant new developments that member

governments raise in the review of the TRIPS Agreement.<sup>50</sup> It adds that the TRIPS Council's work on these topics is to be guided by the TRIPS Agreement's objectives (Article 7) and principles (Article 8).

The topics raised in the TRIPS Council discussions include:

- a) how to apply the existing TRIPS provisions on patenting biotechnological inventions. The discussion has included the extent to which life forms should be patentable.
- b) the meaning of effective 'sui generis' protection for new plant varieties (i.e. alternatives to patenting such as the 1978 and 1991 versions of the UPOV convention). This includes the question of allowing farmers to continue to save and exchange seeds that they have harvested.
- c) how to deal with traditional knowledge, folklore and genetic material and the rights of the communities where they originate. Among the key questions are: how to prevent patents being granted wrongly and whether to support the creation of databases to help patent examiners; to what extent do existing IPRs help to protect traditional knowledge and folklore and to what extent a special purpose (sui generis) law is desirable; and what is the right forum to develop this subject further.
- d) how to implement the TRIPS Agreement and the CBD together and whether the TRIPS Agreement should be amended ; in particular, whether patent applications should have to disclose the source of the traditional knowledge or the genetic material; what kind of approvals researchers and inventors might have to obtain before they can use these in their inventions; and possible methods of sharing benefits with local communities when inventors in other

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<sup>50</sup> DOHA WTO MINISTERIAL 2001: TRIPS, WT/MIN (01)/DEC/2.

countries have rights to inventions based on material and knowledge obtained from the locality.

In October 1999, twelve developing countries from Asia, Africa and Latin America submitted two joint papers to the General Council detailing the implementation issues they were seeking solutions to.<sup>51</sup> Several TRIPS related proposals were put forward. One of the papers argued that TRIPS is incompatible with the CBD and sought a clear understanding that patents inconsistent with Article 15 of the CBD, which vests the authority to determine access to genetic resources in national governments, should not be granted. Several other proposals were directed to Article 27.3(b) and the review of its substantive provisions. One proposal was that the Article 27.3(b) should be amended in light of the provisions of the CBD, taking into account the conservation and sustainable use of biodiversity and the protection of the rights and knowledge of indigenous and local communities.

**Traditional knowledge** has become an especially important element of the debate. On August 1999, the African Group of countries proposed to the TRIPS Council that in the sentence on plant variety protection in article 27.3(b) 'a footnote should be inserted stating that any sui generis law for plant variety protection can provide for [inter alia]: 1) the protection of the innovations of indigenous farming communities in developing countries, consistent with the CBD and International Undertaking on Plant Genetic Resources'.<sup>52</sup> The African Group has expressed concern in its submission on June 2003 that any protection of genetic resources and traditional knowledge will not be effective unless and until international mechanisms

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<sup>51</sup> WT/GC/W/354 and WT/GC/W/355.

<sup>52</sup> WT/GC/W/302.

are found and established within the framework of the TRIPS Agreement.<sup>53</sup> The Group is of the opinion that databases for patent offices, which may be used in examining patent claims to determine whether they meet the requirements of novelty, inventiveness and usefulness, can also be helpful in minimising misappropriation of resources.

With the Doha mandate in hand, developing countries have expectations of restructuring the Articles on review. Towards this end a few developing countries, namely, Brazil, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe jointly submitted a paper to the TRIPS Council on June 2002 on the relationship between the TRIPS Agreement and the CBD and the protection of Traditional Knowledge.<sup>54</sup> The submission stressed the need to modify the TRIPS Agreement arguing that the agreement contains no provisions to preventing a person to claim patent rights in one country over genetic resources that are under sovereignty of another country. Neither does it ensure a member's claim to enforce prior informed consent nor fair and equitable benefit sharing. The paper, noting the relevant provisions of the Bonn Guidelines, proposed that TRIPS be amended to provide that WTO member states must require that, 'an applicant for a patent relating to biological materials or to traditional knowledge shall provide as a condition to acquiring patent rights:

- (a) **disclosure of the source of and country of origin** of the biological resource and the traditional knowledge used in the invention;
- (b) **evidence of prior informed consent(PIC)** through approval of authorities under the relevant national regime; and

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<sup>53</sup> IP/C/W/404.

<sup>54</sup> IP/C/W/356.

(c) **evidence of fair and equitable benefit sharing** under the relevant national regime of the country of origin.

However the TRIPS Council remained divided over the need to harmonise the two treaties as a means to prevent 'biopiracy' because most developed countries including the EU, the US and Japan insisted that the two treaties could be simultaneously applied. The US, in particular, has so far strongly opposed the inclusion of disclosure requirements in patent applications, which they say would be incompatible with the TRIPS Agreement since they added another substantive condition on patentability beyond those already provided. Many developing countries, however, view the inclusion of the disclosure requirements as part of the effort to establish a legal regime for access and benefit sharing and traditional knowledge protection in addition to developments in related fora. They argue that this would be more cost-effective than to divert national resources to expensive judicial processes for the revocation of patents that include illegal genetic resources (as experienced by India and Amazonian countries in challenging patents abroad over their genetic resources).

The same group of developing countries, excluding a few, carried on with the demands based on the submission of June 2002. The group reiterated the previous proposals in June 2003 emphasising that disclosure of the source and country of origin and evidence of PIC and fair and equitable benefit sharing in a patent application would play a significant role in preventing biopiracy and misappropriation and in some cases, prevent the issue of 'bad patents' awarded without due regard to prior use and knowledge with regard to the resource.<sup>55</sup> This group forwards the following as advantages of fulfilling the said conditions: (a) reducing instances of bad

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<sup>55</sup> IP/C/W/403.

patents; (b) enabling the patent office to ascertain more effectively the 'inventive step' claimed in a particular patent application; (c) enhancing the ability of countries to track bad patents in the instances where they are granted and challenge the same; (d) improving compliance with their national laws on PIC and fair and equitable benefit sharing prior to accessing a biological resource and associated traditional knowledge. These countries want to establish a link between the CBD framework with the norms of disclosure of a patent application in the TRIPS Agreement so as to institutionalise a mechanism for ensuring that patents are not granted, or are invalidated if granted in violation of the rights of the countries and communities over their resources and knowledge respectively. This group is also the strongest proponent of international mechanism to arrest biopiracy. The main shortcoming of national patent offices to prevent biopiracy and to ensure reward to traditional knowledge holders is that they do not *ipso facto* lead to similar action on patent applications in other countries.

In March 2004, Brazil, Cuba, Ecuador, India, Peru, Thailand and Venezuela presented a 'checklist of issues' pertaining to all the three conditions which they demand to be fulfilled before obtaining a patent.<sup>56</sup> Another proposal by the group including Bolivia and Pakistan submitted in December 2004 focused on PIC, the second of the three elements identified in the 'checklist' prepared as the basis for future negotiations. The proposal paid particular attention to Article 15 of the CBD, according to which Contracting Party is obliged to disclose PIC for patents that involve the use of biological resources, unless otherwise determined by the country that provides those resources.<sup>57</sup> This submission follows a proposal by the same group of countries in September 2004, which focused on the first of the checklist's elements,

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<sup>56</sup> IP/C/W/420.

<sup>57</sup> IP/C/W/438.

namely disclosure of origin.<sup>58</sup> This proposal first considers ways that disclosure requirements could improve patent examination and prevent 'bad patents'. In this regard, it provides examples of biopiracy in which, for example, traditionally used herbal remedies have been patented by TNCs, with no revenues flowing back to the communities where the genetic material was sourced.

The US supported by Japan remains unchanged in its belief that there is no inherent conflict between the TRIPS and the CBD and instead favours a contract-based approach through national laws outside the patent system, which could include commitments on disclosure. The EU maintains an ambiguous position, suggesting that a mandatory system of disclosure would be suitable in principle, while not making any proactive move on how to best implement this in practice. Many developed countries including Canada, Australia and New Zealand remain undecided on how best to resolve potential conflicts between the TRIPS and the CBD. On the other hand Switzerland, even with its endorsement of voluntary disclosure system, has been proposing that the World Intellectual Property Organisation (WIPO) would be a more appropriate forum to discuss these issues. It has proposed an amendment to WIPO's Patent Cooperation Treaty so that domestic laws may ask inventors to disclose the origins of genetic resources and traditional knowledge when they apply for patents.<sup>59</sup>

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<sup>58</sup> IP/C/W/429.

<sup>59</sup> IP/C/W/400/Rev.1, IP/C/W/423, IP/C/W/433.

## *WIPO: How viable to protect Traditional Knowledge and Genetic Resources?*

The discussion on genetic resources and traditional knowledge was initiated in the WIPO at around the same time when the TRIPS was open for review. A document submitted by Columbia in September 1999 entitled 'Protection of biological and genetic resources' in the WIPO Standing Committee on Law of Patents raised many controversial points.<sup>60</sup> The document proposed that the Patent Law Treaty, which was in the drafting stage, include an article based on the two proposals. The first was that 'all industrial property protection shall guarantee the protection of the country's biological and genetic heritage. Consequently, the grant of patents or registrations that relate to elements of that heritage shall be subject to their having been acquired legally'. The second was that, 'Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof where the goods or services for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin'.<sup>61</sup>

The idea of linking patent application with access and benefit sharing regulations gained the support of many developing countries namely, Barbados, Bolivia, Cameroon, Chile, China, Costa Rica, Cuba, India, Kenya, Mexico, Namibia, Paraguay and South Africa. Many developed countries like the US, Japan, the EU and South Korea opposed the idea. The discussion however gained momentum in subsequent sessions of WIPO, which enabled the creation of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge

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<sup>60</sup> In WIPO (1999), SCP/3/10.

<sup>61</sup> Ibid.



and Folklore (IGC) in 2001 with huge support from the developing countries. The IGC has focused its attention on two possible approaches to promote benefit sharing and prevent misappropriation of traditional knowledge, which are,

- a) to require patent applicants to disclose the origin of genetic resources and/or associated traditional knowledge in related patent applications.
- b) to improve the availability of public domain traditional knowledge to patent examiners to prevent cases where patents whose claims extend to traditional knowledge are improperly awarded. This could be done by providing an inventory of publications that regularly document traditional knowledge or by compiling databases of public domain traditional knowledge.

Some countries believe that such applicants should also provide documentary evidence of PIC and compliance with the ABS regulations of the provider countries. India and Brazil have repeatedly stated that such a measure is necessary to make patents supportive of the CBD. They claim that mandatory disclosure would do this by preventing private monopoly rights from extending to illegally acquired genetic resources. However the US makes the same argument as in the TRIPS Council that such requirements would conflict with TRIPS by creating another substantive condition on patentability beyond those already provided by the TRIPS Agreement. As regards the second approach, India has already set up its own Traditional Knowledge Digital Library (TKDL).

The main obstacle to reach at any substantive decision in the WIPO is the lack of agreement among the developed and the developing countries about the involvement of WIPO in the potential international ABS regime and in protecting traditional knowledge. Many developing countries are adamant that CBD rather than WIPO should take the leading role in discussing ABS related disclosure requirements.

Many developing countries including India, Brazil and the African group question that even within the WIPO, is the IGC the appropriate body to respond to the invitation by the CBD<sup>62</sup> to assess the interrelation of access to genetic resources and disclosure requirements in intellectual property protection. The relationship with WIPO has proved to be the most contentious point in discussions on measures to ensure compliance with PIC. The Like Minded Megadiversity Countries (LMMC) has also objected the strengthening collaboration with the WIPO due to concerns that their interests would not be adequately addressed in a forum dealing with IPRs.

However marking a major shift from the earlier positions, one of the most concrete outcomes of the IGC in recent months is that there is growing acceptance of the usefulness of protection of traditional knowledge by the WIPO. The IGC has begun discussing more concrete issues like policy objectives and core principles for the protection of traditional knowledge and folklore. These discussions are expected to provide the foundations for policy making at both domestic and international levels, including a possible international instrument for the protection of traditional knowledge and folklore.

### ***The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (2001)***

This treaty is a revised version of the FAO International Undertaking (1983), an agreement that has been under negotiations for over seven years to harmonise it with the CBD. The revision was necessary because the International Undertaking was based on the principle that plant genetic resources for food and agriculture should be

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<sup>62</sup> Decision IV/9, paragraph 16 (CoP4 to the CBD invited WIPO to take into account the lifestyles and traditional systems of access and use of the knowledge, technologies and practices of indigenous and local communities in its work).

preserved and freely available for use and benefit of present and future generations as part of the 'common heritage of mankind'. The CBD has changed this premise by recognising biological resources as national resources. Recognising both the sovereign rights and the interdependence of countries over their plant genetic resources, the treaty establishes a Multilateral System that aims to facilitate ABS. The Multilateral System can be seen as a particular application of the principles of Article 15, paragraph 2, of the Convention. ABS is to be regulated principally by means of a standard material transfer agreement (MTA), which will apply also to transfers to third parties and all subsequent transfers. The MTA is a contract that sets the minimum standards for access to plant genetic resources for food and agriculture (PGRFA). The standard MTA is fundamental to the implementation of the Treaty, it being the vehicle for facilitating transfer of genetic resources as well as specifying benefit sharing arrangements. The most important aspect of the treaty is the provision on Farmers' Rights (Article 9). The three measures that governments ought to take to promote Farmers' Rights as required by the treaty are:

- (a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture (PGRFA);
- (b) the right to equitably participate in sharing benefits arising from the utilisation of PGFRA;
- (c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of PGFRA.

