CHAPTER 5

Bioprospecting, Benefit Sharing and Biopiracy

Introduction

The relevance of plant genetic resources for human well being is too obvious to be stated. Plant genetic resources form the basis of agriculture and contribute to a significant extent in providing medicines too. But the extinction of biodiversity has to be halted or reduced so that we at least know the value of what is being lost, lost forever. With the advent of biotechnology it became easier to analyze the genetic composition of a plant or a species and isolate the genes with specific qualities. The technology also made possible producing millions of identical copies and clonal propagation could be used to propagate plants facing extinction. Thus species came to be viewed as libraries or depositories or collections which could be used by biotechnology in ways which were not possible before. Echoing this view, speaking to the U.S. Congress in 1981 Tom Eisner advocated this idea and he used the word chemical prospecting.[1] But the term bioprospecting came into vogue later.[2] The Merck-InBio agreement is the first deal to put this idea into practice. Chemical prospecting was used by him in 1989 as North-South model for conservation and sustainable use. The idea is to systematically screen the species native to a country so that useful compounds could be found, categorized, isolated and used in drug development and discovery. Since not many developing nations have the resources for this purpose it was envisaged that pharmaceutical companies would come forward to use the genetic resources and this would result in a win-win situation whereby the country would get an incentive to conserve ecosystems and forests, can raise resources for conservation through agreements/deals with companies on chemical prospecting.

When it became clear that the genetic resources have enormous economic value and can be used effectively only if the resources and the ecosystems are managed in a sustainable manner, the idea of biological prospecting or biodiversity prospecting or bioprospecting was proposed as a win-win solution which would not only save the biodiversity but also will result in effective utilization of plant genetic resources. It should be noted that the biodiversity prospecting is based on a very utilitarian perspective and here the economic value of genetic resources and their potential benefits are the primary reasons, not factors like need the save genetic resources for their own sake or the need to save ecosystems like forests in view of their various functions or for aesthetic resources. This of course raises issues relating to values in biodiversity conservation, which have been discussed elsewhere. Some attempts were made to quantify the potential economic loss if some plants were extinct. For example it was estimated that OECD countries might incur pound sterling 25 billion per annum if the threatened 60,000 species were lost as a medicinal resource.[3]

Thus in theory bioprospecting is a pragmatic response to the biodiversity crisis, which tried to harness the needs of the industry to justify the access to genetic resources in view of their economic value. Of course it was also pointed out that bioprospecting will benefit the developing nations and indigenous people and will also bring in money and resources for conservation. But biodiversity became a contentious issue right from the beginning with opponents arguing that it will only enhance misappropriation of genetic resources of the developing nations with the developed nations getting access to genetic resources and it would not solve the biodiversity crisis.

With the signing of CBD it became obvious that a legal framework regulating access to genetic resources will become a reality in various countries as the CBD tried to encourage access and benefit sharing on terms that are mutually beneficial and it also laid down some principles regarding the same.[4] It is true that CBD did not give detailed guidelines on this and

the provisions of CBD were not clear on some key ideas but the very fact that there is an international convention encouraged many countries to bring in laws or at the regional levels joint declarations and formulation of guidelines.. The CBD is a trade off between the concerns expressed by the developing nations and the interests of the developed nations in the genetic resources. It is a bargain - a bargain about the access to genetic resources and transfer of technology. This bargain resulted in the provisions of CBD which recognize the sovereign rights of the nations and the need to provide access and benefit sharing without discrimination to other nations, subject to the legal framework and principles enshrined in the CBD[5]. But CBD is only a part of the picture as the formation of WTO and TRIPS Agreement indicated the emergence of a global regime on Intellectual Property Rights. Of course with relation to plant genetic resources for agriculture (PGFRA) an Undertaking was in the offing, although the negotiations relating to the same were progressing slowly, under the auspices of FAO.[6]

But in the past countries had tried to refuse access to genetic resources and in the mid eighties seed wars became a contentious issue[7]. The CBD tries to assure that through mutually beneficial terms on access and benefit sharing it will be possible for countries to agree to a regime backed by law and relevant institutional mechanisms.. Bioprospecting by and large refers to genetic resources not related to agriculture and farming, as genetic resources relating to them is covered by IUPGR and under provisions of CBD. But the provisions of CBD are applicable to PGFRA as well.[8] As a matter of convenience and for regulatory reasons nations may have one more than one law for regulating access to genetic resources, benefit sharing, plant breeders rights, farmers' rights etc. The relevant crosscutting issues relating to Intellectual Property Rights and provisions of CBD have been discussed elsewhere in this dissertation at appropriate contexts (e.g. farmers, seeds and Intellectual Property Rights). Hence in this chapter the focus is on bioprospecting, access and benefit

sharing and the Bonn guidelines. There are overlapping issues relating to indigenous knowledge and indigenous communities. As these have been discussed this in detail elsewhere, the points made in that chapter are not repeated here.

Given the fact that in CBD and in negotiations over TRIPS developed nations were keen to ensure that intellectual property rights were given the due importance and as all nations agreed to a basic minimum framework on Intellectual Property Rights in the form of TRIPS any legal framework relating to access and benefit sharing has to be consistent with TRIPS and with CBD as well, if it were to fulfill the mandate of CBD. But if there is an incompatibility between that legal framework and TRIPS, or, with other laws relating to Intellectual Property Rights it could be challenged. Hence crafting a law that facilitates access and benefit sharing without running afoul of TRIPS is a challenge to law makers.

This chapter begins with a discussion on genetic resources, biotechnology and bioprospecting. This is followed by an analysis of questions relating to genetic resources in law and in legal regimes. Then the Bonn Guidelines are examined and some suggestions on the Guidelines is offered. Some important bioprospecting deals and initiatives are discussed in detail and bioprospecting in both theory and practice is assessed. It is pointed out that bioprospecting is bound to fail unless the ground realities are taken into account and to expect that bioprospecting will be a boon for conservation and benefit sharing will be in vain and it is argued that bioprospecting has failed due to the inevitable 'political' factors and it will not be wise to expect too much from bioprospecting.

Genetic Resources, Biotechnology, Bioprospecting

According to CBD genetic resources are genetic material of actual or potential value. Any genetic material will be covered under this as long as it contains functional units of heredity. Thus a broad definition of genetic material is necessary for thanks to developments in biotechnology DNA or RNA extracted from a source could also be used.. Soil samples

which contain microbes or micro organisms will also be considered as genetic material as they have been commercially exploited.[9] Genetic resources whether they are located in situ or ex situ are covered under CBD except in case of material transferred and stored prior to the signing of the agreement.

The national legislation need not strictly adhere to the definition in CBD. For instance a law can cover under genetic resources biochemical extracts, soil samples, derivatives of genetic resources[10]. This is necessary on account of the following reasons:

1. Nations have to adhere to TRIPS norms and have to decide on patentability and exclusion for patentability and hence a coherent approach is necessary. For example a nation may decide not to grant patents on micro-organisms or genetically modified organisms .In such a case it will be logical only if it excludes access to certain materials which otherwise could be patented.[11]
2. In view of the technological advances it is always preferable to bring in a comprehensive law so that the loopholes are not exploited. For example if a nation does not include soil samples or derivatives of genetic materials then it would be difficult to prevent misappropriation of such resources.
3. Traditional knowledge, human genetic materials are also valuable. But including them under the scope of genetic resources is not a wise decision as they need a different approach. So the law has to be unambiguous on this. Bonn Guidelines for examples excludes some genetic resources specifically.

Biotechnology has been defined as "any technological application that uses biological systems, living organisms, or derivatives thereof to make or modify products or processes for specific use". In one sense biotechnology is as old as making curd or producing wine but the modern biotechnology is totally different for it enables manipulating at the level of genes and hence this gives enormous capacity to utilize genetic materials in very different ways.[12] But

as humankind has to rely on nature for the basic resource, i.e. genetic resources bioprospecting facilitates access to raw materials. Hence there is much criticism that bioprospecting is a continuation of colonization and enclosure of the commons in a different name.[13] In this dissertation the discussion refers to bioprospecting as a commercial activity undertaken for some specific objectives[14]. A famous and an often repeated example of using genetic resources to produce what has been called as blockbuster drugs is rose periwinkle. Rose periwinkle was discovered in Madagascar and from that two alkaloids were derived-vincristine and vinblastine but Madagascar got almost nothing in return.[15]. It is true that Madagascar derived no benefit from this discovery. But rosy periwinkle is found in other countries also. So whether only Madagascar should derive benefit from this is an interesting question. In this case for supply of the plant Madagascar is no longer necessary. So even if Madagascar had received some initial payment in the long run it was not the major supplier of the raw material.

Rosy Periwinkle (*Catharantus roseus*) had been used by the healers in Madagascar for centuries for treating diabetes. As early as 1757 it was introduced to the outside world by French explorers and it was used in treatments for sore throat, dysentery and diabetes. It is available in many parts of the world and is used by many indigenous groups. In the 1950s, National Institute of Health (N.I.H) USA and Eli Lilly screened many plants for anti-cancer properties. The above two alkaloids were isolated by scientists of Eli Lilly who found that they had anti-cancer properties. Before this discovery there was no effective cure for childhood leukemia and fatal rate was 95% but with usage of vincristine in treatment the survival rate is 84%. Although many indigenous groups were using it to treat many diseases no group was using it for treating cancer. Thus the question of misappropriation of indigenous knowledge does not arise for it was the efforts of the scientists that led to this discovery. On the other hand although El Lily earns more than $100 million from the sales of

medicines based on the alkaloids derived from this plant, Madagascar the home of this plant does not get anything worthwhile from this. The scientists were the first to discover this specific property and they also isolated the relevant chemical compounds and hence that was novel and there was no prior art for this. In the 1950's there was no international regulation for use and transfer of genetic resources. Even if the NIH & Eli Lilly acquired this germplasm from one of the CGIAR centers or from the market it would have made no difference. Since the plant is found in many parts of the world it would be difficult to prove that it originated in Madagascar first and hence asserting sovereign rights by Madagascar would be questionable.[16] One can compare this with soil samples taken from Norway way back in the 1960s when there was no awareness about the need to exercise control over access and asserting sovereignty over natural resources.[17]

If scientists could synthetically produce the alkaloids without the need for the plant, they would no longer need the plantation or any other plant source. So if even if as a part of bioprospecting arrangement if the scientists first screen the plants and isolate useful compounds and pay for the same to the country which is the source or origin of the genetic resources, there is no guarantee that the country would emerge as a major supplier and earn revenues, as the compounds could be derived or synthesized from non-plant resources also.

Drug discovery or finding a potential chemical involves enormous work and the probability is quite low. According to one estimate about 10,000 plant samples will have to be screened to get a single useful lead.[18] But the companies still prefer bioprospecting for they gain not only from the resources but also the indigenous knowledge as well.

Bioprospecting has become controversial because of the conflicts between various stakeholders, NGOs, government agencies etc.[19] It has been assessed as a failure by some because Shaman Pharmaceuticals failed commercially and ended in bankruptcy[20]. But it is too early to write off bioprospecting as a failure or to celebrate it as a grand success. One

reason for this is although CBD is in force for almost a decade and many nations have passed laws bioprospecting has not taken off as expected. The advent of CBD and national laws have changed the rules of the game and in many instances the conflicts at the local level have resulted in either projects being scaled down or withdrawn. One reason for this is that NGOs have become active in biodiversity related issues and bioprospecting has been equated with biopiracy. But some institutions are conscious of such accusations and try to evolve policies that seem to be fair. For instance University of Illinois, Chicago (UIC)'s policies dictate that 50% of net royalties should be shared with source countries in the event of a company discovered and developed and these are deposited in a trust fund.[21]. However what is fair and unfair is difficult to define and by and large many NGOs have been critical of bioprospecting in theory and in practice. Hence the hostility has more to with the opposition to the idea than with the terms per se.

The CBD and Bioprospecting

With CBD coming in to effect on 29 December 1993 it offers the basic framework to design laws and regimes on bioprospecting, access and benefit sharing. Under CBD the sovereign rights of the states are recognized under Article 3 and Article 15 makes an explicit mention about the authority of the State to control access through laws. CBD also makes it clear that access is subject to Prior Informed Consent and is on mutually greed terms. Thus CBD has established the basic principles for bioprospecting. By the explicit recognition of the sovereignty over genetic resources CBD has put an end to the era of unfettered access and Common Heritage of Mankind principle. But the powers of the state in this are also circumscribed by obligations to facilitate access and not to impose restrictions that are against the objectives of the CBD.[22] The rules of CBD are applicable from 29 December 1993, the date on which CBD entered in to force and hence the sovereign rights is with effect from this

date only. Further CBD does not cover collections in ex situ gene banks removed prior to this date. The reason for this has been stated elsewhere in this dissertation.

The key provisions relating bioprospecting are in Articles 8(j), 15(6), 15(7),16 and 19(1)(2).

'Sharing equitably benefits arising from use of traditional knowledge' is the primary objective of Article 8(j). Since this issue has been dealt at length elsewhere it will not be discussed here. Article 8(j) does not view traditional knowledge merely in terms of its economic value or commercial utility.[23] A reading of Article 15(6), 15(7) with Article 19(1) indicates that the objective of CBD is to promote scientific research and cooperation in research among the Contracting Parties.[24] Articles 16 and Articles 19 provide for sharing of technology, participation in biotechnological activities. But these Articles in this regard sound more like wish lists than anything else and they remain so only.

Articles 15(4) and 15(7) indicate that access to genetic resources be on mutually agreed terms and benefit sharing be also on mutually agreed terms. Hence CBD calls for Contracting Parties for establishing a framework to facilitate sharing of benefits. Articles 19(1) and 19(2) reinforce the same.[25]

Thus Articles 15(7) and 19(1) stress that benefit sharing has to be on fair and equitable basis. But what is fair and equitable is difficult to define. However with the framework of CBD attempts have been made to ascertain how this has been put to practice. It should be noted that there is no obligation on the part of the country of origin to spend the monetary benefit received solely for the purpose of conservation of genetic resources or for biodiversity related purposes. But in IUPGR 'benefits flowing from development of PGFRA' are to directed to conservation purposes. Countries have adopted different methods to implement what they consider to be 'fair and equitable'.

For example, the Manila Declaration Concerning the Ethical Utilization of Asian Biological Resources recommends the development of adequate national legislation to exercise control over the collection and export of biological material by Asian countries. It includes a Code of Ethics for Foreign Collectors of Biological Samples that recommends a set of actions by foreign collectors to ensure that developing country signatories providing biological samples are not disadvantaged. Accordingly, the Philippines required that the grant of a permit to collect biological resources was conditional on the conferral to the Philippines of rights to share information and technology. In the case of commercial application, a license was required to manufacture any patented product derived from the genetic resources collected. Similarly, five Latin American States have signed an Andean Pact Resolution to regulate foreign access to their genetic resources. African nations had imposed a ban on access to in situ biological resources, including PGRFA, by collectors when proper informed consent had not been granted. More broadly, the Declaration of Cancun created a "Group of Like-Minded Mega diverse Countries" to promote the preservation and sustainable use of biological diversity, including equitable sharing of benefits by means of a regime that promoted informed consent and mutuality in transfer agreements.[26] However it is worth noting that fairness and equity can be defined in many different ways and this has been a major issue in the context of global warming.[27]

Article 16(3) deals with transfer of technology but does not call for transfer of technology to the country that provided the genetic resources. Article 16(4) deals with developing and transfer of technology by private sector, but there is no compulsion on the part of private sector neither to develop technology jointly nor to transfer the same.

A reading of Article 16(5) and Article 16(3) coupled with Articles 20, 21 indicates the following:

1. The CBD recognizes that patents and Intellectual Property Rights may have an impact on implementation of CBD,
2. The Contracting Parties are to ensure that IPR regimes are not against the objectives of CBD but should be supportive, and
3. These rights are subject to national legislation and international law.

The word may indicate the ambivalent attitude towards IPR's impact on technology transfer.[28] Article 16 sets out only a minimum requirement and leaves the matters to be decided by the Contracting Parties. A closer look at the Articles dealing with technology and technology transfer in CBD reveals that these Articles are mere expressions of intent. One reason for this is the fact the CBD is a compromise between North and South and North did not want CBD to be used as an instrument that mandates technology transfer in exchange for access to genetic resources. The US took a clear cut stand in this. Moreover given the range of technologies involved, particularly biotechnology it would not be possible for a framework like CBD to deal with them extensively. The very fact that even after a decade of CBD not much has happened in terms of technology transfer reveals that these provisions have little impact.[29]

The CBD provides only a set of guidelines and principles but how to put this to practice has been left to the Contracting Parties. As the Contracting Parties exercise sovereignty over genetic resources the CBD leaves it to them to enact appropriate laws. As noted earlier many terms in CBD are vague or ambiguous and often they sound like a wish than like a mandate, and so, how best bioprospecting could be put to use depends on how sound and effective are the laws of respective nations. This raises questions about law, legal institutions, various actors and role of the state in biodiversity issues.[30] But the CBD process is an on going attempt to interpret CBD in the context of global biodiversity and related developments, including national level laws.[31] A study done by a team based in School of

International and Public Affairs, identified some key issues and pointed out the problems in implementing policies relating to access and benefit sharing. An earlier study in 1999 also came to similar conclusions.

In view of the issues and difficulties in implementing provisions of CBD regarding this the COP at its meeting in May 2000 decided to form an open-ended working group to draw guidelines and other approaches. The group submitted the draft guidelines and the same was adopted at the 6th meeting of COP in 2002. These guidelines also known as Bonn Guidelines. The discussion on Bonn Guidelines in this chapter is as much as they relate to Intellectual Property Rights and biodiversity and hence both a description and an analysis of the various provisions of the same are not given[32]. It is suffice to say that Bonn guidelines does not substitute any Article of the CBD. Rather they should be read as guidelines that give some suggestions for the Contracting Parties, particularly in minimizing transaction costs associated with access and benefit sharing, vide Bonn GL clause 7a, 7c. They in no way affect the rights and obligations of the Contracting Parties under the CBD. They are only suggestive or indicative but not prescriptive. It is suggested that Bonn guidelines should be read in the context of Article 6 of the CBD. Ultimately how to design a regime is left to the states concerned and the CBD has no powers to assess whether such regimes are suited for fulfilling the mandate of the CBD. Hence it is up to the countries to decide about the Bonn guidelines and countries are free to disregard this.

Prior Informed Consent

Prior Informed Consent (PIC) is a term used in many Multilateral Environmental Agreements and with reference to both CBD and Bonn Guidelines the importance of PIC and what constitutes PIC is controversial.[33] Under the Bonn guidelines on PIC users and intermediaries should obtain PIC of original owners of the genetic resources.

Given the fact that the States are not always the owners and diverse stakeholders have diverse interests on genetic users getting access is not always easy and Bonn Guidelines acknowledge this in Para 17. The Bonn Guidelines specifies the responsibilities of both users and providers under PIC. The idea behind the PIC procedure mentioned in Bonn Guidelines is to ensure cost effectiveness, clarity, timeliness and to ensure that relevant stakeholders are aware of their consent under PIC (vide Para 26). Bonn guidelines ensure that the providers are well aware of what they are providing and with what conditions and under what circumstances. Similarly it avoids a blanket permit to use by stipulating that if the resources are used for a purpose different from what has been indicated a new PIC must to be obtained.(vide Para 34 and 16(b)(vii).

Regarding Intellectual Property Rights the guidelines are not indicating any specific restrictions. It calls for a closer examination of the role of IPR in genetic resources; their access and scientific research (vide 59- Section C Decision VI/24-2002). In Para 2 it invites Parties to encourage the disclosure of origin and of the use of any indigenous knowledge in patent applications for genetic resources.[34]

But the key questions is a binding protocol on access and benefit sharing with this condition will discourage or eliminate biopiracy or misappropriation of indigenous knowledge and genetic resources. The Bonn guidelines or any binding protocol on this may be necessary but they will not be sufficient even if, for the sake of argument, it is accepted that these are viable solutions. This issue is being studied by the WIPO Intergovernmental Committee on Intellectual Property, Traditional Knowledge and Folklore (IGC). One possibility is that the Patent Cooperation Treaty can be amended to incorporate these conditions. But the larger battle is at WTO TRIPS Council where countries are trying to bring in disclosure of origin as a condition in TRIPS. For instance India has argued so.[35] But this

has not been acceptable to other countries who argue that PIC and access and benefit sharing are beyond the mandate and objectives of TRIPS.[36]

In view of such developments the Bonn Guidelines do not have much to offer regarding IPR issues. If the provisions of IUPGR on Intellectual Property Rights are vague or contested, from the Guidelines we learn nothing new. One reason is that as Bonn Guidelines are non-binding and is a guide to good practices countries need not pay heed to it at all. Rather the battles are fought in other fora and hence some pious statements here and there in the guidelines make no difference. In the WSSD even after protracted negotiations countries could not agree on a binding instrument on access and benefit sharing and USA preferred a voluntary regime.[37] Thus the Guidelines are not of much relevance in IPR issues. This is because the battles on Intellectual Property Rights are being fought in different fora and it is too early to predict the outcome. Although PIC as a concept has been well established and has been tested extensively, in Bonn Guidelines it does not offer much in terms of IPR issues.

Mutually Agreed Terms (MAT)

Under CBD it is essential that both access and fair and equitable benefit-sharing be negotiated on mutually agreed terms. The guidelines suggest the essential requirements for MAT and indicate what items should figure in a contract on the basis of MAT. The Guidelines indicate that a standardized agreements and framework can facilitate subsequent access and benefit sharing for similar uses for the similar resources.

Regarding Intellectual Property Rights the clause 43 suggests that the following can be a guiding parameter in the contractual agreements:

1. Provision for use of Intellectual Property Rights include joint research, obligation to implement rights on inventions and for providing licenses by common consent and
2. Possibility of joint ownership of Intellectual Property Rights based on the quantum of contribution.

However these are easier said than done as it has been pointed out early Intellectual Property Rights and technology transfer have been contentious issues even during the negotiation of the CBD. Generally joint ownership of Intellectual Property Rights is an idea which is not favored by countries which want to use genetic resources to produce and market new products. Assessing the quantum of contribution is all the more difficult particularly when more than one genetic resource from one or more countries is involved. So if the intention is to include Intellectual Property Rights as a parameter it is better to do so on unambiguous terms. It is better to make conditions on Intellectual Property Rights explicit in Material Transfer Agreements or in the main contract on access and benefit sharing. The contentious issue will be Intellectual Property Rights on derivatives of genetic resources or on products developed using the genetic resource. In this the discussion on Intellectual Property Rights and Multilateral Framework under IUPGR are relevant here.

This is because both North and South do not consider CBD process to be the primary fora to sort out the issues. Another reason is that countries are evolving their own ABS regimes and trying to modify IP regimes also. So Bonn guidelines will continue to be just guidelines. The scope for countries agreeing on a binding framework for ABS is limited in view of the sharp differences in the opinions and a non-binding framework may emerge after negotiations.

The Bonn guidelines illustrate the weakness of the CBD and its limitations as a framework convention. For matters relating to Intellectual Property Rights and genetic resources the other fora like WIPO, WTO have become more important than CBD. So it is better to assess the access and benefit sharing regimes of countries and laws in terms of their rules on Intellectual Property Rights and genetic resources rather than to discuss this issue in the context of a non-existent global regime on ABS.

Access and Benefit Sharing and Intellectual Property Rights in National/Regional Regimes

Regional Frameworks & Regimes

Although CBD was ratified by the requisite number of countries and came into existence in 1993 there has not been great progress on formulating and implementing ABS Regimes. Almost all countries have ratified CBD. One reason for the tardy progress is that CBD does not differentiate between genetic resources for agriculture and genetic resources useful for other purposes like producing drugs, extracting genetic components etc. As a result there is no clarity about the genetic resources that should be covered by ABS regime.

The assessments about the national legislations and access regimes vary and there are methodological problems in assessing them as there is no way to quantify and measure what an optimum or ideal regime is. Similarly comparing with Bonn guidelines as a base is of little use as the guidelines themselves do not constitute a regime. Countries have different objectives and different priorities in formulating ABS regimes.[38]

But apart from case studies there are hardly any studies that assess the impact of ABS regimes or policies or, evaluate them with reference to IPR laws or their impact on national IP regimes. One reason for this is perhaps it is too early to come to any conclusion and not many nations have developed a coherent policy framework supplemented by laws or legal regimes. In many cases there are contracts with specific terms on benefit sharing without being formulated under a law. Another problem is that there are many declarations or model laws or decisions that give an idea about the intentions of the States but many states have not even set up a basic framework to regulate ABS. One study reports that about fifty countries have adopted or in the process of adopting measures to exercise sovereign rights over natural resources.[39] But it is not clear as to how many have really translated this into practice by establishing specific regimes for ABS and for implementing provisions of CBD. The Report

of Experts on Benefit Sharing has made some observations on the practical constraints in this regard.[40]

In 2002 mega-diverse countries came together and issued Declarations on Access to Genetic Resources, Traditional Knowledge, and Intellectual Property Rights and indicated that they would be building up regulatory capacity.[41] To formulate a functional ABS regime the countries should have a basic inventory of the genetic resources, traditional knowledge and an assessment of existing regulatory frameworks has to be made. It is estimated that more than 100 countries are doing taxonomic assessment of biological resources, inter alia, for formulating national biodiversity strategies.[42] Still many countries have long way to go in terms of implementing CBD which they had ratified long ago.