The most crucial part of the Article is the final paragraph that points out that, 'Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm saved seed/propagating material, subject to national law as appropriate'.

The treaty has come into force in June 2004 and unlike the WIPO, the FAO has got positive response from many developing countries as an appropriate forum to discuss traditional knowledge especially that of the farmers' rights. They believe that the Treaty might provide an important precedent for the unresolved discussions on the review of Article 27.3(b) at the WTO Council for TRIPS. On the other hand, the US, Canada and Japan are vocally skeptical regarding consistency between the Treaty and the TRIPS.

An overlapping area concerns the Treaty's provisions on benefit sharing which provide for monetary contributions derived from the commercialisation of products developed from PGRFA accessed under the Multilateral System. The payment is mandatory when commercialisation of the product restricts the product's availability for use in further research and breeding, and voluntary when the product is freely available for such purposes. Depending on how governments incorporate the provisions into their IPR regulations, the possibility might arise that they could be challenged on the basis that in doing so, they contravene their TRIPS obligations under Articles 27.1 and 29 by imposing additional conditions for IPR protection.<sup>63</sup> These are the apprehensions of some of the developed countries, which want that the TRIPS should not be subordinate to any other international treaty.

The FAO treaty could be of much help to protecting farmers' varieties in the developing countries. Apart from the Convention on Biological Diversity, it is the only international instrument to directly address access and benefit-sharing by establishing a Multilateral System for a list of more than 60 plant genera, which include 64 major crops and forages. The treaty is unique in its treatment of farmers' rights as opposed to the commercial breeder's rights. It recognises farmers' rights as a

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<sup>63</sup> 'FAO International Treaty finally adopted' in <http://www.ictsd.org/weekly/01-11-06/story2.htm>

means of regaining control over the resources they are losing through the international patent regime. The implementation of the treaty depends on how much its provisions are incorporated into national *sui generis* and other legislations to protect plant varieties and traditional knowledge.

### **Proposals to Protect Traditional Knowledge: An Evaluation**

Most developing countries believe that traditional knowledge needs to be protected legally from its misappropriation by the formal IPR regime. Despite the growing recognition of traditional knowledge as a valuable source of knowledge and as a kind of 'technology' by the CBD, international intellectual property regime continues to treat it as part of the 'public domain', freely available for anybody. Countries have come up with various ways and means to grant international legal protection to traditional knowledge at the various fora where it is being discussed. The proposals made by the developing countries can be broadly categorized as 'defensive protection' and 'positive protection'.<sup>64</sup> 'Defensive protection' responds to their concerns about their traditional knowledge being subject to monopolisation and commercialisation through IPRs to the advantage of unauthorised persons without sufficient opportunity for the indigenous people to obtain an equitable benefit sharing. So this kind of protection would mean a restructuring of the patent regime to accommodate rights of the traditional knowledge holders. 'Positive protection' applies to the possibilities of traditional knowledge holders themselves obtaining some kind of intellectual property protection to make effective use of their knowledge.

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<sup>64</sup> Dutfield, Graham, 'Protecting Traditional Knowledge and Folklore: A review of progress in diplomacy and policy formulation', Issue Paper No.1, UNCTAD-ICTSD Project on IPRs and Sustainable Development, (Geneva, ICTSD), 2003.

## *1. Defensive Protection*

Two important proposals have emerged from the negotiations in TRIPS Council and the WIPO IGC to provide 'defensive protection' to traditional knowledge through the patent system, namely,

- (1) to require disclosure of origin as a condition to obtaining patents,
- (2) to compile databases of published information on traditional knowledge to identify potentially novelty-destroying 'prior art'.<sup>65</sup>

### *(a) Disclosure of Origin*

The requirement of compulsory disclosure of origin of the genetic material and associated traditional knowledge for obtaining patents is opposed by many developed countries who consider it as another substantive condition to the already existent conditionalities according to the TRIPS. Some of them propose that disclosure should be voluntary. The EU for instance maintains in its 1998 Directive on the Legal Protection of Biotechnological Inventions that,

"Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents".

However voluntary disclosure means nothing to the countries and communities whose resources and knowledge is illegally accessed. On the other hand it lays the burden of proof on the countries and the communities to provide necessary

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<sup>65</sup> Ibid.

evidence of illegal access. The proponents and supporters of mandatory disclosure argue that it is hardly an added conditionality because a full disclosure of the invention should essentially include the traditional knowledge if applied. It can be seen as complementary to the obligations in the TRIPS (Article 29) to disclose the invention in a manner sufficiently clear and complete as to be carried out by a person skilled in the art, and also to identify the best mode to carry out the invention.<sup>66</sup> Graham Dutfield is of the view that ‘by helping to describe prior art against which the purported inventive step needs to be measured its disclosure ought to be required anyway’. Further, regarding the disclosure of the source of the genetic material used, he adds, ‘it is difficult to see why inventors should not be required to indicate where they got it from’.<sup>67</sup>

The disclosure of origin is a common procedure in various national laws based on the principle of good faith of the applicant. Some Southern countries require this in some form in their national legislations to regulate access and benefit sharing. Notably, the Indian Patents (Amendment) Act, 2002 has added two new grounds for revocation. It says that patents may be revoked on the grounds, “that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention”, and “that the invention so far as claimed in the claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous communities in India or elsewhere”.<sup>68</sup>

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<sup>66</sup> Engui, David Vivas, ‘Requiring the Disclosure of Origin of Genetic Resources and TK: the current debate and possible legal alternatives’ in Christopher Bellmann et al (eds), *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability*, (London, Earthscan), 2003, p 200.

<sup>67</sup> Ibid, p 34.

<sup>68</sup> The Patent (Amendment) Act, 2002 (India)

Similarly, the Andean Community's Common Intellectual Property Regime (common for Bolivia, Columbia, Ecuador, Peru and Venezuela) that took effect in December 2000, requires that patent applications must contain: "a copy of the contract for access, if the product or processes for which a patent application is being filed were obtained or developed from genetic resources or by products originating in one of the Member countries; and if applicable, a copy of the document that certifies the license of authorization to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in one of the Member Countries"(Decision 486).<sup>69</sup>

Also the Brazilian provisional measure 2.186-16 of 2001 indicates that: "the grant of industrial property rights by the competent bodies for a process or product obtained using samples of components of the genetic heritage is contingent on the observance of this Provisional Measure, the applicant being obliged to specify the origin of the genetic material and the associated traditional knowledge, as the case may be".<sup>70</sup>

However 'disclosure of origin' may have practical bottlenecks. While mandatory disclosure may operate well for pharmaceutical products, it may be difficult for plant varieties because genetic material may come from more than one source. Lack of documentation make it all the more difficult to identify the origin. It is by no means certain that provider countries are the actual countries of origin. Nevertheless, mechanisms like disclosure of origin are essential to create mutual supportiveness between the IPR regime and the proposed ABS regime.

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<sup>69</sup> Ruiz, Manuel, 'The Andean Community Regimes on Access to Genetic Resources, Intellectual Property, and the Protection of Indigenous People's Knowledge' in *Ibid*, pp.238-240.

<sup>70</sup> WIPO/GRTKF/IC/7/6, p.15, August 27, 2004



*(b) Traditional Knowledge Databases*

Documenting traditional knowledge is perceived by many developing countries, including India, as an effective form of protecting traditional knowledge from the biopirates as they would provide documented 'prior art' for reference of patent offices. This is not a very controversial proposal because there is no question of compatibility with the TRIPS agreement. Neither has the WIPO IGC had any debate on the idea, although there have been some differences of opinion on whether traditional knowledge databases should be made publicly available only or provided for the exclusive use of patent offices. There is much concern among many in the developing countries that the availability of such databases to the public may instead boost up biopiracy, as these would be easily procured by corporations and research institutes, which would otherwise have to conduct time-consuming literature searches to acquire the same information. This would enable them to skip the process of bioprospecting and directly plunge into further biopiracy. These concerns are quite valid in the present context when the international patent regime is a perpetrator of biopiracy. Traditional knowledge databases would be effective in checking biopiracy only when the patent regime is made fully supportive of the CBD. This essentially means fulfillment of the demands by the developing countries to incorporate compulsory disclosure of origin, evidence of PIC and evidence of fair and equitable benefit sharing in the TRIPS Agreement.

The debate in the WIPO IGC holds much stake for the traditional knowledge holders as this would be their only weapon to prove 'prior art' in the documented form. But considering the vastness of such knowledge held by local and indigenous communities over the centuries, it is doubtful how comprehensive a database could be and the undocumented knowledge would not be accepted as evidence of 'prior art' by

the patent examiners. The communities whose knowledge is not documented would not be entitled to any benefit arising from the commercial use of their knowledge.

Further, the efficacy of the traditional knowledge databases would depend on the interpretation by national patent laws of a 'novelty-destroying prior art' because national and regional patent laws vary with respect to how information in the public domain should be described in order that they constitute novelty-destroying prior art. Even traditional knowledge databases would not make any impact in challenging biopiracy cases in some countries like Japan and the EU. For instance, in Japan, "novelty-defeating disclosure...has to be enabling, i.e. it teaches those skilled in the art how to make and use the claimed invention. If novelty-defeating disclosure fails to provide such information, the disclosure will not be novelty-defeating bar."<sup>71</sup> Thus traditional knowledge databases may not be applicable to challenge bad patents universally. They could be more applicable if the international patent regime recognises the databases as authoritative references. Nuno Carvalho of the WIPO suggests of extending special legal protection to these databases (as in a *sui generis* system). He suggests that such databases be registered with national patent offices and that to avoid the appropriation of the knowledge, enforcement rights be confined to knowledge that complies with a certain definition of novelty.<sup>72</sup>

## *2. Positive Protection*

### *(a) Protection through IPRs*

There is another option of protecting the knowledge of local and indigenous

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<sup>71</sup> Note 22, p. 36.

<sup>72</sup> Quoted by Graham Dutfield, Note 23, p43.

communities through IPRs other than patents, such as copyrights and geographical indications. But copyright protection can be restricted to only that knowledge related to bioresources, which are in the written form.<sup>73</sup> Discussions on extending GIs to products other than wine and spirits (which now enjoy GI protection) are ongoing in the TRIPS Council and the WIPO IGC. Geographical indications (GIs) are proposed as means to protect products of a special region like basmati rice, Darjeeling tea, alphonso mangos, Camembert cheese etc. mainly by some Asian, African and European countries. Some of them believe that by giving value to localised natural products and associated know-how, GIs can provide an incentive to preserve native varieties and the traditional knowledge associated with them. Others, however, are concerned that GIs will only bring new obligations for developing countries while the benefits will mainly go to the developed countries that are better prepared at the national level to take advantage of GI extensions and might use GIs as trade barrier against developing countries' exports.<sup>74</sup> Brazil in particular is skeptical that GIs would not help prevention of biopiracy as they only protect the product but not the genetic resources and associated traditional knowledge, and thus would not prevent their use and patenting by others. However GIs could provide a broad protection to traditional knowledge and would necessitate strengthening of the national legislations simultaneously.

***(b) Sui generis system***

In recent years, many ideas for *sui generis* systems for implementing Article 15 of the CBD have been proposed. A *sui generis* system is said to be adaptive to the

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<sup>73</sup> Sahai, Suman, 'Indigenous Knowledge and its Protection in India' in Christopher Bellmann et al (eds), *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability*, (London, Earthscan), 2003, p. 169.

<sup>74</sup> <http://www.ictsd.org/biores/02/07/11/story1.htm>

particular characteristics of traditional knowledge which are not otherwise protected. A WIPO Secretariat text explains, “....the eventual need for developing....*sui generis* IPR for traditional knowledge arises from the very intrinsic characteristics of such knowledge, rather than from the conditions and terms of protection provided for by existing mechanisms...” Some of these are the 1985 WIPO-UNESCO Model Provisions for National Laws on Protection of Expressions of Folklore against Illicit Exploitation and other Prejudicial Actions; the FAO’s farmers’ rights; defensive publications, discovery rights; reassignment rights; Traditional Resource Rights etc.<sup>75</sup>

The TRIPS Agreement has obliged all the Member States to establish *sui generis* system for protection of plant varieties. Some developing countries have used this to extend farmers’ rights, which are very essential rights to protect farmers’ varieties of crops from being patented by seed companies. But *sui generis* systems cannot be deemed sufficient to protect traditional knowledge as propagated by many developed countries because of the uncertainty and unpredictability involved with them. They will be new with distinct and many unexperimented features. In addition to this there are practical difficulties in developing *sui generis* systems, which require an examination of the legal, social and economic conditions. Moreover the process of developing such systems should be participatory because the local communities should be able to derive benefits out of it. Many of the developing countries may not be able to establish *sui generis* systems because of the time and cost involved to make it a well researched, participatory and workable system. It makes it all the more urgent that traditional knowledge should be the subject of international protection.

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<sup>75</sup> Johnston, Sam & Yamin, Faharna, ‘Intellectual property rights and access to genetic resources’ in John Mugabe et al (eds), *Access to Genetic Resources: Strategies for Sharing Benefits*, (Bonn, IUCN), 1997, pp 253-254.