For instance, Chile, a mega diverse country is a signatory to CBD but it is yet to put in place a regime for ABS or to apply the provisions of CBD.[43] The lack of coherent policies and institutional practices has been highlighted by another researcher who found that there is no ABS regime worth the name and bioprospecting contracts are often unregulated.[44] This is despite the fact that other countries have evinced great interest in the genetic resources of Chile and have used the genetic resources from Chile to develop new varieties, or products. [45]

Thus a mega diverse country is permitting bioprospecting without a coherent basis. And there are many bioprospecting deals basic information on them is not available and in many instances as genetic resources of Chile deposited elsewhere in situ are also being accessed. In the absence of relevant information it is difficult to estimate the value derived out of such genetic resources or to calculate how much the country would have gained had there been an ABS regime. Of course case studies do give an idea but that is not sufficient to arrive at definite conclusions. Countries have been implementing Article 15 in many ways. [46]

The Andean Community Framework

The Andean Community Decision 391 is an example of a regional approach to access to genetic resources. Adopted by the Andean Community members (Bolivia, Colombia, Ecuador, Peru and Venezuela), this decision established an Andean Committee of genetic resources and provided a common framework on access to genetic resources. Access to genetic resources includes genetic resources in both in situ and ex situ conditions and for, purposes, inter alia, research, bioprospecting, conservation, industrial and commercial uses. The Decision aims at preventing countries from undercutting each other through conditions and strengthening the negotiating capacity of the countries.[47] In 2000 the Andean Community adopted a new IPR system under Decision 486. It aims to bring in a sub regional IPR regime that is compatible with TRIPS and implements the provisions of CBD. Under this access contract must accompany for patent applications for a product or process or derivative product , of which the Member state is country of origin (Article 26).In case of patent application for a product or process obtained from traditional/indigenous knowledge of a community in a Member State and for which the State is a country of origin a document of authorization or licensing from the Community should be included and if the patent is granted without this condition it would be nullified.(Article 75).[48]

It has been observed that this Decision and laws in other countries are a step forward in recognizing indigenous rights and incorporating provisions of CBD. The Decision 486 eliminates double protection for plant varieties. Although the Andean model has some positive aspects there are many problems as well.[49] The Decision also gives a list of items that cannot be covered under invention[50]. Thus the Decision is a bold step forward and it has been referred to or cited in various documents. To what extent this has been translated in to practice in terms of laws and ABS regimes is not clear at this, although it has been pointed out that some countries have incorporated the provisions of the Decision 486.[51]

At this juncture it is worth pointing out that such provisions are at odds with the IPR regime envisaged by the USA under FTAA. However whether the countries will amend their laws to accommodate a TRIPS PLUS regime is a question that is beyond the purview of this dissertation.[52]

The OAU Model Law

The OAU Model Law is an ambitious attempt to bring in a comprehensive law relating to benefit sharing, community rights, farmers rights and plant breeders' rights. It tries to incorporate the provisions of CBD and the key principles of this Mode Law includes, inter alia, strengthening food security, recognizing major role played by women.[53] The Model Law provides detailed guidelines on access, PIC, regulating access etc.[54] It has been pointed out that the Model Law assumes that the governments and the indigenous community have common interests and it need not be so always.[55]

Nevertheless the Model Law is an attempt to devise a comprehensive sui generis system and it is only a Model. The national governments are expected to draw laws based on this and form Competent Authority to act as focal point for considering the requests for access. Under the Model Law benefit sharing is defined as "the sharing of whatever accrues from the utilization of biological resources, community knowledge, technologies, innovation or practices.[56] It specifies that the state must guarantee a specific percentage, (minimum 50%) of any financial benefits to the local community. It also stipulates some conditions on patents.[57]

However as this law is applicable to countries in OAU that are willing to apply the rules of the Model Law it cannot prevent patenting life forms and biological processes elsewhere. At the most countries adhering to this law can revoke or deny patents that violate rules of this law. But that is possible only if the countries have adopted all the provisions of the Model Law. A country may adopt many rules regarding access and benefit sharing and

can incorporate provisions of TRIPS also and hence permit patenting biological processes and life forms. But the Model Law reflects the position taken by the African Group on interpreting Article 27.3(b) of TRIPS. Many African countries are yet to implement appropriate laws and only few countries have enacted legislations enabling a sui generis system. Some countries are also opting for UPOV based IP regimes and this goes against the OAU model law. [58] It has been noted that this Model Law tries to restore the balance between private rights and public rights.[59]

But the problem is when the Model Law tries to be too comprehensive it becomes difficult as institutional constraints and lack of capacity make it difficult to implement. Another factor is although the Model Law specifies some conditions on patenting it has to be tested. And of course interpreting TRIPS is yet a contested issue. So in case of ABS regime the ideal solution would be to have an exclusive law, with specific rules and regulations on access, benefit sharing. It is preferable to have the rules relating to IPR specified in legislations relating to IPR regime and remove any ambiguity in this regard. For example both in terms of legality and practice it makes sense to include conditions regarding patenting, including declaring access of origin in laws relating to IPR than in laws relating to ABS. The linkage can be clearly specified. There are some other regional frame works on ABS (e.g. The ASEAN regional framework) but these do not seem have resulted in many legislations and institutional frame works.

Thus the regional approach to ABS has certainly resulted in developing common approach to IP issues and in integrating them in ABS regimes. This has also resulted in the reflection of the positions taken by the countries/regional groups in WTO regarding TRIPS. But whether this has resulted in better ABS regimes is difficult to judge.[60] Thus there is scope for improvement in regional ABS regimes/frameworks, particularly on rules relating to IPR issues.

National Laws and Regimes

Although estimates vary many countries have begun to enact laws and frameworks for ABS.[61] Although it is desirable that ABS regimes take in to account IPR issues and address them, the IPR system may not be of much help and may even hinder development of ABS regimes.[62] This argument is valid to a great extent, countries need to develop well meaning and enforceable ABS regimes that provide for clear cut rules on Intellectual Property Rights. The dilemma before countries is how to recognize indigenous knowledge and at the same time create an IPR regime that inspires the confidence of firms interested in bioprospecting. Firms interested in bioprospecting will hesitate to invest monetary and other resources if there are many restrictions on IP rights that can be claimed or if they need approval/consent from many parties before actualizing the potential of genetic resources. Many countries however try to have different laws for ABS and Intellectual Property Rights. The Costa Rica's 1998 Biodiversity Law excludes DNA sequences per se, plants and animals, micro organisms (not genetically modified), among other things. Prior consultation with National Commission for Biodiversity Management (CONAGEBIO) is a must before granting Intellectual Property Rights on innovations based on biodiversity components. Certificate of origin and Certificate of Prior Informed Consent are necessary. In developing laws and rules it is desirable that the principles are clearly mentioned in the laws and regulations are based on them. But if the law is ambiguous on the ownership of genetic resources the regulations cannot rectify that.

The Costa Rican law is an ambitious attempt to reconcile diverse interests of different stakeholders. Such attempts often end up satisfying none of the major stakeholders for one reason or other. Use of certificate of origin is a good idea fraught with practical difficulties. Bioprospectors need unambiguous rules and fewer restrictions on IPR claims. A broad exclusionary criterion is not in the interest of the local industry also and when it borders on

vague clauses it is all the more frustrating. And certainly a law on biodiversity is not the right place to frame rules on Intellectual Property Rights and food security. In case of Philippines overregulation in the form of a law that mandates too many procedures and approvals has resulted in potential prospectors not to prefer bioprospecting in view of inadequate intellectual property rights.[63]

The tendency to over regulate or to adopt a maze of procedures and approvals stems from the attempt to achieve too many objectives through ABS laws/regimes. It is true that indigenous knowledge/traditional knowledge should be protected and the customs of indigenous people should be respected and protected. But linking that with ABS in the form of complex procedures is not the option. As countries are not sure to what to protect and what to cover under ABS and how to regulate access they tend to over regulate. This results in the increased transaction costs, uncertainty and the country does not get the benefit of the ABS regime. Countries should realize that they can use access and benefit sharing to develop the local industry and to derive more benefit from genetic resources. This involves not only capacity building but also the strategic plan to use biodiversity and apply biotechnology[64]. In that case the countries should be clear about what should be regulated and how it should be done. To do that the ownership and property rights on genetic resources should be stated unambiguously and IP issues should be dealt separately than through the law on ABS. The objectives of bioprospecting vary and scientific/academic bioprospecting should be differentiated from commercial bioprospecting. And laws complicate the process by putting too many conditions.[65] How reasonable are these rules will be tested only when bioprospecting regime is functioning seeking prior approval from NBA is needed even for applying for IP protection is restrictive. The point is NBA can at the most impose these conditions when the bioprospector applied for IP protection in India. But to apply and obtain a patent in USA or EC this is not a pre requisite. The rules framed by individual countries do

not apply beyond their borders and most bioprospectors are from countries like USA which do not insist on certificate of origin or confirmation of PIC. And until such conditions are accepted by PCT or a change is brought in TRIPS they are not of much relevance internationally. The conflict of interests between North and South over access is obvious.[66]

Thus the tendency to over regulate and to fulfill too many objectives through ABS laws/regimes will be counter productive. In the name of safe guarding from bio piracy and protecting indigenous knowledge countries are developing ABS regimes that hinder than promoting bioprospecting. Regarding Intellectual Property Rights countries have to take a stand and ensure that there is a consistency among various laws. They have to decide on the optimum level of protection that is necessary to promote bioprospecting. This takes us back to the issue of bioprospecting and whether bioprospecting is always a win-win proposition. If the intention is to prevent biopiracy or misappropriation of indigenous knowledge then using ABS regime for that is not of much help. As we argue elsewhere biopiracy is a legal issue that had to be tackled legally and by questioning the norms relating to novelty, prior art etc. So an ideal ABS regime will try to balance the interests of various stakeholders and will facilitate access and will regulate the IPR issues by a separate IPR regime. The ABS regime should facilitate access and promote sustainable use of genetic resources. Countries have a long way to go in this. Countries tend to under regulate as in the case of Chile or over regulate as in the case of Philippines. Thus the linkage between ABS regime/laws and Intellectual Property Rights is not yet very clear. There have been few studies on ABS regimes and there is hardly any study on the impact of ABS regimes on IPR claims. One reason is that many countries are implementing ABS regimes are also modifying their IP laws and the role of Intellectual Property Rights in biodiversity conservation and use is not clear.

Hence it can be said that bioprospecting regimes are yet to be fully functional and the laws on ABS regimes reflect the concerns about Intellectual Property Rights. But as countries struggle to satisfy the demands of various stakeholders and meet multiple objectives bioprospecting regimes are contested terrains.

Case Studies on Bioprospecting and IPR

The case studies on benefit sharing are interesting as they indicate how IPR issues have been tackled in bioprospecting contracts and agreements. There are many case studies and their number is increasing.[67] In this section some are taken up for analysis.

The Kanis and TBGRI (India)[68]

In this case the scientists at TBGRI filed for patents based on the indigenous knowledge of the Kani tribe and the two Kanis were also included as co inventors in the patent. The patent resulted in commercialization of a successful product Jivani and the technology was licensed to a private firm with specific benefit sharing rules. But due to problems in the availability of raw materials and inter agency/departmental feuds the product could not manufactured in enough quantities to meet the ever growing need. To distribute the benefits a community trust was formed .This trust channels the money received into various schemes for the welfare of the community. This benefit sharing model was evolved when there was no law in India on this. The initial discovery about the usefulness of the traditional knowledge was found out in 1987 and the process patent was obtained in 1995 by TBGRI for a herbal drug composed of four compounds. The technology was licensed for a period of seven years, with a license fee of US $ 25,000 and 2% royalty on ex-factory sales for ten years from the date of commercial production. One interesting aspect is that the indigenous people became suppliers of the raw materials and for about 700 families this became a major source of income until there were restrictions by the Forest Department on cultivation by Kanis.