## Chapter 3

### India and Biopiracy: Vulnerability and Defense

India is one of the twelve mega-biodiversity countries of the world. With only 2.4% of the land area, India has already accounted for 7%-8% of the recorded species of the world. This number is based on a survey of 65 to 70 per cent of the total geographical area of the country. Over 47,000 species of plants and 81,000 species of animals have been recorded by the Botanical Survey of India and the Zoological Survey of India respectively. It is anticipated that some of the remaining areas may be far richer in biodiversity than most of the areas already surveyed. India is also one of the twelve primary centres of origin of cultivated plants and is tremendously rich in agricultural diversity. India is equally rich in both coded and informal traditional and indigenous knowledge.<sup>76</sup>

The level of dependence of the local and indigenous communities of India on biodiversity is equally tremendous. For most people in India biodiversity is linked to their survival and sustenance. According to an ethnobotanical survey, there are 7,500 species used as medicinal plants by the indigenous medical traditions of India. These traditions are practised by 3,60,740 Ayurveda practitioners, 29,701 Unani experts and 11,644 specialists of Siddha. In addition, millions of housewives, birth attendants and herbal healers carry on village based health traditions.<sup>77</sup> Seventy per cent health care needs in India are still based on traditional systems based on the use

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<sup>76</sup> 'Protection of Biodiversity and Traditional Knowledge: the Indian Experience', paper submitted by India to WTO Council for TRIPS, 14 July 2000, WT/CTE/W/156 and IP/C/W/198.

<sup>77</sup> Quoted by Vandana Shiva in *Protecting Our Biological and Intellectual Heritage in the Age of Biopiracy*, (New Delhi, Research Foundation for Science, Technology and Natural Resource Policy),

of medicinal plants and eighty per cent of seeds used by farmers still come from farmers' seed supply.<sup>78</sup> At the same time, India's rich biological resources and associated traditional knowledge have been targeted by Northern corporate and research houses which are racing to obtain patents over them.

A considerable amount of biological material has been taken out of India in the last few centuries and even within India, large number of wild and domesticated varieties has been just lost. First came the colonisers who practised unprecedented transfer of biological resources from India, following the principle that genetic resources are common heritage of mankind. Then came the wave of green revolution, which forced Indian farmers to buy and plant high yielding varieties, displacing many traditionally domesticated crop varieties. The third wave of exploitation came in the form of biopiracy. Biological material, especially plant germplasm endemic to India have been used by seed, pharmaceutical, biotechnological companies and research institutes of the North to make products claiming them as patentable 'inventions'. Examples of such cases are ample. Apart from the most infamous patents on *Basmati rice (Oriza sativa)*, *Neem (Azadirachta indica)* and *Turmeric (Cucurma longa)*, there are patents around the world on, *Anar*, *Bagbherenda*, *Brinjal*, *Chamkura*, *Dudhi*, *Erand*, *Gulmendi*, *Jamun*, *Karela*, *Salai*, *Jar amla (Phyllanthus niruri)*, *Sarpagandha (Rauwolfia serpentina)*, *Pomegranate (Punica gragantum)*, *Amaltas (Cassia fistula)*, *Black paper (Piper nigrum)*, *Arjun (Terminalia arjuna)*, *Aswagandha (Withania somnifera)*, and numerous other highly valuable species of Indian origin.<sup>79</sup> These are only some of the known cases of biopiracy. Considering the

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1996, p.1 from Vandana Shiva, *Biodiversity Conservation: Whose Resources? Whose Knowledge?* (New Delhi. INTACH), 1994.

<sup>78</sup> Ibid, p.2.

<sup>79</sup> Biopiracy Factsheets, Research Foundation for Science, Technology and Ecology, New Delhi.

ignorance among the common people and the late response of the concerned government departments to the issue, it can be assumed that many more cases just go unnoticed and unreported.

Some of these patents have been revoked by the competent national authorities following challenges by interested parties. The Council for Scientific and Industrial Research (CSIR) of India had challenged a US patent (No. 5 401 5041) awarded to the University of Mississippi Medical Centre for the wound healing capacities of turmeric (*Cucurma longa*). The CSIR was finally able to get the patent revoked by the USPTO in 1997 because it was able to prove the traditional use of turmeric in India for centuries with the help of thirty two written sources in English, Hindi and Sanskrit.<sup>80</sup> The CSIR, India had challenged a European patent (No. 436257) granted to WR Grace Company and the US Department of Agriculture for the claimed 'invention' of pesticidal qualities in neem (*Azadirachtin indica*). The European Patent Office (EPO) was forced to revoke the patent in 2000 after confirming that its use on similar grounds has been known in India for centuries.<sup>81</sup> On the request of CSIR, to re-examine the US patent (No. 5 663 484) granted to Rice Tec Inc. on basmati rice lines and grains, the corporation has responded by withdrawing 15 of its 20 claims.<sup>82</sup>

But this is certainly not the best practice to protect the traditional knowledge of local and indigenous communities. The process of challenging a patent granted by a foreign country to a foreign institution or corporation is not only cumbersome but also mostly uncertain. The cases have to be challenged either at national patent offices

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<sup>80</sup> Agarwal, Anil and others (eds), *Green Politics (chapter 2)*, (New Delhi, C.S.E.), 1999, p. 128.

<sup>81</sup> Sahai, Suman, 'Indigenous Knowledge and its Protection in India' in Christopher Bellmann et al (eds), *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability*, (London, Earthscan), 2003, p 168.

or the WTO. Considering the huge cost involved in such cases and different standards of 'prior art' required by different countries, it is impractical and unjust that the developing countries should be left with it as the only option to protect their genetic resources and traditional knowledge. Most of the patents are not challenged because of these problems or are simply invincible because of the lack of coded proof of their 'prior art' in traditional practices.

The question here is not about the patents per se because technically, companies holding patents derived from indigenous communities cannot prevent members of these communities from continuing to use their knowledge. But as Graham Dutfield feels, it is equally important to understand how knowledge of indigenous communities is placed in the public domain and disseminated, without their PIC and without respect for their customary laws and regulations concerning access and distribution of knowledge.<sup>83</sup> Therefore the developing countries should not be complacent in winning a patent case here and there, but they have far more proactive role to play in creating international regimes that protect the rights of the communities over their knowledge, that ensure fair and equitable benefit sharing and that does not allow patenting of so-called 'inventions' developed by tinkering with traditional knowledge.

Lot is at stake for these countries in the diplomatic fora as the whole issue of biopiracy has become a diplomatic challenge that can be tackled with nothing but international cooperation. Besides these, the developing countries ought to utilise the existing frameworks of protection, notably the Convention on Biodiversity, which is to be implemented essentially at national levels through national policy and legislative

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<sup>82</sup> Ibid.

<sup>83</sup> Quoted in Note 4, p. 156.



frameworks. Most importantly, it is the responsibility of national governments to legitimise the relationship of the local and indigenous communities with genetic resources for ensuring their share of benefits from foreign corporations. The strategy for India is a similar one. India's rich biodiversity and cultural heritage are factors that shape India's response to the issue of biopiracy.

India's concern with development and economic growth has also played a major role in the biopiracy debate. Biopiracy is a serious threat to India because it causes the following problems and the strategies taken by India at national and international levels should be guided by these: (a) loss of genetic resources and traditional knowledge; (b) alienation of communities from genetic resources; (c) marginalisation of community rights and farmers' rights; (d) impoverishment of the local and indigenous communities.

## ***India at the International Environmental Fora***

### **India and the CBD Negotiations**

India's approach at the global negotiations for the creation of a convention for protection of biodiversity was based on a few objectives, two among which were (a) international protection of traditional knowledge and (b) prevention of IPR regimes from engaging in biopiracy.<sup>84</sup> India's objectives closely corresponded with those of many other developing countries.

The biodiversity negotiations took shape amidst the North-South differences on most of the issues, including sovereignty over natural resources, protection of traditional knowledge, access to genetic resources, sharing of benefits arising from

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<sup>84</sup> Rajan, Mukund Govind, *Global Environmental Politics: India and the North-South Politics of Global Environmental Issues*, (Delhi: Oxford University Press), 1997, pp.194-201.

their use, sharing of biotechnology, and intellectual property rights. India was the architect of the 'sovereignty over natural rights' principle as against the then existent 'common heritage' principle.<sup>85</sup> India was also one of the pioneers to emphasise the linking up of access to sharing of commercial and technological benefits, which is now considered the standard principle of international contracts on use of biological resources. India also sought recognition and reward of informal innovation by local people including farmers' rights, which gained maximum support of the other Southern countries.<sup>86</sup> However the CBD had nothing to offer as farmers' rights although Article 8(j) recognises the importance of traditional knowledge and the need to share benefits with the local and indigenous people.

The issue of IPRs also could be hardly influenced by the developing countries because most of the developed countries including the US, Japan and the European countries were reluctant to deliberate on IPRs within the scope of biodiversity. IPRs have remained an inconclusive issue even after twelve years of the CBD's existence. The issue is very crucial to the debates on biopiracy and it pervades almost all the other issues relating to biodiversity and traditional knowledge like benefit sharing and community rights.

While CBD envisages that access to genetic resources and realisation of benefits is subject to national legislation through formalisation of prior informed consent (PIC) and mutually agreed terms (MAT), India has been emphasising that such national action alone is not sufficient to ensure realisation of benefits to the country of origin or provider country. This is particularly so in cases where genetic

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<sup>85</sup> Ibid, p.203.

<sup>86</sup> Ibid, pp.203-228.

material sourced from one country is utilised in another country for developing products and processes on which patent protection is obtained.

India is of the view that the onus of benefit sharing must also be shared by the user country to create an enabling environment and confidence through legislative measures so as to ensure compliance of PIC stipulations and equitable sharing of benefits as visualised in the Convention. To ensure this, India was one of the very first countries to carry on the debate on IPRs in the subsequent CoPs to the CBD. Indian delegates raised the issue of IPRs vis-à-vis genetic resources, community rights and traditional knowledge systems in the very first CoP.<sup>87</sup> At the second CoP to the CBD, India argued for changes in the existing IPR regimes, which would ensure that they insist on the fulfillment of the CBD's provisions by all IPR applicants. Indian delegates insisted that the applicants should provide at least:

- the source of biological material, and method of collection;
- proof of PIC and mutual agreement with the country of origin as per the provisions of the Convention;
- description of any existing traditional knowledge related to the biological material, especially identifying an that was used in the product/process for which IPRs are being claimed; and
- a declaration and proof that all laws and customary rules of the country/community of origin have been complied with.<sup>88</sup>

Many key developing countries like Brazil, Malaysia and India came together to get the IPR regime and the CBD at par with one another. They proposed a 'patent application disclosure policy', which did not gain any ground among their developed counterparts. After years of speculation and failed diplomacy at the CoPs

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<sup>87</sup> Agarwal, Anil and others (eds), *Green Politics*, (New Delhi, Centre for Science and Environment), 1999, p.145.

to influence the IPR regime, they finally turned to the WTO TRIPS Agreement in 1999 when the TRIPS Agreement was placed under review.

### **India at the TRIPS Council Discussions**

India and other developing countries shifted their attention to the TRIPS Council review process that had started since 1999 to review Article 27.3(b) and the whole of TRIPS under Article 71. If the CBD was not considered appropriate to discuss IPRs, the TRIPS should have been the right place to right the incompatibilities, but here too the cooperation of the developing countries is not forthcoming.

India has submitted series of papers along with other biodiversity rich countries to the WTO Council on TRIPS on restructuring the criteria required for granting patents. The crux of their arguments is that the disclosure of origin, evidence of PIC and evidence of fair and equitable benefit sharing should be compulsory criteria for granting patents. India's own submission to the WTO Council for TRIPS in July 2000 has highlighted India's concerns on biopiracy, citing the biopiracy cases of Turmeric, Karela and Brinjal.<sup>89</sup> India has not shown laxity in criticizing the TRIPS regime in aiding the exploitation of biological materials. The Indian submission also emphasises the practical limitations in the process of patent revocation considering the time, effort, and money involved in getting individual patents examined and revoked in foreign patent offices.

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<sup>88</sup> Ibid. p.145-47.

<sup>89</sup> IP/C/W/198, 14 July 2000, 'Protection of Biodiversity and Traditional Knowledge-the Indian experience', Submission by India.

India has argued since the beginning of the review process that the problem of bio-piracy may not be resolved with such revocation actions and domestic biodiversity legislation alone. There is a need to provide appropriate legal and institutional means for recognizing the rights of tribal communities on their traditional knowledge based on biological resources at the international level so that they get their due share of benefits. India has proposed, in this context, that patent applicants should be required to disclose the source of origin of the biological material utilized in their invention under the TRIPS Agreement and should also be required to obtain prior informed consent (PIC) of the country of origin.<sup>90</sup>

India argues that if this is done, it would enable domestic institutional mechanisms to ensure sharing of benefits of such commercial utilization by the patent holders with the indigenous communities whose traditional knowledge has been used. In addition to all these, there should be acceptance of this practice of disclosure and PIC by all patent offices in the world and therefore it is essential that the TRIPS Agreement should require these as conditionalities for acquiring patents.<sup>91</sup>

## **India at the FAO**

It was at the FAO Conference of 1979, that India had begun the move towards national sovereignty over natural resources. Many developing countries began to feel by the late 1970s that the 'common heritage' regime for genetic resources was not operating fairly and protest began in the FAO. These protests culminated in the shift to national sovereignty principle in 1992 with the adoption of the CBD. India has been a key participant in these international developments and played an important

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<sup>90</sup> IP/C/W/161, 20 October 1999, 'Review of the Provisions of Article 27.3(b)', Communication from India.

role in the FAO debates in the 1980s. India was a prominent leader among the developing countries that pushed forward the sovereign rights issue during the negotiations.<sup>92</sup> India's role has been significant in developing the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, adopted in 2001.