The indigenous knowledge was successfully converted in to a product and a process patent was obtained. But this patent is yet to be filed under PCT and hence the protection is available only in India. In the absence of a product patent, a process patent was the option available to TBGRI. But a process patent for a similar drug cannot be ruled out and hence the knowledge could be used/ appropriated by others by obtaining another process patent. The indigenous community has been acknowledged in the patents as two Kanis have been termed as co inventors. The indigenous knowledge could be further protected if the following could be accomplished:

1. Registering, the product and the Kani, Kerala identity as a Geographical Indication to distinguish from similar or competing products. This makes sense in the context of promoting Kerala as a destination for traditional health care and rejuvenation.
2. Register Jeevani as a trade mark in USA as well as in Europe.

Further the possibility of using indigenous knowledge to develop further products can be explored. In this case another important issue is the sustainable harvest of the raw material and the increasing demand for that. The plant grows in specific areas and attempts to grow that elsewhere have failed. Hence the supply is from a particular region which is inside the forest area, covered under The Forests Act. Hence developing a sustainable supply of the raw material is important. This case has been projected as a win-win solution by the Government of India. But the long term sustainability of the model depends on the supply of the raw material. Instead of making indigenous community to be mere suppliers the potential for value addition by them should be explored. The community does not have any control over the patent. The benefit sharing has resulted in tangible benefits for the community. This is a unique case because the scientists involved believed in honoring the indigenous knowledge and wanted to ensure a mutually beneficial benefit sharing arrangement and the patent was obtained by TBGRI, established by the government.

The Kava

The kava is a shrub endemic to Pacific islands and it has been used by the indigenous communities for more than 2000 years. About 120 cultivars are in use. This is used extensively as a mood altering substance and is used in religious ceremonies, gatherings etc. Pacific islands are the major suppliers of Kava which is one of the best selling herbal medicines.[69]. Kava has been used in Pacific islands for few thousand years as a mood altering substance. The major suppliers are from this area although the buyers are trying to get it from other areas. There have been attempts to patent processes, preparations based on kava.[70] .It has been suggested that Kava could be protected through a Geographical Indicator.[71] It has been suggested that an unique country based indicator could be developed based on the unique characteristics of Kava cultivated in each country and identifying their genetic components. However Kava related trademarks have been registered (e.g. Kava Pure, Kavatrol). The Geographical Indication, similar to Appellation of Origin can be used to denote Kava grown in a particular region, i.e. Pacific Islands. This will distinguish the Kava from that region. However this is not a simple solution as the Islands have to prove that there is a long history of use and innovation in cultivating and using Kava and the Kava has some distinct qualities/specifications which separates it from Kava grown in other areas. As in the case of Basmati where Texmati was sought to be registered in Kava also a similar trademark may be used by companies dealing in Kava.

Kava indicates both the positive aspects and negative aspects of the globalization of traditional/herbal medicine. On the positive side the increased demand makes Kava cultivation profitable and benefits the economies of that region. On the negative side it results in (mis)appropriation of the knowledge and increasing commoditization of herbal medicine. Unsustainable cultivation and depending on the vagaries of the market are the other negative aspects. However if Kava is cultivated on a large scale in other regions of the world the

dependency on the islands will be reduced and ultimately a major portion of the supply may come from other regions. (compare with the case of rosy periwinkle, of which Madagascar is not a major source today, but Texas is). Hence while IPR in the form of Geographical Indication is a good source of protection, in reality it may not be very helpful in this case. This illustrates the limitation of the IPR regime to protect indigenous knowledge, or, traditional medicine. In the absence of a universally accepted standard of novelty and prior art patents that show no novelty or originality can be obtained using Kava. Thus there is no easy solution for this issue and Intellectual Property Rights seem to be of limited use to Pacific Islands. The only possible solution is that they should concentrate on value addition and should develop products for the global market instead of being just suppliers of raw materials.

Hoodia

In this case the knowledge of the San (Kalahari bushmen) about the Hoodia Cactus was used by the Council for Scientific Research and it obtained a patent in 1995 on the Hoodia's appetite suppressing element. However after much protest in 2002 only CSIR recognized the San as the originators of the indigenous knowledge on the use of Hooda to suppress hunger and thirst. A benefit sharing mechanism was evolved in 2003. Under this CSIR gets milestone payments and royalties from Pfizer and Phytopharm. If the technology is commercially successful CSIR will be able to receive tens of millions of US $ during the life of the patent. CSIR in turn will pay San 8% of all milestone payments from license and 6% of royalties CSIR receives on account of commercialization. However these are subject to technical performance, successful clinical development. It is expected that this will happen by 2008. Neither Pfizer nor Phytopharm are expected to share the benefits with the San and CSIR is the intermediary who represents the interests of the San. The community is barred from using its knowledge of Hoodia for commercial application.

Although the amounts may seem large, in reality the San is expected to receive hardly 0.03% of the net sales of the product. This is again subject to commercialization of the technology. The patent rights to the compounds of Hoodia related to suppressing appetite are with CSIR and other related patents are owned by foreign firms. The CSIR has licensed the technology and the firms can do further product development and commercialization. The money received by CSIR has been used for capacity building.

A trust has been formed to ensure that the money received on behalf of San community is used for their welfare. About $33000 has been received by the trust as the share of milestone payments.

This deal is considered as a milestone as CSIR has developed a technology and obtained a patent on that. The benefit sharing terms are neither too low nor too high although the amount that will be received by the San community will be less than 1% of the sale proceeds. But everything depends on successful commercialization and it is expected that only by 2008 that can happen. In terms of Intellectual Property Rights except the patent CSIR has no hold. On the other hand the foreign companies can use their patents and licenses for further development. So how far this will benefit the San and South Africa in the long run is difficult to gauge. In this case also although the CSIR has acknowledged the San as the originators of the knowledge they have not benefited substantially from this. Their position is like something is better than nothing. Ultimately even if the product fails commercially the companies and CSIR can continue research and come up with new products/processes for drugs and it is doubtful whether the San will ever get a part of the profit from this.

The MSI- University of Utah Agreement

This is one of the few cases where bioprospecting of marine bio resources is involved. It is also one of the successful biosprospecting agreements in Philippines, with University of Utah as principal collector and Marine Science Institute of University of the Philippines as

co-collector. The materials received from University of Utah are transferred to Wyeth-Ayerst for further research, development and commercialization. The Research Agreement relates to collecting marine organisms from some areas in Philippines and export to USA for evaluation for potential anti-cancer activity. This bioprospecting agreement is regulated by Presidential Executive Order 247 (EO 247) which provides the legal framework for ABS in Philippines.

The two collectors have agreed to share the IP rights on a equal basis and the benefits will also be shared equally. This has been benefited the MSI to work closely with University of Utah. But so far there has not been a breakthrough as none of the compounds seem to have potential to apply for IP rights. The indigenous communities in the marine areas have been helped by NGOs. But they do not seem to figure in any benefit sharing arrangements except for a possible training in marine related studies to a qualified candidate, if there is any. Thus one can assess the effectiveness of this agreement only if there is successful commercialization.

The INBio- Merck Agreement

This agreement entered in 1991 is one of the most studied, cited and controversial agreement on bioprospecting.[72] The agreement signed initially in 1991 was renewed last in 1998. Under this agreement INBio will provide Merck samples (processed plants, micro organisms etc) and Merck will use them for further development and commercialization. It should be noted that INBio as an institution has several other agreements and the one with Merck is just one of them. INBio does not seek samples in areas where indigenous people live nor deals with indigenous knowledge. The INBio model is based on the premise that bioprospecting can result in monetary and non monetary benefits and these in turn can be used to conserve biodiversity. INBio works with local institutions/firms also.

The contributions and payments from INBio's bioprospecting unit have fluctuated over the years, as low as $385141 in 1997, to $874712 in 1991-93 to $609328 in 1998-2002.

Merck initially paid INBio $1 million besides providing $130,000 worth equipment and materials. A significant aspect is that a minimum 10% of any bioprospecting budget would be allocated for supporting management and protection of conservation areas and 50% of royalties would go to the Ministry of Environment and Energy, to be used for management and protection of conservation areas. Although to date there has been no commercial products from these deals, it is expected many would emerge within the next few years and of these some of these would be significant in terms of royalties. Since INBio works with many institutions and the range of items covered under bioprospecting is vast it is probable that some of these may succeed. But the fact that even after eleven years nothing commercially significant has emerged only strengthens the critics who question the utility of bioprospecting as a viable strategy.

A major criticism against such deals is that they promote the view that biodiversity could be used profitably and can be used as a strategy to promote sustainable development. This has been dubbed as 'selling nature to save it' or green developmentalism.[73]

The INBio bioprospecting model has brought in money for conservation but the dependence on bioprospecting to raise resources for conservation is based on the assumption that it would raise adequate resources for this. In the case of bioprospecting proving to be a failure or an unviable strategy this model will collapse. Thus the long term viability of using bioprospecting as a development mechanism is doubtful.

In case of INBio-Merck deal if one assesses the deal in terms of the biodiversity of Costa Rica, it will be clear that Merck is getting access to one of the richest collection of genetic resources, in terms of biodiversity for a pittance. Although many terms of the deal are confidential it has been pointed out that it has amounted to selling biodiversity cheap to Merck.[74]

Thus although INBio Merck deal has been considered as a successful model for bioprospecting it also reveals the weaknesses in the bioprospecting model. There is no guarantee that some commercially successful product will come out of such arrangements. Valuing biodiversity or genetic resources and arriving at the monetary compensation or equivalent for the same is problematic. But one cannot always expect that the bioprospecting will generate adequate resources, monetary or otherwise for conservation. Even after a decade bioprospecting has not proved to be a suitable model for this. So hitching conservation to the biodiversity bandwagon is not a good strategy. Hence it is early to pass judgement on the Ibibio-Merck deal as a failure or success. In any case INBio cannot rely on a single model or agreement to raise resources for conservation as income from bioprospecting is between 11% -17% of its income. Intellectual Property Rights form part of benefit sharing in this deal.[75]

It can be pointed out that as far as Intellectual Property Rights are concerned there is lot of ambiguity in benefit sharing deals and the lack of clarity arises due to many factors. In most cases the bioprospecting agreements are either based on models developed by institutions or are permitted and regulated under national laws. While many institutions have policies on access and benefit sharing, PIC, ethical practices to be followed regarding Intellectual Property Rights there are only vague statements as Intellectual Property Rights are sensitive issues. And often Intellectual Property Rights form part of the individual agreements and perhaps institutions deem that it is better that this issue is settled on an agreement to agreement basis. Moreover the issue of Intellectual Property Rights arises only when one of the parties decides to claim IP rights but for that the research should have reached a stage where it is worth claiming IP rights. Since natural products cannot be patented per se and as many countries have explicit rules which exclude patenting biological processes, naturally occurring organisms it does not make sense to claim IP rights on them.

[76]Apart from this as countries have taken different positions on interpreting article 27.3 (b) of TRIPS the national laws and policies vary considerably on IPR issues. Thus what is patentable in USA may be barred from patenting in Costa Rica. The (in) compatibility between TRIPS and CBD is another factor that has created much uncertainty about the role of Intellectual Property Rights in bioprospecting. As a result of all these factors much confusion prevails on this issue. i.e. Bioprospecting and Intellectual Property Rights and unless a solution is found at the global level the issues of incompatibility, diverse criteria adopted in national laws on IPRs, etc, will continue to haunt bioprospecting.

An extensive analysis on bioprospecting and its future is beyond the scope of this chapter. Nevertheless bioprospecting has not lived up to its expectations. Thus although there are many bioprospecting agreements in vogue, bioprospecting seems to have failed on many grounds. The hope and expectations on bioprospecting was based on many assumptions which have become questionable or untrue. Right from the beginning there was a dispute about the viability of bioprospecting as a model for conservation and for generating adequate resources for conservation. Further some have questioned whether bioprospecting will yield the drugs or the basic compounds needed for the industry. Given the low probability of finding a useful compound or drug, it is doubtful whether the industry will be willing to invest so much, particularly when there is so much uncertainty regarding access, benefit sharing etc. It is true that the knowledge of the indigenous knowledge and developments in ethnopharmocology will be relevant. But the controversies over indigenous knowledge and rewarding indigenous communities and recognizing their rights have only made bioprospecting all the more controversial. Moreover it is difficult to value the indigenous knowledge or ethnobotanical knowledge and derive a method to compensate the indigenous communities.

It has also been pointed out that although the usefulness of the tropical forests and genetic resources in drug discovery is too well known, the interests on this has waxed and waned. Technological developments have increased the efficiency in assessing samples and in isolating compounds, but it is possible to synthesis similar or equivalent compounds once the active compounds are identified. The resources from forests and elsewhere are needed only up to a point and drug manufacturers need not depend on such sources for a continuous supply. Another factor which has made bioprospecting a less favored option is the controversy over bioprospecting agreements which have often been termed as biopiracy agreements. In many instances the civil society or NGOs or groups representing indigenous communities or indigenous community organizations have challenged bioprospecting deals and as a result collecting materials for research or gaining access or doing collaborative research with institutions/communities has become problematic and often impossible. Issues relating to representation, legitimacy and conflict of interests among stakeholders are central to such controversies. But this also raises many questions about PIC, ethical guidelines etc but the very fact that even academic bioprospecting has become controversial only indicates that perceptions about bioprospecting vary considerably and extreme viewpoints are becoming inimical to the whole enterprise.

Another significant matter is the failure of Shaman Pharmaceuticals to successfully commercialize any product based on its benefit sharing projects and utilization of ethnobotanical knowledge. It may be argued that this failure has more to with the problems in commercial models adopted by the company and faults in its business strategy than with ethnobotanical knowledge per se. But the failure of Shaman has raised many questions about the viability of bioprospecting.

The bioprospecting model or arrangements involve participation and collaboration of many stakeholders and support from institutions and ABS regimes. But in view of conflicts in

interests and other problems the future of bioprospecting is uncertain. The problems relating to Intellectual Property Rights, add to the uncertainty. Thus whether it is Bonn Guidelines or local level laws and ABS regimes the ambiguous response to Intellectual Property Rights is creating more problems than it solves. And it is likely that bioprospecting will get a boost only if these ambiguities are resolved, although it is doubtful as to whether bioprospecting is the right model for promoting conservation and sustainable use of genetic resources.[77]

Bioprospecting could not meet the expectations, partly because the industry was not wholly dependent on such exercises in drug developments. The uncertainties over access and benefit sharing, the opposition from a section of civil society and indigenous people have only made its success less doubtful. But basically the bioprospecting model was built on a naïve understanding of the issues.[78] But the problems with assumptions regarding bioprospecting are becoming clear the communities are responding in many ways to bioprospecting. In the process the questions relating to IPRs, benefit sharing are asked with a new understanding. Thus such developments have revealed the serious problems with bioprospecting in practice.

Biopiracy

Biopiracy has been defined as "the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions seeking exclusive monopoly control over these resources and knowledge".[79] There have been many instances of such appropriation and these have been widely discussed.

In this section some of the examples are discussed, particularly in the context of IPRs and it is pointed out that biopiracy is possible because of the IPR regime and unless some changes are brought in it will continue unabated. In addition to the suggested changes few more may be needed and they are discussed elsewhere in the dissertation. Obviously this cannot be reduced to a legal issue for this involves issues of ethics and justice. But morality

has very little to do with IP regime and IP laws do not bother about morality unless it is prohibited by public policy. Of course the issue of piracy is significant for that was one of the reasons for an agreement on IPRs under WTO.[80]

Turmeric

In 1995 the USPTO granted a patent to Dr.Suman Cohly and Hari Har P., scientists at the University of Mississippi for use of turmeric in wound healing, covering the following six claims. They also included a discussion of the prior attempts to isolate the active agent and test the healing powers of turmeric.[81]

This was challenged by the Council of Scientific and Industrial Research which contended that all the six claims were neither novel and were anticipated by prior art. In support of this CSIR filed evidence from many sources, including an article published in the 1950s in the Journal of Indian Medical Association, The Ayurvedic Pharmacopoeia of India (1986). CSIR also contended that the claims were inadmissible as there was no novelty in them. Further it also proved that all of them were anticipated by prior art. The patent was re examined and the contention was upheld. Finally in 1998 a Re-examination certificate was issued rejecting all the claims made in the patent application.[82]

Although an objection was filed the examiner rejected them. It is easy to understand that the claims were nothing but cosmetic changes and it was argued that powder and paste had different physical properties. But ultimately all the objections were rejected. One significant reason for the rejection was that they were unpatentable over the combined teachings.[83]

In this case almost all the claims were widely known in India and were in public domain. The healing properties of turmeric were too well known in India. Yet when a patent was granted getting it invalidated was a difficult task. Although this knowledge was widely known to establish that there was no novelty and all the claims were anticipated by prior art

the CSIR had to furnish proof from many sources, including unpublished manuscripts and texts in languages other than English. Some of them had to be translated and authenticated. And all the claims had to be refuted with reference to the documentary evidence produced, indicating one by one, how, there was no novelty in the claims and the prior art is well established regarding turmeric. Moreover they had to also produce evidence to negate the claims as they were cosmetic changes on well known facts. It took a team of experts to overturn this patent. An organization like CSIR which has governmental support and access to intellectual resources could do so. In the end it became clear challenging misappropriation of indigenous knowledge in public domain also needed printed publications and other evidences. The gap in the availability of information for examining patents was a reason for this patent being awarded in the first place.

Although the USPTO did not remove the patent from the databases it suggested that a database on traditional knowledge may be created.[84] The case was hailed as a proof that western IPR system causes biopiracy.[85] One cannot fully agree with this for the patent claims were rejected under the patent rules of the USA once the prior art was established and the novelty was proved to be nonexistent. This is a proof that the western IPR system can be used against biopiracy and the problem is not with TRIPS per se. Further globalization IP regimes will result in expanding the scope of the prior art. Hence one has to distinguish what is the problem and what is not the problem. In this case it was not definition of prior art that was the problem, the problem was lack of access to the relevant prior art. This is more an administrative or institutional issue than an issue relating to criterion for patenting. In such cases the issue how to ensure that prior art relating to indigenous knowledge is made available to examiners, irrespective of the location of the office granting patents. And if any changes are needed in TRIPS to prevent such patents what are they?. Yet this does not mean that USPTO or any other patent granting office should stop issuing any patents on processes

or products that use turmeric. As long as the conditions relating to novelty and prior art are met there is no bar on them. So it will be ridiculous to claim that any claim on turmeric is an example of biopiracy. In the above mentioned patent it was proved beyond doubt that the particular claims do not meet the criterion for novelty and were anticipated by prior art or was a part of the prior art.

Cumulative innovations are the norm in many industries.[86] And traditional knowledge can be used for this. But if it is claimed that since almost all of this knowledge arose in India, India should have a share in every invention based on turmeric will that make sense. In this context the global public domain will be impoverished if a too restrictive attitude prevails. So the question is how do ensure that IPR laws promote innovations and inventions without aiding biopiracy. One suggestion is that countries like India should have laws that do not aid biopiracy and establish databases that could be shared with other countries. The others which include including the origin of genetic resources, PIC certificates have been discussed elsewhere.

Basmati Rice

Basmati rice, known for the aromatic rice is grown and exported from India and Pakistan. It is estimated that there are about 400 varieties of Basmati. Basmati I grown in a particular region and is not grown in major rice producing states like Andhra Pradhesh and Tamil Nadu. In 1997 Rice Tech Inc, a Texas based company applied for many patents on basmati rice and grain lines.[87]

Rice Tec's claims relate to a specific rice plant, for the grain produced by the plant, methods of selecting plants for breeding and propagating specific grains of rice. Thus twenty claims were filed by Rice Tec. Besides this it also applied for a trade mark, the mark Basmati USA but it was given up later. The patents were challenged. USA imports Basmati rice from Asia. The Indian government filed an application for re examination through APEDA

(Agricultural and Processed Food Products Export Development Authority). Rice Tec agreed to withdraw some claims. In January 2002 the USPTO issued a Reexamination Certificate. Through this it cancelled claims 1 to 7, and 14 to 20. The cancelled claims include the broad claims covering the rice plant. But amendments to claims 12, 13 were allowed and claim 8,9,11 are valid. This includes claims, A rice plant produced from Bas 867 seed having accession no. ATCC 75941,a rice plant produced from RT1117 having accession no. ATCC 75939 and a rice plant produced from RT1121 seed having the accession no. ATCC 75940.

Thus although India has won a partial victory the issue is far from settled. Rice Tec is using the term Texmati as the trademark in USA, it is also using the trademark Texamati in UK. But it is using basmati in the packaging in the USA but not in UK. In UK the term Basmati could be used only for rice grown in India or Pakistan. It can be argued that use of basmati is USA creates confusion. But the issue is what exactly is basmati – is it is a trade mark or a geographical indicator or a descriptive mark. The differences in laws in different countries and the interpretation of Geographical Indicator complicate the issue.

The Indian government views that Basmati should be treated like "champagne" and "Burgundy". The TRIPS Agreement categorically states that trade mark protection for geographical indicators as applied to wines and spirits is not permissible. But Basmati is yet to be accorded that status internationally although the Indian government could do so in the IPR regime in India. It can be argued that as Basmati is unique to that region, or geographical area it should be treated as a Geographical Indictor. At the same time the term Basmati means fragrant and hence basmati is a descriptive mark which indicates an attribute. Rice Tec can also argue that the term Texmati indicates Texas and hence there is no confusion about the origin of the produce. It can also argue that basmati is a generic term and a generic term cannot be protected as a trademark or as a Geographical Indication. At present the TRIPS is not in favor of India for basmati is not a Geographical Indicator, it denotes one attribute of

the rice (smell) but not its origin. But through usage the term Basmati has come to indicate rice grown in India or Pakistan only. Thus Basmati can be protected by a Geographical Indicator globally only if the attempts by India succeed in convincing the applicability of G.I to Basmati.

Neem

Neem also known as Indian lilac is native to India but is found in Africa, Australia etc and has multiple uses in many cultures.[88]

In India neem has been used for various purposes and extracts from neem have been used as pesticides, medicine and fertilizer. A patent search indicates that there are more than 200 patents based on extracts from neem in one way or other. The controversial patents to Grace & Co were granted in 1990, and 1994. The first patent was "for improving the storage stability of neem seed extracts containing azadirachtin. The second one was for

"Storage of stable insecticidal composition comprising neem seed extract " which enabled "increased shelf-life stability of azarirachtin solution" . These two patents became very controversial and were cited as another example of biopiracy. Although these patents were filed in the USA and hence do not affect the rights of the people in India to use neem in any manner this was projected in a different light.

Interestingly it has been pointed out that neither research on using extracts from neem to develop products and processes nor patents on them was new. There are many patents on neem based products by Indian companies.[89] But many products have failed commercially because of the relative instability when exposed to sunlight. Thus there are hundreds of known uses of neem and its extracts but commercially there have been few success stories only.[90] The research activity and the number of publications on neem have increased considerably only in the last two decades. Neem has been the focus of research in USA in view of the utility of azadirachtin as an insecticide.[91] Thus neem is a classic case of continued

western interest on traditional knowledge. The controversy over neem products also indicated how patent laws in different countries treat prior art and novelty.

The patents granted to W.R.Grace & Co were challenged by Foundation on Economic Trends and others before US PTO. The US P.T.O rejected the challenge and the patents were held as valid. But in May 2000 the Opposition Board of EPO withdrew the patent granted to W.R. Grace & Co and U.S.D.A for a patent for a process to extract oil from neem tree. The panel found that there was no inventive step involved in this as neem has been used as fungicide and there was no novelty in the patent granted. Thus the opposition to neem patents outside India resulted in a victory. But this does not mean that there are no patents on neem based products. Apart from USA patents have been obtained in Japan also.[92]

The patent granted by EPO and later revoked was for a method to control fungi on plants.[93] This was challenged in 1995 by a group including IFOAM, RFSTNRP. They invoked two reasons against the patent, one relating to inventive step and novelty, and the other challenging patent on a plant variety. (Fungicidal effect of hydrophobic extracts of neem seeds was known and used for centuries on a broad scale in India, both in Ayurvedic medicine to cure dermatological diseases, and in traditional Indian agricultural practice to protect crops from being destroyed by fungal infections. Since this traditional Indian knowledge was in public use for centuries, it would seem that the patent application in question lacked two basic statutory requirements for the grant of a European patent, namely novelty and inventive step (in the U.S. non-obviousness). In addition, the Opponents charged that the fungicidal method claimed in the patent was based on one single plant variety (Azadirachta indica) and hence resulted in at least partially monopolising this single plant variety. Since the European Patent Convention (EPC) explicitly prohibits the patenting of plant varieties, the patent should therefore be revoked.