India has constantly emphasized the importance of an effective benefit sharing arrangement and funding strategy, which finally, formed an integral part of this treaty. India's role, in reaching a compromise on important issues like farmers' rights, coverage of crops in the Multilateral System, intellectual property rights on material accessed from the Multilateral System, benefit sharing arrangements etc. has been widely appreciated.<sup>93</sup> With support from developing nations, India played a vital role in finalising the article on Farmers' Rights, one of the important components of the Treaty.

### **India and the LMMC**

Recognizing the urgent need to develop human resources, capabilities and legal and public policy to enable countries rich in biodiversity to take an active part in the new economy associated with the use of biological diversity and biotechnology, seventeen countries rich in biological diversity and associated traditional knowledge have formed a group known as the **Like Minded Mega Diverse Countries (LMMCs)**. The like-minded group was formed in February 2002 at a meeting in Cancun. The aims of the Group, as set out in the Cancun Declaration, include working together to obtain fairer access and benefit sharing terms in the use of

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<sup>91</sup> Refer to Note 74.

<sup>92</sup> Ramanna, Anitha, *Patents, Biotechnology and US agribusiness interests in India: a study of Indo-US conflict on IPRs*, Phd. Thesis, CA&WAS, School of International Studies, JNU, 1999, pp.75-82.

biological resources, developing biological resources, protecting traditional knowledge and rights of indigenous peoples, addressing issues of intellectual property rights, and seeking common positions in international negotiations.<sup>94</sup> These countries are Bolivia, Brazil, China, Columbia, Costa Rica, Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, South Africa, and Venezuela.

The LMMC Group, which holds nearly 60-70% of all biodiversity, is now well recognized as an important negotiating block in the UN and other international fora. At the World Summit on Sustainable Development in 2002, members of the Group (supported by the Group of 77) succeeded in getting a decision to negotiate an international regime, within the CBD framework, to promote and safeguard the fair and equitable sharing of benefits arising out of the use of genetic resources<sup>95</sup>. The recently held conference of the LMMC group at New Delhi in January, 2005 to develop a common position on biodiversity issues, especially to evolve a common position for developing an international regime on ABS, ended with a declaration on their common stand. The New Delhi Declaration asserted that the cornerstone of an international ABS regime would be a legally binding agreement between the CBD members. The push for a mandatory disclosure of origin found another support house in the LMMC group. The declaration very much asserted that, the proposed international regime on access and benefit sharing should include "mandatory disclosure of the country of origin of biological material and associated traditional knowledge in the intellectual property rights application, along with an undertaking that the prevalent laws and practices of the country of origin have been respected and

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<sup>93</sup> 'India signs Treaty on Plant Genetic Resources', Press Information Bureau, June 24, 2002.

<sup>94</sup> [http://www.undp.org/biodiversity/docs/Summary\\_Report\\_Delhi\\_Megadiverse\\_17\\_21Jan05.doc](http://www.undp.org/biodiversity/docs/Summary_Report_Delhi_Megadiverse_17_21Jan05.doc)

mandatory specific consequences in the event of failure to disclose the country of origin in the IPR application".<sup>96</sup> However the member countries of the LMMC are not unanimous about how best to protect their biological resources and traditional knowledge and what should be the nature of the proposed international regime. The group being relatively new, it is yet to come up with a concrete vision of what its members want from the CBD.

India has been emphasizing that national action alone is not sufficient to ensure realization of benefits to the country of origin or provider country. This is particularly so in cases where genetic material sourced from one country is utilized in another country for developing products and processes on which patent protection is obtained. India has been demanding that the onus of benefit sharing must also be shared by the user country to create an enabling environment and confidence through legislative measures so as to ensure compliance of PIC stipulations and equitable sharing of benefits as visualized in the Convention. Indian government should concentrate its diplomacy to utilise this forum for building an alliance to get the best out of the future negotiations at the CBD, just when the time is the most appropriate to bargain because now there is at least an international understanding that an ABS regime is indispensable.

### ***India's Domestic Legislative Initiatives***

India's initiatives at the legislative front to combat biopiracy are and ought to be framed as those regulating access to genetic resources and traditional knowledge; ensuring financial as well as non-financial returns to the communities from the use of

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<sup>95</sup> <http://www.biodiversityasia.org/LMMCreportnologos.pdf>

<sup>96</sup> <http://in.rediff.com/money/2005/jan/24fund.htm>



such resources and knowledge; determining communities' rights over resources; controlling IPRs; protection of traditional knowledge through documentation and through community rights over such knowledge. The implementation of the CBD also requires national legislations that govern access, benefit sharing and PIC.

### **The Biodiversity Act, 2002**

Accordingly, the Indian government has enacted in 2002 the National Biodiversity Act which establishes a three-tier system of governance of the **access, benefit sharing and prior informed consent** pertaining to biological materials through the following bodies: National Biodiversity Authority (NBA), State Biodiversity Board (SBB) and Biodiversity Management Committee (BMC).<sup>97</sup>

For the acquisition of IPR, the Act requires the applicants obtain clearance from the NBA before applying for any intellectual property for an invention, except protection of Plant Variety, which is based on a biological resource, obtained from India.<sup>98</sup> However in case of patent application, where priority dates are of utmost importance, an exception has been made such that the permission may be obtained after acceptance of a patent but before its grant.

As to the question of from whom the prior informed consent should be obtained, the Act tries to solve this problem by appointing the central body, the NBA, for the grant of consent. The CBD requires PIC of the 'contracting parties'. Indian lawmakers have conveniently interpreted this to mean that the government is the contracting party entitled to give PIC on behalf of the communities. The NBA lays

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<sup>97</sup> Sections 8, 22 and 41 respectively of the Biological Diversity Act, 2002.

<sup>98</sup> Section 6, the Biological Diversity Act, 2002.

down guidelines for the access to biological resources, and for fair and equitable benefit sharing besides advising the Central Government on conservation of biodiversity.

The Act contemplates a variety of monetary and non-monetary compensation of the benefit claimers. For e.g. the NBA has the power to not only order monetary compensation but to direct terms relating to transfer of technology, joint ownership, location of research facilities within a certain area, the association of local scientists and if necessary, the setting up of venture funds. Under Section 6(2) NBA may impose benefit sharing fee or royalty, the collection of which would be utilized for the benefits to the right holders, or conservation of the resources or for the social economic development of the areas from where the resource has been accessed (Section 27(b)). Foreign corporations may use this loosely worded provision to almost freely access the country's seeds, crops and farmers' varieties.

While the second tier in the Biodiversity Act, that is the SBB, advises the State Government on any guidelines issued by the Central Government on matters relating to conservation of biodiversity, its sustainable use and equitable sharing of benefits, the bottom tier i.e. the BMC is at the local level for the purpose of "promoting conservation, sustainable use and documentation of biological diversity" (Section 41).

The NBA and the SBB are required to consult BMC while taking any decision pertaining to the use of local biological resources and associated knowledge occurring within the jurisdiction of BMC.<sup>99</sup> Technically the Biodiversity Management Committees are the direct link to the people, which would enable local communities to have some voice in the conservation, sustainable use and equitable benefit sharing of biological resources.

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<sup>99</sup> Section 41.2, the Biological Diversity Act, 2002.

However, the latest **Biological Diversity Rules of April 2004** have diluted the scope of the BMC to be participatory and to empower local and indigenous communities. The Rules have minimised the role of the BMCs, requiring them to only prepare Peoples' Biodiversity Registers (PBRs) that document local knowledge and biological resources. This immensely undermines the rights of local communities who are the most important stakeholders when it comes to conservation of biological resources.<sup>100</sup> The Rules have very well assigned the task of preparing PBRs to the BMCs, but without any power at all to ensure their safekeeping.

Many local and indigenous tribal communities as well as non-governmental organisations and independent activists are skeptical about the constitution of the NBA, which is the apex authority to grant clearances for the access and use of the country's biodiversity. The Biodiversity Act requires "five non-official to be appointed from amongst specialists and scientists having special knowledge of, or experience in, matters relating to conservation of biodiversity, sustainable use of biological resources and equitable sharing of benefits arising out of the use of biological resources, representatives of industry, conservers, creators and knowledge-holders of biological resources".<sup>101</sup> But the NBA does not have any 'conservator', 'creator' and 'knowledge holder' of biological resources. This is the best example of how the spirit of the Act is nipped at the bud. With such practices at the domestic level, it is doubtful whether any kind of international protection will reach out to the local communities whose rights the laws are supposed to protect.

### *Peoples' Biodiversity Registers*

PBRs are community registers. A PBR is a documentation of the resources

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<sup>100</sup> Kohli, Kanchi, 'Biodiversity ruled out!', <http://www.indiatogether.org/2004/jul/env-bdrules.htm>

and knowledge of local communities at the local, regional and national levels by the peoples themselves for the purpose of rejuvenating the ecological basis of agriculture and the economic status of the farmers. They also ideally serve as tools to deal with IPR regimes, which seek to claim private intellectual rights over common knowledge when such knowledge has no recorded originator or innovator. Once it is documented and put into the public domain, it should become protected from patent claims. Unfortunately that is a premise that the US continues to defy as it grants patents on well-known compounds derived from traditional knowledge.

Documentation of traditional knowledge has been accepted by many countries as a means to determine that a community has right to benefits arising out of their resources and knowledge. But documentation, per se, does not facilitate benefit sharing with the holders of traditional knowledge. In India local communities needs special protection because the concept of community rights over biological resources do not exist. There is no system of registering transactions of genetic material and knowledge at community levels. Therefore a system is needed to ensure that equitable benefit sharing complements access to resources and knowledge, by recognising and rewarding efforts to sustainably use and conserve biodiversity and related traditional knowledge.<sup>102</sup>

The system of PBR originated in 1994 in South India as 'community registers' to document the traditional knowledge and skills of villagers and recognised them as 'prior art' to contest related IPR claims. It was updated as 'community biodiversity

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<sup>101</sup> The Biological Diversity Act, 2002, Section 3.4(d).

<sup>102</sup> Utkarsh, Ghate, 'Documentation of Traditional Knowledge: Peoples' Biodiversity Registers' in Christopher Bellmann et al (eds), *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability*, (London, Earthscan), 2003, p 192.

registers' in 1995 to link to the principles of the CBD.<sup>103</sup> The current reference as PBRs was made to dispense with the debate that communities alone could hold traditional knowledge. It is important to note that not all traditional knowledge is communally held. There could be a single individual who hold or two individuals who share certain knowledge. Another uniqueness of India's PBRs is that they do not block access to knowledge. But at the same time it is the responsibility of the assigned authorities to make sure that these PBRs do not become tools of further piracy, as they would be easily accessible. Indian legislations are not implemented efficiently to ensure that the PBRs are protected from further biopiracy.

#### *Traditional Knowledge Digital Library (TKDL)*

India has developed a digital library of public domain traditional knowledge related to medicinal plants as a measure to stop biopiracy. The TKDL has been developed on an innovative software programme, which facilitates the classification of traditional knowledge, making it compatible with the International Patent Classification. The TKDL will be made available to patent offices all over the world so that patent examiners are aware of the prior art relating to a particular medicinal plant. As opposed to the availability of the Peoples' Biodiversity Registers to the public, the TKDL is based on the principle of secrecy and would be made available solely to patent examiners. This should hopefully save the huge costs involved in fighting legal battles against patents, which are obtained through misappropriation of traditional knowledge. But even then, there is no full proof assurance that such TKDLs are absolutely out of reach of biopirates. Many in India are apprehensive that it might give way to easier biopiracy in the absence of international guarantee that

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<sup>103</sup> Ibid, p193.

they will be protected against biopiracy. All the zeal about documentation of traditional knowledge, sponsored by international donors, is doubted as a means to make such knowledge easily and legally available.<sup>104</sup>

### **The Patents (Second Amendment) Act, 2002**

Corresponding with the obligations under the Biodiversity Act, the amended Section 10 of the Indian Patents Act, 1970, i.e. Section 10(4) of the Act of 2002 creates an obligation to deposit and disclose the source and geographical origin of the biological material in the patents specification. A breach of these obligations, i.e. non-disclosure or wrongful disclosure would offer grounds for a successful opposition or revocation (Section 25). However, if the biological material is available to the public then these obligations do not appear to apply; but then care must be taken to ensure that the invention is not a mere modification of traditional knowledge. The amended Patent Act categorically takes traditional knowledge from the realm of patentability. Section 3 of the Act lists inventions that are not patentable. An invention 'which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components' is added to this section to exclude traditional knowledge from patentability. The Indian patent regime as updated on January 1, 2005 has not made any changes pertaining to seeds and traditional knowledge. But in the absence of any *sui generis* protection of traditional knowledge in India and any international protection, the Indian law itself is not enough to stop the patenting of traditional knowledge. The law may infact act as the door to our traditional knowledge systems because it allows patents to be granted to TNCs.