The patent granted by EPO was a modification of the patent granted by US P.T.O. Had the reasoning adopted by the Opposition Board of EPO been applied in the USA, the patents in USA would have been revoked.[94] The patents applied for in the EPO are improvements over the process patents granted in the USA. So if an improved version could not be granted in the Europe, process patents would also have been revoked. This indicates that it is relatively easy to obtain process patents in the USA, compared to Europe.[95]

But a larger issue relates to the discrimination in the U.S law in deciding what is prior art and what is no under Section 102 of U.S. Patent Act.[96] There is also a distinction between domestic and foreign prior art.[97] This discriminates against indigenous knowledge and permits patents based on indigenous knowledge and as a result such patents have to be challenged at great cost.[98] It has been pointed out that as early (or late?) as 1966 the Presidential commission On Patent System suggested that geographical limitation to statutory bar in section 102(b) should be eliminated. This was suggested for many reasons including making the US Patent system compatible with European Patent Laws and to bring in a universal standard of prior art. This would also prevent granting U.S patents on inventions which are in public use or common knowledge elsewhere.[99]

The Sustentative Patent Law Treaty under Article (1) eschews such discrimination by declaring that "all information, which has been made available to the public anywhere in the world in any form" is prior art and further it does not discriminate between domestic and foreign prior art. This is in conformity with Japanese Patent Law and EPC. But still under the U.S Patent Law only information which is described in a published patent or printed publication constitutes the prior art if the invention has become available outside the United States. If information is not in a written form but has become known or used, such as sale of an invention without any written disclosure, the information must be available in the United States to constitute the prior art under 102(a) and (b).[100]

While it can be contended that there is no inventive step or novelty in a process for producing neem oil, the case law in USA reveals that although a substance may occur in nature, in a non-purified form, a compound in purified form can receive a patent.[101] Thus prima facie the patents on processes to derive neem based products seem to fulfill all the criteria laid down by the 35 U.S.C Sections 101,102,103 in terms of utility, novelty, non obviousness, and unanticipated by prior art in the USA. Under 102(a) and (b) foreign knowledge can defeat a patents claim in USA only if that knowledge appeared in a printed publication prior to the invention or in the application by the U.S applicant. The response to neem patents in India was mixed. While there was much opposition, to some the patents obtained by Grace were not another instance of misappropriation or biopiracy.

Thus although the patents on neem based products and processes created a lot of controversy except for the decision of the Opposition Board in EPO nothing came out. Thus the opponents had a limited victory but this highlighted the problem with the U.S patent law. Had India adopted TRIPS at the time and provided for patents, if W.R. Grace & Co had applied for and received a patent it would have received a different response. This controversy also highlights the issue of technology development and transfer. Although neem is widely used in India, neem is found in other countries also and is also used for various purposes. In the absence of a universally accepted prior art it would still be possible to obtain patents in USA for processes based on the knowledge in any country. At the same time it will be unfair to deny patents for inventions and new processes. But here again patent laws vary in their approach to defining novelty. So until these laws are harmonized and the patent offices are linked and have access to databases on traditional knowledge to find out the prior art such patents will continue to get issued.

Obviously there can be no objections to granting patents on genuine inventions, even when they use traditional knowledge to develop novel processes and products. Thus while

neem may be widely used in India, other countries also use neem for various purposes. So a comprehensive database on neem is a must and this should be available internationally.

Enola Beans and The question of Geographic Limitation

In 1999 a patent was issued to Larry Proctor for an invention, described as 'a new field bean variety that produces distinctly colored yellow seed which remains relatively unchanged by season'. Apart from this he was also granted a Plant Variety Protection Certificate for this variety. But the beans in question are being cultivated in Mexico and exported to USA. Further it has been pointed out that the patent claim is patently absurd as it allows a protection of a color per se. As a result of this patent exports of this variety of beans to USA from Mexico are affected. The Mexican government has protested this patent. The patent has been challenged .The CIAT has challenged this patent as it fails to meet the criteria of novelty and non-obviousness and ignores the prior-art as well. Still as it often happens in such cases a patent is valid till it is negated by PTO. It has been pointed out that bean varieties substantially identical to the claims made in patents were available with accessions in CIAT. The origin of this patented variety is interesting.

Larry Proctor who owns a seed company in USA bought a bag of mixed edible beans in 1994 in Mexico. He brought them to USA and chose the yellow beans from them and planted them. Then until he got a uniform population of yellow beans he cultivated them and this was obtained using self pollination. In 1996 a patent claim was filed and in 1999 a patent was issued. Using this patent he has been able to stop imports of any beans in the specific color range as claimed in his patent and it has been reported that he demanded a royalty of six cents per pound of beans imported from the importers. [102] In this case the question of prior art is of much significance.[103]

Apart from this there are cases like patent on Ayahuasca. which was granted first by U.S.P.T.O, revoked later on protest by indigenous groups and C.I.E.L but the same was

revalidated later.[104] . As discussed in the previous paragraphs this anomaly has been pointed out by many others who argue that it is high time this differentiation is removed and the U.S patent law is brought in tune with patent laws of Japan, EC etc.[105]

Indeed as Bagley has pointed out the Opposition Board of EPO took into account the evidence produced by the group that challenged the patent and the evidence included evidence by a researcher who testified about a trial using neem based product as a fungicide and also revealed the details about the farmers who took part in that. Eliminating this differentiation is necessary to prevent biopiracy although this it self will not make that impossible. At least it will ensure that this loop hole is taken advantage of, to misappropriate indigenous knowledge. [106] The results of using prior art to revoke patents based on indigenous knowledge has been mixed.[107] In some cases new applications and improved methods have resulted in the new claims being accepted. Thus while eliminating the 'Geographic disparity'may be necessary that by itself is not sufficient. This should be seen in the larger context of using indigenous knowledge as prior art at the international level. Hence there is a need to use more than one approach in cases related to biopiracy.

Biopiracy : The Rhetoric and Beyond

In the debate on Biopiracy some have challenged the idea or the usefulness of this rhetoric.[108] On one hand the rhetoric has successfully focused the attention on the misappropriation on indigenous knowledge and this resulted in the debate over using IPRs to protect indigenous knowledge and the problems with current IPR regimes in preventing such misappropriations. Due to protest and legal battles some patents were revoked or withdrawn but many patents have been issued. In the debates on biopiracy there has been more heat than light and except some specific suggestions like removing the geographical limitation of prior art, creating a digital database not much work has been done to unravel the complexity of the issues involved. Thus extreme view points have become common in these debates.

But a closer look reveals that some important questions have not been asked or ignored. For instance would the patents on neem would become an instance of biopiracy had they been applied before U.S P.T.O by an Indian firm or would it be regarded as a normal practice. In such a case the geographical limitation would have been used by the Indian firm to get the patent. The turmeric patent was filed by two persons of Indian origin and was assigned to an institution. In case of neem it is used in Africa and other places. So how does one arrive at the prior art relating to neem. Again had an Indian firm applied for and obtained a process patent in USA based on the indigenous knowledge on neem in Africa would that be a case of biopiracy. In case of neem there have been patents obtained by Indian companies and a transfer of technology is provided by a government institution on a process.

It is obvious that Grace & Co or anybody else could not patent neem seed or neem tree per se. Unless they genetically modify they cannot get a patent on neem seed. Thus the patent in USA does not bar in any way the use of neem in India by farmers or others, but will create problems for export of neem based products, if they are found to be identical to the products on which the patents have been obtained. So most of the arguments in this case, projected the patent and grant of patent as barriers to the use in neem are wrong. At the same granting the patents at USA but the revocation of patents based on the ones granted at USA, by the Opposition Board raise serious questions about the patent laws. But will revising the patent laws of USA will prevent biopiracy. There is no easy answer to that for after revocation of the process patents on neem issued to W.R. Grace & Co there are many patents on neem based products have been issued by EPO. Similarly in USA patents on turmeric or related to turmeric are still valid. Thus the question of prior art is not relevant beyond a point. It can be argued that as these patents use indigenous knowledge in one way or other they are instances of biopiracy. But it is difficult to prove whose indigenous knowledge and how this would be a case of misappropriation. A chemist in USA can import neem seeds and can

develop a novel product by overcoming the limitations of those who had tried before him/her to find a solution. The indigenous knowledge on neem may be vast and has evolved over a period of hundreds of years, yet one cannot assert that that is the last word on knowledge relating to neem. Novelty may be possible by going beyond the conventional wisdom or even challenging that. And indigenous knowledge itself is not a static entity. It is also evolving. It may well be possible for one to combine insights from two or more indigenous knowledge systems to arrive at a novel process or product. Indigenous communities also exchange information, and knowledge is the outcome of many interactions in space and time. (see the discussion elsewhere in this dissertation) . Thus any claim of monopoly over knowledge by indigenous societies or nations is questionable. In case of neem let us take up a hypothetical example. Let us assume that the knowledge related to using neem as a effective cure for a disease is known to a family of healers and there is no evidence in the written literature on this. Let us also assume that this knowledge about the healing property of neem is known, but not so widely and people use neem as a cure but there is no guarantee that it always works successfully. The family keeps the secret to itself and the composition of the cream prepared and sold to the patients is based on a secret formula. In such a case the family may well register it as a trade secret and license the use of the same. Is that a case of biopiracy? . If not where does one draw the line between misappropriation and legitimate invention or innovation. The indigenous knowledge on rosy periwinkle was not related to the new drugs developed by Ei Lily for anti-cancer treatment.

In such cases indigenous knowledge has limited use. The ethno botanical knowledge again, as it has been pointed out is very useful and relevant, particularly in screening for compounds but drug discovery is much more than that. Thus while there is much truth in allegations about biopiracy the rhetoric often obscures the complexity and reduces the issue to that of developed vs. developing nations or North vs. South. But the solutions to this have

to be found at different levels. At the international level developing nations are arguing that Article 27.3(b) should be interpreted in such a way that patenting of life forms is not permitted and certificate of origin and disclosure of origin should be included for grant of patents based on genetic resources from developing nations. While such steps are not acceptable to some countries the possibility of all countries agreeing to conditions are remote. On the other hand initiatives like digital databases and providing better search facilities for patent offices are being supported by all the countries and bodies like WIPO.

Since these issues are related to indigenous knowledge and IPRs they have been discussed at length in another chapter. The analysis of biopiracy in this chapter reveals that despite the opposition biopiracy continues unabated and some technical solutions have been offered but these are inadequate to address the moral and justice related issues. Hence these technical solutions are necessary but not sufficient to curb biopiracy.

Conclusion

Bioprospecting as a solution has not been very successful. One reason is the lack of clarity on issues relating to rights and equity. The proliferation of regimes and laws has not made things better. Fundamental questions remain unresolved because the associated concepts themselves are not well defined or vague. On the other hand the economic benefits from bioprospecting have been exaggerated. As a result of all this bioprospecting failed to meet the expectations. The role of IPRs in bioprospecting is a controversial issue and the contradictions between local regimes and TRIPS is yet to be resolved. The tension between the objectives of CBD which advocates access and benefit sharing and the objectives of TRIPS which expands the rights of IP holders and scope of IPRs are evident in bioprospecting arrangements which seek to balance the obligations and claims of different stakeholders. Thus it is possible that individual bioprospecting arrangements which have resolved this tension may succeed but as a concept bioprospecting has a long way to go.

Biopiracy is a complex phenomenon which demands a carefully crafted strategy that could take into account the diverging criteria in the laws of various nations and the solution cannot be merely a technical one. The other dimensions (ethical, equity) deserve equal attention. Hence there is a need to rethink some of the answers offered in the context of biopiracy.

Notes and References

[1] "In these days of genetic engineering, a species is to be viewed as depository of genes that are potentially transferable.... The extinction of species, in light of these [technological] advances, takes on a new meaning. It does not simply mean the loss of one volume from the library of nature, but the loss of a loose leaf book whose individual pages, were the species to survive, would remain available in perpetuity for selective transfer and improvement of other species" cited in Tackas (1996).

[2] See Eisner, Thomas (2003) for an overview and assessment by the person who pioneered this idea. See Weiss C and Eisner T (1998) where in it is argued

" Developing countries naturally wish to begin their .prospecting activities at as high a technological level as possible, so as to maximise their value-added and to avoid relegating themselves to their traditional roles as suppliers of raw materials to industries in more advanced countries" (P489) .

See Moran, Katy *et. al* 2001 for a brief history and key issues relating to bioprospecting.

See Svarstad, H; Dhillion S (2000) for case studies on bioprospecting.

The article by Castree, Noel (2003) provides a 'critique of the critiques' and excellent introduction to the debates on bioprospecting.

See Firn, Richard (2003) for a critique and assessment of some of the assumptions on biopropecting.

The book by Reid etal (1993) popularized this idea and promoted this as a win-win solution that could help both North and South besides resulting in conservation and use of forests for better purposes. See also Balick, M. J, et al. (1996) for articles that assess the importance of tropical forests as a resource for medicinal plants and drug discovery. See Balick, M. J. and. Cox Paul Alan (1996) for a fascinating account of indigenous people, their traditional medicinal knowledge and ethnopharmacology.

See also Rausser; Gordon C and Small Arthur A (2000) for a skeptical view that bioprospecting need not result in substantial financial resources to support conservation. See Simpson R. et. al 1996. also Simpson (1997)

The differences in views about the usefulness of bioprospecting as a strategy give credence to the view that what matters more is the context in which bioprospecting is done, than the grand ambitions

and win-win scenarios projected. Thus a realistic assessment of bioprospecting as a source of finance for conservation would indicate that bioprospecting can at best be a supplementary source, not the primary source, and, to justify bioprospecting in terms of conservation is difficult. However as the value of genetic resources is difficult to arrive at, few success stories are touted as examples in the beginning. But after a decade that rosy picture has lost credibility.

See Brown (2003) for an assessment of bioprospecting in terms of the expectations expressed in the initial stages. The failure of Shaman Pharmaceuticals is also cited as an example of the failure of this model. But that would be an exaggeration as the company had faced many problems and not all could be traced to this idea. The business model of different companies differs and one failure/success cannot be used to prove/disprove a claim.

A recent assessment about bioprospecting can be found in Dalton, Rex (2004)

[3] Pearce and Puroshothamon (1995)

Pearce D.W. and Puroshothamon S. In Swanson T. (ed.) 1995

[4] See the discussion in the chapter on CBD and elsewhere in the dissertation

[5] See Kate Kand Laird S. (1999).

[6] See Urs, Thomas (2002)

[7] See C.Juma (1989), also Kloppenburg, J. (Ed) (1987) for details about this

[8] See the discussion in the chapter on IUPGR

[9] Svarstad , Hanne etal (2000)

[10] Glowka.L(1998)

[11] Llewelyn Margaret and Adcock, Mike (2000) www.quno.info
http://geneva.quno.info/main/publication.php?pid=113

[12] Artuso, Anthony (2002)

[13] Merson (2001)

[14] This is because bioprospecting includes prospecting the marine areas, antartic regions and bioprospecting for noncommercial/research purposes.

[15] "Madagascar's rosy periwinkle produces the anti-cancer compounds used for cancer drugs like vincristine and vinblastine, yielding millions of dollars annually to Eli Lilly, the American pharmaceutical company that developed the drugs, without any returns to the impoverished source country. Any hope of compensation ended when Eli Lilly successfully cultivated the plant in its Texas plantation, foreclosing its possible interest in Madagascar"

Nwabueze, Remigius N. (2003)

[16] Columbia University case study (1999) P12

[17] Svarstad, H., S.S. Dhillion & H.C. Bugge (2000)

[18] For a discussion on drug discovery and use of resources from forests see Balick, M. J., et al. (1996).. See also Artuso op.cit.

[19] For example see Berlin, Brent and Berlin, Elois Ann (2003), also

NIGH, R. (2002) ,Takeshita, Chikako (2000) ,Lans, C. (2003) ,Toly, Noah J. (2004)

Hughes, Alexandra (2002) ,Hayden, Cori (2003) ,Greene, Shane (2004)

[20] Clapp R.A.; Crook C (2002)

[21] Soejarto D.D.et.al. in Stepp, et al (2002)

[22] see the discussion in the chapter on CBD

[23] As Duttfield points out

"traditional knowledge should not be respected, preserved and maintained merely because it is relevant to biodiversity conservation and sustainability; even less because some of it has industrial application. A great deal of traditional knowledge has no commercial potential whatsoever, but this does not make it any less worthy of respect or protection". See Dutfield, Graham (2000).

[24] According to article 15(7)

"Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms"

See Peña-Neira, S. Dieperink, C. Addink, H (2002) also

[25] Article 19(1). Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

Article 19(2). Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

[26] Rose, Gregory (2003)

[27] See Blais, Francois(2002)

[28] Glowka (2000)

[29] This has to be viewed in the context of the technology transfer in various sectors.

For example see Brenner, Caroline (1998)

[30] Please refer to the discussion in the chapter on biodiversity.

[31] McGraw (2002)

[32] See Tully, Stephen (2003), GDI(2002), Chambers, Bradnee W.(2003) for discussions on provisions of Bonn Guidelines.

[33] Walløe Tvedt, Morten (2000)

[34] Refer to discussion on this in other chapters.

[35] TRIPS Council Communication from India (IP/C/W/196, 12th July 2000)

[36] For e.g. Communication from U.S.A (IP/C/W/257 13th June 2001) Please refer to the discussion in the chapter on CBD&TRIPS.

[37] ENB Summary 22:51 6th Sep 2002

[38] According to Artuso

This body of research has provided a useful catalog of alternative benefit sharing arrangements but, as evidenced by the continuing debates by the conference of the parties to the CBD, there remain widely divergent views on what constitutes fair and equitable benefit sharing and how best to promote it. Artuso, Anthony (2002)

[39] UNU-IAS (2003)

[40] Report of Experts on Benefit sharing Arrangements UNEP/CBD/COP/5/8 2nd November 1999

[41] Like Minded Megadiverse Countries Cancun Declaration, Cusco Decalartion (Last visited 4th april 2004)

http://www.comunidadandina.org/ingles/document/cusco29-11-02.htm

[42] CBD Access and Benefit Sharing as Related to Genetic Resources: Addendum UNEP/CBD/COP/6/19/Add.1,2002

[43] According to one researcher

There is scarce information about access to genetic resources among public institutions, universities, botanic gardens and herbaria. No common criteria for granting access to the genetic resources. Little application of CBD,

Access agreements are dissimilar, without a common pattern of benefit sharing, with no benefits to local communities for the use of their resources. Some agreements comply with CBD, others do not. Benefits can be substantial in some cases and very low in others, for accessing unique and scarce endangered materials - ISABEL (2003) www.field.org.uk

[44] Flores, Luis et al www.field.org.uk

[45] Isabel, Maria Manzur (2003)

[46] Enactment of specific stand-alone laws with provisions for access and benefit sharing,

Either as a national initiative as in the case of Philippines, or as a part of common regional framework as in the case countries adhering to Andean Pact.

Introduction of laws that cover many objectives including nature conservation, sustainable development and including provisions relating to access and benefit sharing in the same (e.g. Costa Rica's 1998 Law on Biodiversity)

Including provisions that facilitate access and benefit sharing within the environmental laws and designating institutions to develop relevant guidelines

Changing the sectoral laws to incorporate access provisions and regulating access to forests and national parks (e.g. changes in the laws of Sarawak state of Malaysia . Glowka,. L A 1998).

[47] Kate, Ten (1997a) , Barber Charles V.et.al (2002)

[48] Andean Community Adopts new IPR Law-Grain October 2000 (last visited 4th april 2004)

http://www.grain.org/publications/andean-en.cfm, http://www.ictsd.org/dlogue/2002-10-14/Ecologic2002.pdf (P62-63)

[49] "The creation of an Andean paradigm for the protection of resources has been difficult because of the lack of regional legislation to serve as a model, the need for consultation with a wide variety of actors including industrial and commercial sectors, and a defensive orientation which has resulted from the need to control bio-prospecting. High transaction costs also complicate the development of products utilizing Andean biological resources, particularly in the case of agricultural resources. Positive developments include increased coordination between country authorities over requirements for an Intellectual Property Regime, as well as increased discussion of the themes of bio-security and traditional knowledge. " (last visited 4th april 2004)

www.ictsd.org/dlogue/2001-02-22/Report-Cusco.doc

[50] "Any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germplasm of any living thing". (Duttfield. G Protecting Traditional Knowledge and Folklore : A review of

progress in diplomacy and policy formulation (http://www.ictsd.org/pubs/ictsd_series/Intellectual Property Rights/CS_dutfield.pdf 2003

[51] http://www.ias.unu.edu/binaries/UNUIAS_UserMeasures_2ndEd.pdf (last visited 4th April 2004)

[52] See http://www.ictsd.org/dlogue/2003-11-20/docs/IP_tent_report.pdf

[53] See Part I, (e),(k),(h) of African Model Law available in www.grain.org also http://www.ictsd.org/dlogue/2001-07-30/Ekpere.pdf (last visited 4th April 2004)

[54] "Central to the OAU model law is the requirement of consultation and of written Prior Informed Consent (PIC) from both the national competent authority and the concerned local community. PIC is defined as "the giving by a collector of complete and accurate information, and, based on that information, the prior acceptance of that collector by the government and the concerned local community or communities to collect biological resources, or indigenous knowledge, or technologies."

The absence of such PIC is deemed to render access to TK invalid, as is granting of access by the national competent authority without prior consultation with the concerned community or communities to ascertain their content to the access to TK. The model legislation also calls for an advance payment under benefit sharing arrangements, prior to the commencement of collection of knowledge or materials. It also calls for the establishment of a national information system of biological resources, with support for local communities establishing their own databases of biological resources and TK."

Bodeker, Gerard (2003)

[55] "The OAU model assumes that governments and traditional communities have common interests and objectives. Clearly, the history of governments and indigenous groups, as testified to by the organisations such as Survival International and the UN High Commission on Human Rights group on Indigenous Peoples, does not support such an assumption. If both community and government dispute ownership of TK, this will affect the OAU model's provisions for PIC and benefit sharing to the possible disadvantage of traditional knowledge holders. Clearly, this is a matter in need of resolution before the model legislation is implemented regionally." Bodeker, Gerard (2003)

[56] From the text available at www.grain.org

[57] "Patents over life forms and biological processes are not recognized and cannot be applied for. The collector shall, therefore, not apply for patents over life forms and biological processes under this legislation or under any other legislation relevant to the regulation of access and use of a biological resource, community innovation, practice, knowledge and technology, and the protection of rights therein."

From the text available at www.grain.org

[58] "Fairly recently, Francophone countries in Africa negotiated the Bangui Agreement, a new law to be administered by the African Intellectual Property Organization (OAPI), which requires members to adopt UPOV-type legislation for the protection of plant varieties as dictated by article 27.3(b). This agreement, signed by OAPI's 15 member states in February 1999, introduces a regime of intellectual property rights on seeds and is largely contrary to the OAU model legislation adopted at the OAU Summit in 1998.The Bangui Agreement was revised recently and restricts the rights of farmers to save seeds from their harvests and imposes a system of royalty payments on commercial planting material." Nnadozie, Kent, Lettington, Robert et. Al. (2003) at P. 48.

[59] Zerbe, Noah (2002)

[60] "Complex access procedures with high transaction costs have proved to be a burden for implementing Decision 391 and the lack of incentives in the Andean regime for the owners and managers of biological resources to conserve them, making it very difficult for them to receive part of the benefits deriving from the use of the genetic resources, has also played an important role in its implementation" Diaz (2000).

[61] Although the following table is not up to date it gives an overview of the strategies being adopted by countries

General environmental framework laws (which enable future legislation on ABS) e.g. Gambia, Kenya, Malawi, Republic of Korea, Uganda

Sustainable development, nature conservation, biodiversity framework –further legislation on ABS Costa Rica, Fiji, Mexico, Peru

Specific exclusive laws or orders on regulating access-The Philippines, Sarawak (Malaysia)

Changing existing laws to include ABS Provisions-Nigeria, Malaysia, Western Australia

Regional Framework- Andean Pact, OAU Model Law, ASEAN Framework (Glowka 1998).

[62] Downes, David, Wiser, Glenn (2002) -p382

[63] See Barber, Charles V, Glowka, L. La Vina A.G (2002)

[64] Artuso, Anthony (2002)

[65] For instance in case of India

"While Clause 19(2) of the NBL requires an applicant to seek 'previous approval' of the NBA for applying for intellectual property protection, Rule 19(4) of the Draft Rules calls for an agreement to be signed between the bioprospector and the NBA, in the event of a bioprospector seeking IPR for a product based on biological material or knowledge obtained from India." (Damodaran 2003)

[66] "In a sense, Northern countries presume that open and reasonably free access to genetic resources will best serve all interests, whereas Southern countries presume that controlling access to genetic

resources will best serve all interests. Although both systems are valid, their differences present difficulties in establishing common standards to regulate access, use, and eventual distribution of benefits from genetic resources ' (P. 97)

Bass, Susan Perkoff ,Muller, Manuel Ruiz (2000)

[67] See for an overview www.biodiv.org Unless otherwise mentioned the information on case studies is based on the following sources : GDI(2002), www.ictsd.org www.grain.org www.etcgroup.org and other web based sources and searches in magazines and newspapers.