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<sup>104</sup> Sharma, Devinder, 'Biopiracy by another name: Traditional Knowledge', *Deccan Herald*, 24 /04/02

## **The Plant Varieties Protection and Farmers' Rights Act, 2001**

This is a *sui generis* legislation enacted to fulfill India's obligations under the TRIPS Agreement (Article 27.3(b)) to protect plant varieties either by patents or by an effective *sui generis* system or by a combination of both. Technically, most countries do not allow patents on plants, but parts of plants such as genes, cell lines and characteristics or properties are considered patentable.

India opted to enact its own law to protect plant varieties instead of the other option of adopting the International Convention for Protection of New Plant Varieties (UPOV), which is not very different from patents. The UPOV does not recognise farmers' rights as arising from their role as breeders who innovate and produce diverse farmers' varieties. UPOV is more suitable in the OECD countries where only about 2% of their populations are farmers. UPOV is based on an agricultural structure where the farmers are consumers of seeds provided by the seed companies. It would not be applicable to India where farmers' varieties cater to 70% of the seed requirement.

The Indian legislation is different from the UPOV in one sense that it includes farmers' rights apart from the mandatory plant variety protection that TRIPS demands.<sup>105</sup> However most of it is influenced by the UPOV and the TRIPS. The Indian legislation is considered to be a bold attempt in providing protection not only to new varieties but also to extant varieties, thereby taking into account the interests of various stakeholders like farmers, plant breeders and seed researchers.<sup>106</sup> The major provisions of this Act are:

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<sup>105</sup> Section 39, the Protection of Plant Varieties and Farmers' Rights Act, 2001.

<sup>106</sup> Lalitha, N, "Intellectual Property Protection for Plant Varieties: Issues in Focus", EPW, 39 (19), 2004 (8-14 May), pp. 1921-27.

- (a) Breeders or farmers can claim IPR for their varieties provided that it meets the criteria of **novelty, distinctness, uniformity and stability**.
- (b) This IPR comes in the form of **plant breeder's rights** defined as "exclusive rights to produce, sell, market, distribute, import or export the variety".
- (c) **Farmers' Rights:** a farmer can save, use, sow, resow, exchange, share or sell his farm produce including seeds of the protected variety in the same manner as before except 'branded seed', i.e. seed in a package or container and labeled as a protected variety.
- (d) **Benefit sharing:** after receiving a claim and examining the case, the authority would decide the amount of compensation that a breeder must pay and this would be deposited in the **National Gene Fund**.
- (e) Full disclosure of the source and origin of varieties and complete passport data from breeders are required.
- (f) Prohibition from using sterile (terminator) seed technologies in breeding.
- (g) Farmers are exempted from fees if they wish to examine documents or papers or receive copies of rules etc.
- (h) Protection from innocent infringement.
- (i) In providing a liability clause in the section on farmers' rights, the farmer in principle is protected against the supply of spurious or bad quality seed.

But the concept of farmers' rights being in a very nascent form at domestic as well as international arena, it is not clear as to how this right is going to be practically useful. It is not clear as to how will the farmers' varieties meet the given criteria of novelty, distinctiveness, uniformity and stability. These provisions are influenced by the UPOV and the TRIPS. Meeting with such conditions will be difficult for local land races and wild relatives of economic plants.



Further, the uniformity and stability requirements can be fulfilled only by commercial breeders who can produce genetically uniform varieties. Land races of local communities are generally rich in intra-varietal genetic diversity. These varieties would not be protected because of their genetic diversity.<sup>107</sup> It seems that the Act has not considered the fact that farmers' varieties are not new and exclusive, but have been developed by millions of farmers across large geographical regions. Unless the given requirements are modified to be applicable to farmers' varieties, the concept of farmers' rights will not hold any good to the farmers. Critics of this Act allege that the Act, while creating IPR on seeds of all agricultural crops, denies farmers their rights to agricultural diversity.<sup>108</sup>

The national strategy should aim at ensuring adequate access to agricultural resources along with establishing ownership rights. The creation of People's Biodiversity Registers to document local seed varieties is encouraging in a way that it puts the knowledge about local varieties in public domain. The process is premised on people's participation. The cooperation of local communities having knowledge of such varieties is essential in creating and updating a national database of such varieties. This kind of documented information would also enable benefit sharing whenever such varieties are exploited for further development. But even then, the idea of protecting plant varieties restricts access of farmers to agricultural resources. India and other developing countries should be conscious that while protecting plant varieties, they should not severely restrict access to resources so as to maintain the food security.

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<sup>107</sup> Ibid, p.1924.

<sup>108</sup> Shiva V. and Jafri, Afsar, H. 'The Need for a Genuine *Sui generis* Law to defend Farmers Rights as Traditional Breeders: the inadequacies of the PVP Act, 2001' in [http://www.vshiva.net/articles/pvp\\_act2001.htm](http://www.vshiva.net/articles/pvp_act2001.htm)

The agricultural structure in India demands that there cannot be complete private rights over agricultural resources. Such private rights could be fatal to the millions of farmers who largely use farm saved and open-pollinated seeds for whom free exchange of seeds among them is a precondition. Critics also apprehend that even exchange among farmers would be termed as commercial sale under this Act.<sup>109</sup> This Act would be especially beneficial to the commercial seed sector that is primarily engaged in research on hybrid technology in a few commercial sectors whose primary motive is to make the farmers use the commercial varieties.

It is also apprehended that all the provisions on benefit sharing with the farmers is merely lip service because it is near impossible to determine who are the innovators of local land races and therefore the beneficiaries in terms recognised by the Act. Moreover benefit sharing is subject to the commercial utility of the 'new' derived varieties and to claim only.<sup>110</sup> The District Magistrate is empowered to determine the beneficiaries and the amount of payment. This system of benefit sharing which have no say from the farmers cannot be considered equitable by any means. No amount of benefit sharing can be fair and equitable if it is not based on the premise that farmers' rights are actually collective rights. There should be a system that rewards the collective breeding of farmers by respecting them as collective rights and not putting them at par with private rights of the seed companies.

This legislation claims to be *sui generis*, which means it should have been developed keeping in mind the specific characteristics of India's agricultural economy and community agricultural systems. However its application would be limited if its most critical features are not modified to suit Indian conditions.

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<sup>109</sup> Ibid.

<sup>110</sup> Ibid.

The law could have incorporated the spirit of the FAO Treaty of 2001, in whose drafting India had played an important role. The treaty perceives farmers' rights as a means of regaining control over the resources they are losing through the international patent regime. But India's own law has failed to recognise the role of farmers as 'breeders' and 'innovators', by limiting their role as 'conservers' and 'cultivators'.

We need a middle path, which ensures that agricultural resources are not freely available but also that exchange within a community or between communities should not be based on a bilateral commercial basis. The alternative could be developing a *sui generis* legislation for protection of traditional knowledge, which recognises farmers as breeders and protect their community rights to their collective, cumulative innovation.

### **Geographical Indications of Goods (Registrations and Protection) Act, 2001**

A GI is a sign used on goods that have a specific geographical origin and possess qualities or reputation due to the place of origin. Agricultural products typically have qualities that derive from their place of production and are influenced by specific local factors such as climate and soil. While the Act does not make provisions for individual ownership, any association of persons or producers or any organisation or authority representing the interests of the producers of the concerned goods can apply for registration in accordance with the provisions Section 11 of the Act. The Indian legislation claims to give protection to Indian products like basmati rice, Darjeeling tea, alphonso mango etc. The process of compiling the list of products for which India will seek national and international protection under the Geographical

Indications category is underway. Negotiations have been taking place at the TRIPS Council and WIPO IGC to extend GIs to products other than wine and spirits. India is in favour of this extension, but the negotiations are not yielding results desired by India. However, India's own Act on GIs has been considered inadequate to prevent biopiracy and to protect traditional knowledge for the simple reason that biopiracy is not restricted to products of geographical identity like Basmati. The Act is ill equipped to prevent the piracy of thousands of medicinal plants and local crop varieties. The scope of GIs is limited also because they address only exports of small number of commodities and not the rights of farmers to use, save, exchange and improve their seeds for domestic production. GIs could be used to protect a few export commodities like the Darjeeling tea or the alphonso mango but the broader issues of patenting of life forms and traditional knowledge have to be addressed through a revision of the patent regimes.<sup>111</sup>

### **The Fight Against Biopiracy and the Indian Civil Society**

It was undoubtedly the civil society led by a few NGOs, which rose up to the threat of biopiracy much before the Indian government. There is a notable contribution of the Indian NGOs to the shaping of the present position of the government against biopiracy. Though they did not substantially influence India's diplomatic strategy during the negotiations that resulted in the CBD, there has been a considerable change in the scenario since then. The manifestation of their influence was noted for the first time in the country wide uproar by angry farmers following the

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<sup>111</sup> Shiva, V. 'The Basmati Battle and Its Implications for Biopiracy and TRIPS', [http://www.vshiva.net/aticles/basmati\\_battle.htm](http://www.vshiva.net/aticles/basmati_battle.htm)

piracy of the basmati rice in mid-1998.<sup>112</sup> This nation wide stir definitely acted as a wake-up call to the government and acted as a push behind Indian government's position taken in the TRIPS Council the following years. The Indian government has denounced biopiracy openly in the WTO, also adding that the TRIPS Agreement is aiding exploitation of biodiversity by privatizing biodiversity expressed in life forms and knowledge.<sup>113</sup>

The NGO community's role is more pronounced in building national as well as local capacity to check biopiracy, especially in drafting legislations, in documenting traditional knowledge systems associated with biodiversity through People's Biodiversity Registers (PBRs), in creating political awareness and in organizing campaigns against biopiracy, many of which have culminated in revocation of patents in foreign countries. The recent victory in the long drawn case against the European patent on the fungicidal properties of Neem, granted to WR Grace and the US Department of Agriculture<sup>114</sup> is a success story of Indian civil society. Dr. Vandana Shiva of the Research Foundation for Science, Technology and Ecology (RFSTE), along with the International Federation for Organic Agriculture Movement and the Green Party in the European Parliament, had been opposing the patent since it was granted in 1995.<sup>115</sup> This instance of actual revocation of a European patent is indeed a historic moment for the local communities and traditional knowledge holders.

Indian public interest groups have been very instrumental in raising

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<sup>112</sup> 'Biopiracy: TRIPS and patenting of Asia's Rice Bowl', <http://www.geocities.com/RainForest/7813/0921/rice.htm>

<sup>113</sup> 'Protection of Biodiversity and Traditional Knowledge: the Indian Experience', IP/C/W/198, 14 July 2000, WTO TRIPS Council.

<sup>114</sup> The patent was initially challenged by the CSIR, India and was revoked in 2000 by the EPO. The revocation was subsequently followed by an appeal. (Refer to Note 65)

<sup>115</sup> "India wins neem patent case", *The Hindu*, March 8.

national concern about biopiracy. The Delhi based NGO Gene Campaign had made the pioneering nation wide campaign against patents on seed and life forms. Their demonstrations to protest the TRIPS Agreement were crucial in creating political awareness and focusing national attention on the issues of biopiracy, farmers' rights and their relationship with livelihood of local and indigenous communities.<sup>116</sup> The RFSTE has taken up similar campaigns to protect Indian products like Basmati rice, Neem, Mustard etc.<sup>117</sup>

The activities of these organizations follow a multi pronged strategy at several levels, ranging from local and indigenous communities to governments. Civil society groups have been campaigning and lobbying for national legislations to protect our biodiversity and traditional knowledge as well as farmers' rights. The Gene Campaign had launched a seven-year campaign to secure farmers' rights in the context of patents on seeds. The framing of the Protection of Plant Varieties and Farmers Rights Act, 2001, had strong intervention of the Gene Campaign. The interpretation of *farmers' rights* as that to sell not only their own seed but also the protected varieties has been incorporated with its intervention. In fact, the Public Interest Litigation filed by the Gene Campaign in the Delhi High Court to restrain the Indian government from joining the UPOV, made possible the formulation of India's own *sui generis* legislation.<sup>118</sup>

The drafting process of the National Biological Diversity Act, 2002 has substantial inputs from concerned civil society groups. Prolonged lobbying by

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<sup>116</sup> [http://www.genecampaign.org/about\\_us/activities.html](http://www.genecampaign.org/about_us/activities.html)

<sup>117</sup> <http://www.vshiva.net/archives/campaign.htm>

<sup>118</sup> [http://www.genecampaign.org/about\\_us/achievements.html](http://www.genecampaign.org/about_us/achievements.html)

civil society groups for a law specifying the products for which India would claim geographically indicated rights, culminated in the Geographical Indication Act, 1999.<sup>119</sup> With their sustained campaigning, these groups have succeeded in gaining protection of indigenous knowledge in the Indian Patent (Second Amendment) Act, 2002.