[68] This analysis is based on to a great extent on Laird(2002), Ramani (2003), Subramanian(2002)

[69] Laird, S.A. (1999).

[70] http://www.grain.org/publications/issue4-en.cfm

These include French companies LOreal (EP 0672046) and Sederma S.A. (WO 9925369), Germanys Willmar Schwabe (DE 4028945), and Japans Lion Corp (JP 1007464) and Shiseido (JP 09067238).

[71] http://www.ictsd.org/issarea/Intellectual Property Rights-sd/docs/PolicyPaperIntellectual Property Rights.pdf p 37 Last Visited 10th April 2004.

[72] INBio states that it is an "institution leader in the search and popularization of the knowledge about biodiversity and its sustainable uses" and its mission is to "promote a new awareness of the value of biodiversity, and thereby achieve its conservation and use to improve the quality of life." Instituto Nacional de Biodiveridad, at http://www.inbio.ac.cr/en/default.html (last visited Dec 17, 2003).

[73] For a discussion see Hayden (2003)

[74] "The "model" example of such an initiative is that of the major pharmaceutical company, Merck. In 1991, a year in which the firm made profits of $8.6 billion, a contract was signed with Costa Rica, home to between 5 per cent and 7 per cent of all the world's species. In exchange for exclusive rights to screen, develop and patent new products from plants, micro-organisms and animals, a total of $1.1 million was paid to a local biodiversity programme and the National Environment Ministry. With an estimated 500,000 species this represents a fee of $2 per species and on a global scale means that at such a rate of exchange the world's genetic resources could be purchased for $20 million!" Stenton (2004).

[75] "Intellectual property rights apply and contemplate the possible participation in discoveries of INBio's scientists (joint patents and publications)" Gamez (2003)

"The INBio–Merck agreement is explicit in its treatment of patents, marketing, and licensing. Each party is authorized to independently prepare, submit, follow-up, and maintain all patents, provided they consult the other party on all plans and developments. The agreement does not address Intellectual Property Rights of any other stakeholder. However, it does conform to the environmental

laws of Costa Rica. As so far no products have been commercialized it is presumed that Intellectual Property Rights have not been filed for by Merck or by INBio. Further the law in Costa Rica explicitly prohibits patenting " DNA sequences per se and inventions derived from knowledge associated with traditional or cultural biological practices in the public domain." (Columbia Univ. op.cit).

[76] According to the Columbia University study

In the case of genetic resources the nature of Intellectual Property Rights is even less clear. There are two different standards for allocating Intellectual Property Rights. Most of the agreements explicitly grant Parties the right to patent innovations derived from the research. Nonetheless, the standard for indigenous knowledge is less generous: in many of the agreements indigenous knowledge is recognized, but the knowledge is not granted protection by Intellectual Property Rights. For example, in the INBio–Merck agreement the Parties have the right to apply for patents from innovations realized during the study. But a similar provision recognizing indigenous Intellectual Property Rights was not included in the agreement despite a Costa Rican law that recognizes and protects the practices and innovations of indigenous peoples..... the development of a comprehensive property rights regime is essential to successful genetic resource access legislation and agreements. Property rights ensure that the various Parties in control of the real property, genetic property or intellectual may be entitled to share in the benefits derived from the use of the genetic material. Nevertheless, as we have seen in the case studies, most countries are still attempting to define these various property rights in the context of access to genetic resource agreements and legislation. The relatively short conceptual history of genetic resources as pure genetic material has added to the confusion in this respect.".

[77] According to Brown (2003)

"It is too soon to know whether we are seeing a permanent shift toward industrial practices that acknowledge the rights of indigenous communities in their traditional crop varieties and knowledge of local flora and fauna. What we know is that the world's tropical forest regions continue to shrink with each passing month, and with them the planet's biodiversity. The argument that rain forests should be saved for the sake of their biochemical riches has resulted in a few encouraging developments and a great deal of polarizing conflicts" (P143).

[78] "A number of inter-related problems and questions arise with the relative proliferation of benefit-sharing as a redistributive idiom. The first ten years of CBD-sanctioned experiments in the realm of bioprospecting have made evident the many difficulties that benefit-sharing is likely to confront in *any* context. Here, matters of sovereignty mix with the delicate questions not just of 'how much' should be shared, but with whom, and on what basis? These are not simply logistical questions but conceptual matters that suggest significant fault-lines at the interface of conventional frameworks of community, nation, market, and rights. "Hayden (2003a).

[79] www.etcgroup.org

[80] For example see Ryan, Michael (1998), Halbert, Debroah (1999). The idea that piracy resulted in losses running into billions of dollars every year was repeatedly used by U.S industry and business to argue for stronger IPRs all over the world. See Drahos, Peter, Braithwaite, John (2002).

[81] Thus, this patent claimed the following as subject matter :

"Administration of an effective amount of turmeric through local and oral route to enhance the wound healing process and accordingly restricted the main claim to ``promoting healing of a wound through administration of an effective amount of turmeric" and the dependent claims defend the wound as a surgical wound and administration of turmeric through oral or topical or and topical/oral routes. The dependent claims further qualified the wound as an ulcer/surgical wound".

[82] Gupta, R.K. Balasubrahmanyam, L. (1998) See also http://stp.unipune.ernet.in/ipr/turmeric.htm Lat visited 10th April 2004

"In his observations, the examiner rejected all the claims under obviousness over combined teachings of the cited references."

[83] According to U.S.C 103(a)

"A patent may not be obtained though the invention is not identically similar or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

[84] "The USPTO came up with a suggestion of creating more easily accessible non-patent literature databases that deal with traditional knowledge. It said developing countries should take up a project in cooperation with the International Patent Classification (IPC) Documentation Committee of Experts for the purpose

(Confusion over turmeric patent cleared Somasekhar Mulugu: The Business Line September 27, 1999 http://sdnp.delhi.nic.in/resources/patents/news/bl-27-9-tumeric.html (last visited 11th April 2004)

[85] This case was hailed as a victory. Vandana Shiva urged that European Patent Convention, TRIPS, patent laws of USA should be revised as "all of them fail based on global cross cultural scrutiny and on investigations about 'prior art' though TRIPS and PCT are imposing global IPR frameworks on countries like India. Global recognition of patents without global recognition of prior art is a recipe for biopiracy"

http://www.vshiva.net/aticles/turmeric.htm last visited 11th April 2004.

[86] e.g. Cohen, Julie ,Lemley, Mark (2001) (pointing out that the software industry "is characterized by rapid sequential innovation")

[87] This included a patent , patent number 5,663,484 (484 patent), claims that rice produced from this rice line has "characteristics similar or superior to those of good quality basmati rice."

[88] National Research Council 1992 Neem : A Tree for solving global problems gives details about the origins of neem and its various uses.

[89] http://www.neemfoundation.org/patents.htm last visited 11th April 2004

[90] Gupta, Anil (1996) Kocken, J. Van Roozendoal (1997), Passano, Paige (2000)

[91] Raghavan –neem patent revoked http://www.twnside.org.sg/title/revoked.htm

(last visited 11th April 2004)

[92] Aoki (1998)

[93] "A method for controlling fungi on plants comprising contacting the fungi with a neem oil formulation containing 0.1 to 10% of a hydrophoobic extracted neem oil which is substantially free of azadirachtin, 0.005 to 5.0% of emulsifying surfactant, and 0 to 99% water." http://www.ifoam.org/press/neem_back.html last visited 11th April 2004

[94] Ghosh.S (2003) Ghosh.S(2003a)

[95] Ghosh op.cit.

[96] It was held that the relevant prior art depends upon what a skilled person in that field would be expected to know in connection with his art. (Continental Can Co. v Old Dominion Box Co. (1968, CA2 NY) 393 F2d 321, 157 USPQ 353.). In case of neem the knowledge was too well known and constitutes prior art.

Generally, all patents, publications, and prior uses which were in existence prior to patentee's date of invention or more than year prior to his filing date are referred to as "prior art." Mohasco Industries, Inc. v E. T. Barwick Mills, Inc. (1963, ND Ga) 221 F Supp 191, 139 USPQ 148, affd (1965, CA5 Ga) 340 F2d 319, 144 USPQ 288, reh den (1965, CA5 Ga) 342 F2d 431, 145 USPQ 305 and cert den (1965) 382 US 847, 15 L Ed 2d 86, 86 S Ct 61, 147 USPQ 540. Prior patents, reductions to practice, publications, and public uses in art are all considered in determining anticipation of patents on device. Elfab Corp. v NCR Corp. (1979, CD Cal) 204 USPQ 999. Source: 35 USCS § 102

(taken from www.lexis.com)

[97]"The United States distinguishes between domestic and foreign prior art as a statutory bar to patentability. There is little uniformity in the rest of the world for dealing with this domestic/foreign prior art dichotomy" Sabatelli, Anthony D, Rasser, J.C. (1995) see also Campbell, Randy. L. (2003).

[98] As Kadidal points out

"In summary, under section 102 a patent application is anticipated when there is evidence of prior knowledge sufficient to teach the invention (constructive reduction to practice), or there is prior use or invention not specially hidden from the public. From this analysis it seems safe to conclude that casual, private knowledge, use or invention of W.R. Grace's neem stabilization techniques by Indian corporations or "scientific agriculturalists" would void Grace's patent, but for the historical oddity of section 102's blanket exclusion of such foreign activity from consideration as prior art" Kadidal, Shayana (1997) at 384.

[99] LaMarca, William (1996).

[100] See Takenaka, Toshiko (2003) for a discussion on the SPLT and the comparisons between the patents laws of USA, Japan and EC.

[101] In re Kratz, 592 F.2d 1169 (C.C.P.A. 1979) Merck v. Olin Mathieson Chemical, 253 F.2d 156, 116 USPQ 484 (4th Cir. 1958); Merck v. Chase Chemical, 273 F.Supp. 68, 155 USPQ 139 (D.N.J.1967).

[102] See the literature available at for details and discussions on this issue. Rattray, Gillian. N. (2002), Bagley, Margo A. (2003), Duttfield, Graham (2003) for details and discussions on this issue.

[103] " Nevertheless because of 102(b)'s geographical limitation on prior art, if information on the yellow bean were not in printed form, it might be impossible to invalidate Proctor's patent, despite the fact that the beans were in "public use" right across the border from the United States and public had access to this knowledge. This is because even if the patented bean is identical to, or an obvious variant of, the bean Proctor purchased in Mexico, the evidence of those purchased beans is not admissible prior art in the United States" Bagley, Margo A. (2003).

[104] " In The U.S P.T.O Request for Reexamination of U.S. Patent No. Plant 5,751 (Patentee: Loren S. Miller)" by CIEL 1999 available at
http://www.ciel.org/Publications/ReexaminationofUSPlantPatent5751.pdf last visited 10th April 2004

"Loren Miller traveled to Ecuador where indigenous people gave him samples of ayahuasca, a vine which they had been using for religious and healing purposes for generations. Because he obtained this information outside of the United States, his subsequent patent application was not required to contain any acknowledgment of the traditional knowledge supplied by the indigenous tribes people. Due to the increased ease of traveling to other countries and the frequency with which researchers go to developing nations to find specimens of plants used in traditional medicine, information gathered in foreign countries, whether previously published or not, should be credited as prior art under the Patent Act". Fecteau, Leanne M.(2001).

[105] It has been pointed out Japan amended the laws in 1999 and abolished the geographical prior art distinctions. The EPC did not have such a limitation. Under Article 54 of EPC 1, An invention shall be considered to be new if it does not form part of the state of the art. 2. The state of the art shall be

held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application. EPC, art 54 Bagley, Margo A (2003).

[106] "Elimination of the "in this country" limitation on non-patent or published prior art in U.S. patent law is long overdue. The U.S. Constitution requires it, and the benefits from harmonization, improved patent quality, and reduced prices due to healthy competition for subject matter in the global public domain, are significant. Elimination of the hypocritical and imperialistic practice of denying the value and legitimacy of foreign knowledge or use simply because it did not occur within U.S. borders is also long overdue. Changing the definition of prior art is not a complete solution to the problems engendered by patents covering foreign knowledge or use; however, it is a necessary action for the United States to take in this small, small world." Bagley, Margo A (2003a) See Nard, Craig Allen (2003) also. Bagley contends irrespective of the controversy over appropriation of IK/TK the geographical limitation is bad in law.

[107] Hansen (2002)

[108] Heald (2003)