With grassroot association with the local masses, these organizations have sought to aware and mobilize them against the oppressive patents regime. Bija Satyagraha and Bija Yatras across the country are by and large people's movements to oppose the colonisation of life through patents and to mobilize social action to keep seed free from corporate control.<sup>120</sup>

Other much organized and widespread attempt of these public interest groups has been towards initiating documentation of traditional knowledge. Gene Campaign has undertaken work on documentation of biodiversity and traditional knowledge among the Munnars in South Bihar, the Bhils of Madhya Pradesh, and the Tharus of the Terai region. Medicinal plants and related traditional knowledge have been documented with the active involvement of tribal youth, on the basis of the information and understanding gathered from village elders and tribal healers.<sup>121</sup>

SRISTI, the Society for Research and Initiatives for Sustainable Technologies and Institutions based in Ahmedabad, through its Honey Bee initiative, has been involved in documenting innovation developed by individuals at village level. It has documented innovations and traditional practices to form a 10,000 strong database

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<sup>119</sup> [http://www.genecampaign.org/about\\_us/impact\\_efforts.html](http://www.genecampaign.org/about_us/impact_efforts.html)

<sup>120</sup> [http://www.vshiva.net/archives/campaign/bija\\_satyagraha.htm](http://www.vshiva.net/archives/campaign/bija_satyagraha.htm)

<sup>121</sup> Refer to Note 119.

(Honey bee Database of Grassroots Innovation).<sup>122</sup> It aims, through this documentation and subsequent accrual of benefits, to provide a platform through which biodiversity and local knowledge bases can be conserved.

The Research Foundation of Science, Technology and Ecology (RFSTE) initiated a movement called the Jaiv Panchayat: Living Democracy started in early 1999. This movement aims to establish ownership of the local communities over their biological resources. Activists from RFSTE and Navdanya have been interacting with local villagers in different parts India to constitute informal community-level institutions called Jaiv Panchayats, comprising volunteers from villages. The members of the Jaiv Panchayat are entrusted with the task of inquiring and recording information on biological resources, and various uses of the same in the form of Community Biodiversity Registers (CBRs).<sup>123</sup>

Kalpavriksh and the Beej Bachao Aandolan (Save the Seeds Campaign) have collaborated to document the various bio-resources used by the community and conservation practices in the Tehri-Garhwal district of Uttaranchal with the association of the villagers. The Beej Bachao Aandolan has been involved for a number of years in reviving and spreading indigenous crop variety.<sup>124</sup> By mutual agreement between Kalpavriksh and the villagers, it was decided that a copy of the register would be kept in the village and another copy would be kept by Kalpavriksh. All the information in the register can be used be distributed only with the consent and knowledge of the villagers.

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<sup>122</sup> <http://www.sristi.org/honeybee.html>

<sup>123</sup> <http://www.vshiva.net/campaign.htm>

<sup>124</sup> Shiva Vandana, *Campaign Against Biopiracy* (New Delhi, Research Foundation for Science, Technology and Ecology), 1999, pp.18-26.



These groups are vehement critics of the government's legislations on biodiversity, plant protection and patents. Emphasizing that the government has paid only lip service to the concepts of farmers' rights, benefit sharing etc., they have been pressing for modifications in the laws. Overall, the NGOs can be seen to be quite proactive. Some of them have formed coalitions with other like minded organisations in other developing countries to lobby in the international negotiations. However, the parameters of the role of the civil society groups in India is still constrained by the largely bureaucratic policy making process. There has not been much structural intervention of these groups in the government's diplomatic strategies in the international fora.

## Chapter 4

### **Legislating Against Biopiracy: Different Experiences**

(Andean Pact countries, Costa Rica and the Philippines)

The CBD requires that Member Countries implement its provisions through national legislations and policy. Extending protection to traditional knowledge, ensuring sustainable use of biodiversity as well as fair and equitable access and benefit sharing mechanisms are the responsibility of national governments, well before negotiating on international protection and standards. Countries have choices in determining what would comprise, for instance, an ABS legislation, including modification of exiting laws and regulations, integration of ABS concerns in new framework environmental or biodiversity laws, and the creation of new legal instruments focused specifically on ABS issues. It is also an entirely national decision to promote, tolerate or discourage bioprospecting.

Based on such considerations some countries have shaped their laws and policies to regulate ABS and to protect their genetic resources and associated TK. These legislations are indispensable weapons to combat biopiracy and to ensure that any flow of resources and local knowledge is regulated by national authorities. It is discouraging that till date only thirty-six countries have legislated or reformed existing legislations in some form to fulfill their obligations under the CBD. These measures are varied in nature, scope and content. These countries are at various levels of implementation of ABS laws and *sui generis* legislations, reflecting their national administrative structures, priorities, cultural and social specificities. In a number of these countries, general laws on environment, sustainable development and

biodiversity address access and benefit-sharing in varying degrees of detail and provide for the establishment of guidelines or regulations on access and benefit-sharing. Some countries refer to access and benefit-sharing in their national biodiversity strategy or their environmental or biodiversity legislation but have not yet regulated access and benefit-sharing in any detail. There are others that have a biodiversity or environmental law with some general provisions on access to genetic resources or biological resources, which may include a provision for the establishment of a regulation on access and benefit-sharing. There are some countries which have addressed access and benefit-sharing in greater detail.

A comparative analysis of existing and draft access legislations done by Charles V Barber and others reveal that countries are basically adopting five approaches.<sup>125</sup> The first approach includes general environmental framework laws, such as those in Gambia, Kenya, Malawi, Republic of Korea and Uganda. Their enactments are basically enabling laws that merely charge a competent national authority to examine ABS issues in order to provide guidance for more specific legislation or regulation in the future. They do not in themselves, establish any sort of national legal or administrative framework. They may in future, formulate more detailed legislation.

The second approach involves inclusion of ABS issues in framework sustainable development, nature conservation or biodiversity laws, with examples found in Costa Rica, Eritrea, Fiji, Mexico and Peru. Their laws are more detailed in the sense that they clearly establish the principles of mutually agreed terms and PIC. However these are not yet fully developed into functioning ABS regimes.

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<sup>125</sup> Barber, Charles V et al, 'Developing and implementing national measures for genetic resources access regulation and benefit-sharing' in Sarah A. Laird (ed), *Biodiversity and Traditional Knowledge: Equitable Partnership in Practice*, (London, Earthscan Publications Ltd.), 2002, p. 375-378.

The third approach is the development of specific national laws or executive orders on access to genetic resources. India's Biodiversity Act, 2002 is an example of this kind. The Philippines Executive order of 1995 is the only example of an executive order that is implemented to regulate access to genetic resources.

The fourth kind is to modify existing laws and regulations such as those governing wildlife, national parks, forestry, fisheries etc. to include provisions on ABS. Nigeria and Malaysia have followed this model so far. One advantage pointed out for such measures is that the country can use existing administrative measures, policies and institutional structures.

Finally, legislative action can be taken at the regional level like in the case of the Andean Pact, which creates a common regime on access to genetic resources. The countries of the Association of South-East Asian Nations (ASEAN) also initiated discussions during 1998 aimed at creating a common ASEAN policy framework on access. A draft ASEAN Framework Agreement on Access to Biological and Genetic Resources has been submitted for further consideration in June 2001.<sup>126</sup> In Africa, Model Legislation on Community Rights and Access to Biological Resources, prepared by the Organisation of African Unity (OAU), was recommended for adoption by the organisation which resulted in the African Model Law for the Protection of the Rights of Local Communities.<sup>127</sup> A draft Central American Agreement on Access to Genetic Resources and Bio-chemicals and Traditional

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<sup>126</sup> <http://www.grain.org/brl/?docid=785&lawid=1261>

<sup>127</sup> Ekpere, Johnson A, 'The African Union Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders and Regulation of Access to Biological Resources' in Bellmann, Christopher et al (eds), *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability*, (London, Earthscan), 2003, pp.232-236.

Knowledge has also been developed for consideration to be adopted by the Central American countries.<sup>128</sup>

All these approaches have comparative advantages and disadvantages but nevertheless they serve the purpose of regulating access and benefit sharing at the national level. Their existence do not minimise the need of an international ABS regime because the debate at the international level is based on additional demands. Many developing countries argue that while national laws regulate access to resources, there should be a binding international regime that requires the user country to formulate laws that binds itself to follow the regulations of the provider country. This chapter looks into the some of the exiting national ABS laws to find out how effective they may be in controlling and regulating access and benefit sharing and in protecting traditional knowledge systems from biopiracy.

### **ABS Regime for Andean Pact Countries**

The Andean Community is an economic and social integration treaty formed by Venezuela, Columbia, Ecuador, Peru and Bolivia. Intense debates among the Andean community since 1992 on the issues of access to genetic resources, IPRs and their impact on biodiversity and the protection of TK have resulted in the **Decision 391** on a Common Regime on Access to Genetic Resources (1996), **Decision 486** on a common regime on Industrial Property (2000), **Decision 523** on a Regional Biodiversity Strategy (2002) and **Decision 524** on an Indigenous Peoples Regional Working Group (2002). The member countries may implement the rules directly (by

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<sup>128</sup> Medaglia, Jorge Cabrera, 'The Central American Regional Protocol on Access to Genetic and Biochemical Resources' in *Ibid*, pp. 246-253.

officially acknowledging the Decisions as national laws) through complementary national implementing legislations.

**Decision 391** of the Andean Pact is a legally binding instrument and is more elaborate than the other regional instruments. The basic features of Decision 391 that establishes the regional legal regime on ABS are: (1) the definition of 'access' which implies access to and use of genetic resources or their derivatives for commercial, industrial or scientific purposes; (2) the objective of the common regime, which is to ensure benefit sharing, enhance scientific and technical capacities, promote conservation and strengthen negotiating capacities of member states; (3) the scope of the regime, which applies to genetic resources and their derivatives of which member states are countries of origin; (4) the legal status of genetic resources, which is that they and their derivatives are patrimonies of the state, but biological resources can be subject to private rights. Since states have rights over genetic resources, the state must be party to any agreement granting access to, and use of, these resources; (5) that indigenous peoples have the right to decide over the use of their knowledge, innovations and practices as they relate to genetic resources. Where genetic resources have an associated traditional knowledge, a discrete access contract must be negotiated and signed by the applicant, the state and the provider of the associated knowledge. This presumably demonstrates the consent of the provider to use the knowledge although the decision has no explicit provision referring to PIC of local and indigenous communities for use of their knowledge; (6) that bioprospecting contracts are the main instrument through which access and benefit sharing will be regulated.<sup>129</sup> A primary access contract between the applicant seeking access to

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<sup>129</sup> Ruiz, Manuel, 'The Andean Community Regimes on Access to Genetic Resources, Intellectual Property, and the Protection of Indigenous People's Knowledge' in *Ibid*, pp.239-240.

genetic resources and the competent authority designated by the government of the country in question would specify the basic conditions for ABS. Apart from the primary access agreement, there may be Accessory agreements related to the biological resources over which communities, individuals, ex-situ centres or the state may have proprietary rights. These agreements could also include agreements for the use of indigenous people's knowledge.

However the main objectives of Decision 391 have not been achieved so far. In the first place, not all member countries have implemented them evenly. There are very few formal bioprospecting activities taking place in the region. Although originally conceived to prevent competition among countries and to promote regional benefit sharing, Decision 391 does not establish the specific mechanisms through which benefits may be shared among the member states. Decision 391 did not require the development of any new national law, it became binding on all the Member countries as soon as it was adopted and was automatically integrated into national legislation. But there are technical ambiguities, social protest, political concerns, and institutional limitations, among other factors, that forced Bolivia, Ecuador, Peru, and recently Colombia to develop national policies to facilitate the implementation of decision 391 into their national context. These cause lots of difficulties at the practical level because countries design measures to implement the rule at national level whereas it needs to have regional implications.<sup>130</sup>

Linked to Decision 391 is **Decision 486** which is another step taken by the Andean community to find ways in which IPRs, ABS provisions and the CBD's principles can be reconciled to ensure that biodiversity components are sustainably used and, especially the benefits derived thereof can be equitably shared. The decision

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<sup>130</sup> Ibid.

basically proposes that since biotechnological inventions may be directly or indirectly derived from genetic resources or related traditional knowledge, applicants for patents must make sure they comply with access and TK regulations as provided under Decision 391. The Decision 486 requires that patent applications should include, if applicable, **a copy of the access contract**, when products or procedure whose protection is requested have been obtained or developed based on genetic resources or the derived product of which any of the member states is a country of origin. It also requires (if applicable), a copy of the license for the use of traditional knowledge.<sup>131</sup> These procedures when followed properly would ensure that all regulations related to ABS and TK are also followed. The greatest drawback of this rule, however, is the 'if applicable' phrase. It requires the national authorities to determine under what circumstances and regarding what inventions they should request these documents.

Neither of these rules specifically protects indigenous peoples' knowledge though they both address the issue in some manner.

### **Costa Rican Law on Biodiversity**

Costa Rica's Biodiversity Law, approved on 23 April 1998, is the culmination of a long process to develop a legal framework that will result in a more equitable distribution of benefits deriving from the commercial exploitation of biodiversity resources. The objective was to draft a law capable of implementing all aspects of the Convention on Biological Diversity in an integrated manner, while contemplating the possibility developing distinct regulations for more specific themes such as biosecurity, biotechnology, access and intellectual property in the future. Costa Rica was one of the first countries to enact a biodiversity legislation following the CBD

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<sup>131</sup> Ibid, p.241.



and also the Costa Rican law is a comprehensive law that takes the Convention on Biological Diversity all together. The main features of the law are:

- (a) Definition of Biodiversity, Bioprospecting, Genetic Resources, PIC, Knowledge. The uniqueness of the legislation is the recognition of bioprospecting agreements as useful means to enable equitable benefit sharing. “Bioprospecting” is defined under the law as the systematic search for, and classification of research for commercial application of new sources of chemical compounds, genes, proteins, micro-organisms and other products of current or potential economic use that are found in biodiversity. PIC is defined as the procedure by which the State, private owners or local and indigenous communities, having been previously supplied with all requested information, agree to permit access to biological resources or to the intangible component associated with them under mutually agreed conditions.
- (b) Establishment of the National Commission of Biodiversity Management that is composed of eleven stakeholders represented by different agencies and organisations. They are (1) Environment and Energy, which presides over the Commission, (2) Agriculture and Livestock, (3) Health, (4) Overseas Trade, (5) The Costa Rican Institute for Fisheries and Aquaculture, the body charged with marine resources, (6) The Executive Director of the National System of Conservation Areas, (7) The Association of National Small Farmers’ Group, (8) The Association of National Indigenous Group, (9) The Costa Rican Federation of National Environment Conservation, (10) The Costa Rican Union of Chambers of Private Industry, (11) The National Council of Rectors
- (c) Access provisions: The basic conditions for access are: PIC of the representatives of the sites where access is to take place, these being the

regional councils of the conservation areas, farm owners or the indigenous authorities when the sites are within their territories; approval of the PIC by the Commission's Technical Office; the terms of transfer of technology and the fair distribution of benefits, agreed to in the permits, agreements and the concessions, as well as the type of protection of associated knowledge called for by the representatives of the place where access takes place; the definition of the means by which such activities will contribute towards the conservation of species and ecosystems; designation of an in-country legal representatives in cases where individuals or corporate residents reside outside the country;

- (d) Right to cultural objection: The law also recognises the right of local communities and indigenous people to oppose access to their resources and associated knowledge for cultural, social, spiritual, economic or other reasons.
- (e) Access permit for research or biodiversity prospecting: Any research programme or bioprospecting on genetic or biochemical material to be conducted in Costa Rican territory requires an access permit. Such access permits do not grant or delegate rights, and only allow the carrying out of such activities on previously established biodiversity components. The permits must clearly stipulate the certificate of origin, the possibility of prohibition on extracting or exporting samples, or in its absence, the duplication or deposition of materials etc.
- (f) Voluntary Registration: Individuals or corporate entities who wish to carry out bioprospecting should register with the commission. However registration does not provide rights to carry out the activities specific to bioprospecting.

- (g) IPRs: the law provides for State protection of intellectual and industrial property rights through patents, trade secrets, plant breeder's rights, sui generis community intellectual rights, copy rights and farmer' rights.
- (h) Sui generis community intellectual rights: The State expressly recognises protects, under the rubric of *sui generis* community intellectual rights, knowledge, practices and innovations of indigenous peoples and local communities related to the use of biodiversity components and associated knowledge. this right exists and is legally recognised by the simple existence of the cultural practice or knowledge related to genetic and biochemical resources; it requires no previous declaration, express recognition or official registration, and thus may include practices that might acquire such status in the future. The law provides for the creation of an inventory of *sui generis* community intellectual rights that communities ask to be protected, with the understanding that others of a similar nature may be registered and recognised in the future <sup>132</sup>

Costa Rica is the only Latin American country which has fully developed bioprospection and maintains regulated ties with the TNCs. It encourages bioprospecting as part of its national biodiversity policy. A country that wishes to encourage bioprospecting needs to add value to its stock of genetic resources, which involves investing in building scientific capacity. Costa Rica's National Institute of Biodiversity (INBio), for instance, is said to be providing bioprospectors much more than just access to raw genetic material. INBio claims that it doesn't provide

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<sup>132</sup> Vivienne Solís Rivera and Patricia Madrigal Cordero, 'Costa Rica's Biodiversity Law: Sharing the Process' in *Journal of International Wildlife Law & Policy*, Volume 2, No. 2 (1999) pp. 259-265.

unprocessed genetic material but that it adds value.<sup>133</sup> Instead of criticizing the international firms, INBio regards them as partners. The first major bilateral bioprospecting contract that caught international attention was the deal between INBio and the US pharmaceutical corporation Merck & Co. in 1991 whereby INBio would provide Merck's drug screening programmes with chemical extracts from wild plants, insects and microorganisms. INBio has secured prospecting rights to lands which according to national laws are under State ownership, permitting very little in the way of local control. Critics of INBio's policies say that it is a "Trojan Horse" that international "biopirates" use to gain entrance to the country to plunder its riches.<sup>134</sup> Although the agreement with Merck provides benefits for the government and for INBio, no benefits will go to local communities except for the training of a small of "parataxonomists". Furthermore, INBio will not contribute at all to revitalising local knowledge systems because it professes to have no interest at all in such knowledge. In fact, according to D.A. Posey, the Director of INBio was unaware that there were indigenous peoples in the country, although the agreement was for collecting on national lands, including of eight indigenous communities.<sup>135</sup> Notwithstanding the criticisms, INBio's experience has also become enshrined in Costa Rica's legal system. The country's Biodiversity Law, passed by the Legislative Assembly in 1998, models several of its provisions on benefit sharing and intellectual property rights on INBio's principles on access to biodiversity sources.

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<sup>133</sup> Hamilton, Roger, 'Bioprospecting, with no apologies' in <http://www.iadb.org/idbamerica/index.cfm?thisid=2705>

<sup>134</sup> Ibid.

<sup>135</sup> Posey, D.A. 'Biodiversity, Genetic Resources and Indigenous Peoples in Amazonia: (Re) Discovering the Wealth of Traditional Resources of Native Amazonians', in *AMAZONIA 2000: Development, Environment, and Geopolitics*, 24-26 June, 1998.

## **Regulating Access in Philippines**

The biodiversity of the Philippines is depleting at an alarming rate. It is home to some of the world's most diverse forests with a wide diversity in flora and fauna. Its marine diversity is equally rich. The government and the NGOs have taken rapid moves in the past decade to establish a policy framework to slow the alarming loss of biodiversity and to set a course for sustainable use of the country's biological and genetic resources. Notable developments have been the establishment of the Philippine Council on Sustainable Development and the promulgation of the National Integrated Protected Areas System Act (NIPAS) in 1992, the ratification of the CBD in 1993, development of a framework National Biodiversity Strategy in 1994, and the Presidents Executive Order on bioprospecting and its implementing regulations.<sup>136</sup> The Presidential Executive Order (PEO) was issued in mid-1995 to regulate bioprospecting. It was one of the first attempts and first of its kind to respond to the CBD's mandate on access to genetic resources. The Philippines had in place mechanisms to oversee bioprospecting activities even before 1995 such as the Memorandum of agreement entitled 'Guidelines for the Collection of Biological Specimens in the Philippines'. But it contained no provisions on the participation and involvement of indigenous and local communities, or on benefit sharing. The PEO No.247 of 1995, entitled 'Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, Their By-products and Derivatives, for Scientific and Commercial Purposes: and for Other Purposes', is an attempt to remedy the inadequacies of the former system by establishing a more comprehensive and effective regulatory framework for

bioprospecting. The Philippines has adopted a new legislation to address access and benefit-sharing, the Wildlife Resources Conservation and Protection Act (enacted on 30 July 2001), and developed new draft implementing guidelines on bioprospecting. Provisions of the Executive Order 247, that are clearly contradictory to and irreconcilable with the Wildlife Act, are deemed repealed.

The basic features of the PEO are still some of the basic elements that form the framework to regulate bioprospecting. They are:

- (a) A system of **mandatory research agreements**: The order calls for mandatory academic research agreements (ARA) between collectors and the government. Recognises national academic agencies, research institutions and inter-governmental institutions are eligible for Academic Research Agreements (ARA). Research and collection for commercial purposes may only take place under a Commercial Research Agreement (CRA). Both ARA and CRA demand that the collector submit a report on the research and the ecological status of the species to be collected. A set of all specimens collected must be deposited with the national museum and any commercial product resulting from the collection must be disclosed to the government and the relevant local community. The government and all citizens must be assured access to specimens deposited abroad. The agreements are reviewed annually and may be terminated by the government if the collector violates any terms. CRAs also demand that foreign commercial collectors involve

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<sup>136</sup> Barber, Charles V. and La Vina, Antonio, 'Regulating access to genetic resources: The Philippines experience' in Mugabe, John et al (eds), *Access to Genetic Resources: Strategies for Sharing Benefits*, (Bonn, IUCN), 1997, p.117.

Filipino scientists in research and collection of biological resources and in the technological development of any product.<sup>137</sup>

- (b) **Inter-Agency Committee (IAC):** is the regulatory body to ensure that the provisions of the PEO are enforced and implemented. This body is supposed to ensure that the rights of indigenous and local communities under the PEO are protected, especially with regard to PIC procedures. It is empowered to process applications for research agreements and to determine the list of species and amounts of material that may be collected.
- (c) **PIC from local and indigenous communities:** The order has strong provisions requiring the PIC of communities before any bioprospecting affecting them is allowed. It establishes a procedure for assessing, obtaining, and verifying that consent. However PIC has not been defined in the PEO. To ensure that the PIC of the communities has been obtained, the PEO requires that a copy of the application be submitted to the recognised head of the local or indigenous community that may be affected and that no action on the proposal be taken for a period of 60 days, to give the community an opportunity to oppose such application on the basis of possible harm to the local environment and way of life. However the main shortcoming of the PEO is that it doesn't refer to the indigenous knowledge associated with the genetic material and PIC is restricted to that of access to genetic resources. Thus it lacks in the most essential aspect related to local and indigenous communities.
- (d) **Benefit sharing:** Though the PEO provides a framework for benefit sharing, it doesn't elaborate specific mechanisms of doing so, apart from the general provisions on technology co-operation and transfer. It requires that all

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<sup>137</sup> Agarwal, Anil, and others (eds), *Green Politics*, (New Delhi, C.S.E.), 1999, p.154.

agreements contain a provision on royalties, and other forms of compensation may also be negotiated in appropriate cases. The order states that rights of indigenous and local communities must be respected and rewarded, and that royalties or other forms of compensation must be paid not only to the national government but also to the local communities from which resources are taken. Even then no mechanism is specified to make this possible.

The Indigenous Peoples Rights Act (IPRA) of 1997 is another law that is specific about the right of the communities over their indigenous knowledge and which very well complements the PEO because the latter is silent on traditional knowledge. The IPRA requires that granting of patents based on genetic resources, traditional medicines, indigenous knowledge systems and practices etc. is conditional to full PIC of the community in question. The Act recognises that control over indigenous knowledge related to genetic resources requires that indigenous communities possess the right to regulate biological and genetic resources located within their territories.<sup>138</sup>

According to certain authors who have examined the Philippines experience, the following lessons can be drawn: stakeholder participation is essential in developing, enacting and implementing access and benefit-sharing policies, laws, rules and regulations; defining the scope and coverage of a national access and benefit-sharing regulation is a priority concern; the potential impacts on scientific research activities must be carefully considered when designing and implementing national access and benefit-sharing measures; creative approaches to obtaining consent from, and sharing benefits with, local communities, including indigenous peoples, need to be explored and developed; an efficient and effective institutional

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<sup>138</sup> Note 1, p. 384.



system should be put in place; and, in regions where countries share genetic resources, regional mechanisms may be required.<sup>139</sup>

### **Protection of Traditional Knowledge in Peru**

Peru introduced a *sui generis* protection regime in 2002 through legislation. The objectives of the regime are to: (a) promote respect, protection, preservation, wider application and development of the collective knowledge of indigenous peoples; (b) promote the fair and equitable distributions of the benefits derived from the use of their collective knowledge; (c) promote the use of this knowledge for the benefit of indigenous peoples and mankind; (d) ensure that the use of this knowledge takes place with the PIC of the indigenous peoples; (e) promote the strengthening and development of the capabilities of indigenous peoples, and of the mechanisms traditionally used by them, to share and distribute collectively generated benefits; and (f) avoid the patenting of inventions obtained or developed using the collective knowledge of the indigenous peoples of Peru.<sup>140</sup> The main features of the law are:

- (1) PIC: is the main condition to be fulfilled in order to have access to collective knowledge under this regime. PIC is defined as “Authorisation given, under this protective regime, by the representative organisation of indigenous peoples who possess the collective knowledge, in accordance with the rules recognised by them for the execution of a particular activity that entails access to and use of the said collective knowledge, subject to the previous supply of

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<sup>139</sup> ‘Analysis of Existing National, Regional and International Legal Instruments Relating to ABS and Experience Gained in their Implementation, Including Identification of Gaps’, UNEP/CBD/WG-ABS/3/2.

<sup>140</sup> Aguirre, Begona Venéro, ‘The Peruvian Law on Protection of Collective Knowledge of Indigenous Peoples Related to Biological Resources’ in Bellmann, Christopher et al (eds), *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability*, (London, Earthscan), 2003, p. 285.

sufficient information on the purposes, risks and implications of such activity, including the uses that may eventually be made of the knowledge, be it the case, its value". The indigenous people may choose not to give their consent, without which, access to their knowledge will be deemed illegal.

- (2) License Contracts: Access to collective knowledge should be based on a license contract signed between those seeking access and the local communities. The license contract should establish the monetary payments that indigenous people will receive.
- (3) Registers: There are three kinds of registers as established by the law. These are the National Public Register of Collective Knowledge of Indigenous Peoples; the National Confidential Register of Collective Knowledge of Indigenous Peoples; and, Local Registers of Collective Knowledge of Indigenous Peoples. The National Public Register, which registers the public domain knowledge, would act as evidence of 'prior art' for the use of patent offices around the world to screen patent applications in relevant technical fields for novelty and inventive step. However the law does not require PIC or license contract for access to public domain collective knowledge because it would be extremely difficult to determine which indigenous people or peoples possessed the knowledge before it passed into public domain.<sup>141</sup>

These are diverse national experiences on how to regulate access to genetic resources and ensure benefit sharing. While some countries have only adopted one measure, others have adopted a package of measures including, for example, a national strategy, a law and guidelines. Most of these are relatively new. Therefore,

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<sup>141</sup> WIPO/GRTKF/IC/317, "Review of Existing Intellectual Property Protection of Traditional Knowledge", May 6, 2002.

lessons learned or experience gained from their implementation is limited. These countries are also struggling at national level for the implementation of the laws in correspondence with each other. There are some very complex linkages between access to genetic resources, IPRs and indigenous peoples' knowledge related issues and it becomes extremely difficult to address each issue in isolation. If the access and benefit sharing regime is to be fair and equitable, it has to be accompanied by an IPR regime which ensures that the interests of the countries of origin and indigenous knowledge are respected. Any legislation or system of protection of traditional knowledge, at whatever level, has to be responded by an effective ABS regime and a sensitive IPR regime. A single legal mechanism or instrument is insufficient to protect all traditional knowledge and its manifestations, such as a new plant variety or the use of a medicinal herb or single plant. Many developing countries argue that an all embracing international agreement for the protection of indigenous intellectual property could go a long way to ensure better protection.

In the meantime, an international ABS regime is being discussed to ensure that all international dealings related to biodiversity and traditional knowledge take place with total legality. Many developing countries, which have developed national measures to regulate access, are proactive in the negotiations to establish an international regime. In the third meeting of the Ad Hoc Open-ended Working Group on ABS held in Thailand in February 2005, countries deliberated on the nature of a possible international regime. **India**, on behalf of the LMMC group, said the regime should include: prior informed consent of the country of origin; mutually agreed terms (MAT) between the country of origin and the user country; and mandatory disclosure of origin of genetic resources in IPR applications, including sanctions in case of failure to disclose all these. **Peru** underscored national mechanisms for PIC and

MAT, and the need to develop national biodiversity knowledge to ensure ABS. Costa Rica said that international regime should stimulate and support the implementation of national legislation. Highlighting the need for controlling biopiracy and for technology transfer, **the Philippines** said the CBD is the primary framework to address ABS issues and that it is necessary to address the conflicts between TRIPS and the CBD.<sup>142</sup>

One thing that is clear is that the developing countries are very keen on international regimes to protect traditional knowledge and ensure fair ABS. However, many of them are not equally keen on building competent national measures for the same purposes. International regimes are enforced through national measures. The absence of adequate national protection is already dampening the objectives of the Convention on Biodiversity, which was adopted with so much enthusiasm by the developing countries more than a decade ago. The developing countries should, in the first place, enact legislations that would benefit the holders of traditional knowledge and custodians of genetic resources. There are complex issues, which are yet to be settled at the domestic levels. Most important among them is the issue of ownership of biological and genetic resources. Many civil society organisations perceive that without ownership rights over biological resources, communities cannot rightfully claim their share of benefits arising out of the use of these resources. Most of the national laws vest this ownership right on the states, leaving the rights of the local communities as the subjects of constant debates at the domestic circles. Thus even if many countries propose of an international law to protect traditional knowledge, there are serious lapses in the way they themselves treat the subject in their national capacities.

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<sup>142</sup> ABS WG-3 Highlights, Earth Negotiations Bulletin - Vol. 9 No. 307  
Tuesday, 15 February 2005.

But the debate that is overwhelming is about the need for international regimes. One thing that cannot be denied is that there should be an internationally agreed agreement that recognises the national level protection. It would be impractical to have different levels of protection and benefit sharing in different countries, which do not correspond with one another's. There should be an international guarantee that the kind of protection and standards of ABS given by one country is respected by all other countries.

## Chapter 5

### Conclusion

Many developing countries are grappling how to deal with their biological resources and associated traditional knowledge. The manifest problem is biopiracy, but there are far complex issues related to such resources, about which the developing country governments are not unanimous. Their ways of dealing with the resources are varied. Sustainable use of biological resources is a common objective of all the countries, but what constitutes 'sustainability' is still undefined. Though most of them agree that unregulated bioprospecting is the key facilitator of biopiracy, they are still indecisive about whether to ban bioprospecting altogether or if allowed, how much governmental interference is necessary for making the bioprospecting deals mutually benefiting. Not all the Southern countries are keen on biotrade, the way in which Costa Rica and Columbia are engaged in. Columbia, for instance, has an institutional mechanism in place to facilitate biotrade. The Alexander von Humboldt Institute of Columbia through its Sustainable Biotrade Initiative is facilitating the maximization of economic benefits from the sustainable use of biological resources, also aiming to devise possible mechanisms to protect traditional knowledge relating to the use of medicinal plants. It carries out projects for the commercial development of medicinal plants by involving members of indigenous communities. Costa Rica's National Biodiversity Institute (INBio), has been engaged in bioprospecting deals with foreign pharmaceutical companies for more than a decade. Whether such mechanisms benefit the local and indigenous communities who hold the knowledge that is intrinsic to the handling of biodiversity, is a matter of another debate. Even to

begin with, most of the developing countries do not have proper research and study on the economic worth of their biological and genetic resources, in the absence of which, they are in a hung situation. Some governments are skeptical about even legal bioprospecting and are unsure how it would benefit them and their local communities.

One thing is clear after all the years of speculation and international debates, that the panacea for biopiracy is not shutting the doors for bioprospectors but the sustainable use of the biological resources in a legal and mutually beneficial manner. The themes of the international negotiations since the past decade are fair and equitable benefit sharing; granting international protection to traditional knowledge and reviewing of the IPR regime to stop the piracy of biological resources and related TK. The focus is on legalising the utilisation of such resources and knowledge by foreign TNCs and researchers in return of monetary, technological and other non-monetary benefits to the country of origin. However, even legal agreements are not away from criticism because bioprospecting contracts do not by themselves guarantee that the traditional knowledge associated with the resources will not be manipulated. The protection of traditional knowledge should also be ensured by national authorities in the first place and mostly the authorities decide which communities should get the benefits and how much.

The rights of the people to their knowledge and resources are the critical link to the whole issue of benefit sharing. The most difficult decisions are about the return of the benefits to the local and indigenous communities. Even in an elaborate legal bioprospecting agreement, it would be difficult to determine the recipients of monetary and non-monetary benefits within a region where medicinal plants are widely and similarly used or where appropriate individuals, groups or communities are difficult to determine. The more difficult the problem is when these communities

have no rights to the land or the resources as the case is in most of the states. Some communities have no ownership over land, some have only usufruct rights while some have systems of communal ownership. Most states exercise exclusive sovereignty over biological resources. Some like Costa Rica accredit the genetic properties of wild and domesticated elements of biodiversity to public domain. This kind of ambiguous relations of ownership confuses the terms of access and benefit sharing. Local and indigenous peoples often face the complexity of legal practices when it comes to ownership, use of resources, access to resources and mainly when they are supposed to be get a share of the benefits arising from the use of their knowledge of these resources. If the national laws do not recognise the rights of the local communities to make contracts and take decisions and legal action on their own, even the most cautious provision would not benefit the local communities. There will be flow of funds to the national exchequer, but the communities will not be benefited in the manner they would want. The question is not merely of acquiring prior informed consent of the communities whose knowledge is being used, because most of the time PIC is to be given by a governmental agency on behalf of the communities, which may or may not represent the true aspirations of the communities. What some activists and researchers demand and seem to be of more worth to the communities is a right to say no to the bioprospectors (both national and foreign) on their own if they feel that it would not benefit them. RAFI has interestingly termed it as No Intention of Consenting (NIC). This right is important because most bioprospectors consider traditional knowledge as just another value added to the product, which is to be marketed. Traditional knowledge, which is so intrinsic to the handling of biodiversity, cannot be merely perceived as an added value. There is much more cultural significance to it than just economic, and this



needs to be respected to stop their exploitation. It also cannot be assumed that all the developing country governments are bothered about the rights of the indigenous people when they are talking about biopiracy. These are the issues which essentially require to be resolved, in the first place, at the national and local levels by the respective governments.

There is definitely the international aspect, for which the developing countries are pushing forward. International diplomacy for an international ABS regime within the framework of the CBD would probably come forth with one. The mechanism of the possible regime would require that domestic policy and legislations are revised and updated to fit into the regime. These all are feasible as some legislations are already in place. The real problem lies at the heart of the old debate between the CBD and the international IPR regime. It is doubtful that the TRIPS Agreement would be revised to include the three proposed conditions of patentability (namely, mandatory disclosure of origin of the resources and the traditional knowledge; evidence of PIC; and evidence of fair and equitable benefit sharing) with the already existent ones as per Article 29. The other demand for 'no patents on life' has also reached nowhere; on the other hand countries are compelled to grant patents on life forms as required under Article 27.3(b). The demands of the developing countries for the inclusion of the three new conditions are basically aimed to make the IPR regime supportive of the basic features of the CBD. The proposed ABS regime will hold no good to the developing countries and their local, indigenous communities if the TRIPS regime does not revise its conditions of patentability. If the three proposals are incorporated into Article 29, they will also deal with the anomalies in 'novelty', 'invention' and 'industrial application', which in their present form pave way for biopiracy. If at all a patent applicant has to attain PIC of the communities whose knowledge contributes to the

development of the product, it might negate that the product is new and is an invention. But the revision of TRIPS disproportionately depends on the will of some of the developed countries, notably the US and the EU, who claim that the two treaties are in fact compatible and could mutually reinforce each other.

Under such circumstances, it would be more fruitful for the developing countries to maximise their diplomatic clout in other relevant fora. It is a hopeful sign for them that the FAO Treaty has incorporated provisions on farmers' rights as breeders, which can be used to stop the piracy of seeds from the developing country farmers. It is upto individual countries as to how they recognise farmers' rights. If they do not approve of the UPOV model, they can develop *sui generis* models of plant variety protection, which give them considerable amount of freedom to choose the patterns of protection. The effectiveness of *sui generis* protection would depend on the will of the national governments, the process of policy and law making in the state, and the level of involvement and influence of the civil society elements including those that represent the farmers and local communities. The FAO Treaty may provide a model of farmers' rights for *sui generis* systems.

Deliberations at the WIPO to promote benefit sharing and prevent misappropriation of traditional knowledge depend on several factors. On one hand, the requirement to disclose the origin of genetic resources and/or traditional knowledge by patent applicants is obviously opposed by the opponents of the same requirement at the TRIPS. Other major limitation of the WIPO is that many developing countries do not consider that protection by WIPO is enough to guarantee misappropriation of traditional knowledge. This has much to do with the nature traditional knowledge in different countries. For instance, Australia and New Zealand, where traditional knowledge belongs to certain distinct communities, WIPO is

considered a viable option. But in India, for instance, biopiracy is perceived as a national loss, therefore there is more widespread demand to change the patent regime and nothing less than a guarantee from the TRIPS would convince.

The other focus of the WIPO deliberations is on documentation of traditional knowledge, to make them available to patent offices as proof of prior art. Though documentation is widely accepted by many developing countries as one of the measures to check misappropriation of traditional knowledge, it is a highly risk involving option. Due to lack of international safeguard against misappropriation, maintaining a database will only make the knowledge more vulnerable to biopiracy. It cannot be emphatically negated that the databases will not fall into the wrong hands. Databases of public domain traditional knowledge like the people's biodiversity registers are easier to be misused. Even then, documentation has gained acceptance in many states. It is without doubt that unless this process is accompanied by stringent international safeguards, it would serve the purpose of bioprospectors more than anyone else's. International guarantee is essential because national databases are created for patent offices around the world. It should be binding upon all the states to protect such databases from uses other than by patent examiners. The protection of the biodiversity registers that are in the public domain is closely depended on the patent systems. Though traditional knowledge is essentially a matter of *sui generis* protection, its significance for bioprospecting and biotechnology makes it central to all deliberations on international ABS and IPR regimes. National laws on the related issues have to be substantiated by international safeguards. So the ultimate responsibility lies at the international realm. Hence biopiracy, above all the national debates, is a serious diplomatic challenge for the biodiversity rich and culturally diverse Southern countries. Their strategies are emerging, from one negotiation to the

other, from one forum to another. One thing that has clearly emerged is that the common stands of these countries in recent years on the possible ABS regime and on the revision of TRIPS have given tough resistance to the strategies of the U.S. and its supporters. There is more that the group of Like Minded Mega Diverse countries can do in the ongoing negotiations. Their similar stakes in the issues and common challenges have brought them together, but success largely depends on how they develop common strategies for bargaining. Some of have their own national systems and structures of ABS IPRs and traditional knowledge, some do not, but their performance in international negotiations precondition that they leave their national baggage behind while in the fora for combating biopiracy.

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