ENVIS CENTRE ON ENVIRONMENTAL BIOTECHNOLOGY

SUPPORTED BY MINISTRY OF ENVIRONMENT AND FORESTS
GOVERNMENT OF INDIA

VOLUME-19 ISSN : 0974 2476 DECEMBER, 2011

NEWSLETTER

BIOPIRACY

DEPARTMENT OF ENVIIRONMENTAL SCIIENCE, UNIIVERSITY OF KALYANI, NADIA, WEST BENGAL
Email: scsantra@yahoo.com, desku@envis.nic.in, Phone: +91-33-25828750, Ext:372
Telefax :+91-33-2580 8749,Website:http://www.deskuenvis.nic.in, www.kuenvbiotech.org

EDITOR

PROF. S. C. SANTRA
(ENVIS Coordinator)

ENVIS STAFFS

DR. (MRS) ANUSAYA MALLICK
(Programme officer)

MS. AMRITA SAHA DEB CHAUDHURY
(Information officer)

MR SOURAV BANERJEE
(Data entry operator cum web assistant)

INSTRUCTIONS TO CONTRIBUTORS

ENVIS Newsletter on Environmental Biotechnology is a half-yearly publication publishes articles related to the thematic area of the ENVIS Centre. Popular or easily intelligible expositions of new or recent developments are welcome

Manuscripts should be typewritten (font should be Times New Roman and font size ought to be 12) on one side of the paper in double spacing with maximum of 6-8 typed pages

Figures and typed table should be in separate pages and provided with title and serial numbers. The exact position for the placement of the figures and tables should be marked in the manuscript.

Articles should be sent to

The Coordinator
ENVIS Centre
Department of Environmental Science
University of Kalyani, Kalyani-741235
Nadia, West Bengal
Email:**scsantra@yahoo.com**,
desku@envis.nic.in

EDITORIAL

In the pre-TRIPS era, India designed its patent system in accordance with its development priorities. In large measure this system was a successful one. The new regime, which is supposed to be fully implemented in 2005, allows India-as with other developing countries – much less freedom to tailor the system to fit its perceived national interest. Nonetheless, the IPR and biodiversity management laws that the government has drafted and enacted are serous attempts to reconcile the country's international commitments with its concern about access to genetic resources, sustainable use, and equitable benefit sharing. To the extent that such laws are TRIPS-compatible, which they largely appear to be, the global IPR regime does allow a significant measure of flexibility. But many developing countries may encounter external pressure that inhibits them from taking full advantage of this. India's ability to resist such pressure is relatively strong given its importance as an emerging economic power with a huge domestic market. Furthermore, successive governments have faced very strong parliamentary and extra-parliamentary criticisms whenever they have sought to introduce legal instruments to implement the patent and PVP-related provisions of TRIPS, ensuring that the TRIPS implementation process is very slow.

In this newsletter (Vol. no. 19). We have attempted to discuss the biopiracy related issues with respect to India.

(S. C. Santra)

IN THIS ISSUE:

BIOPIRACY

CURRENT NEWS

FORTHCOMING EVENTS

QUERY FORM

BIOPIRACY

The issue of biopiracy has become highly contentious and seems to have played a catalyzing role in the introduction of access legislation in some developing countries. The word 'biopiracy' is applied somewhat loosely to the extent it is not always clear who the victims actually are, or it indeed there are any. But is normally refers either to the unauthorized extraction of biological resources and/or associated traditional knowledge from developing countries, or to the patenting of spurious inventions based on such knowledge or resources without compensation. Developed World companies, and also academic and public sector scientists, are increasingly accused of stealing or 'pirating' the knowledge of indigenous peoples through the act of acquiring patents. Critics of such practices complain that the patent and plant variety protection (PVP) systems are being used to misappropriate traditional knowledge and that such practices are not only immoral but also violation of human rights of the people whose knowledge is being pirated.

WHY BIOPIRACY?

There is an increasing demand from consumers in industrialized countries for herbal products. The driven pharmaceutical companies to seek possible leads in indigenous systems of medicine and the information present with the traditional healers of indigenous and local communities. India and other developing countries are rich in bio-resources and IK are favourite targets and victims of biopiracy. Multi-national companies hire people who camp in villages and interact with local communities to identify plants and their local, and indigenous use.

Take the case of turmeric (*haldi*). Its used in wound healing, and treating common cold, has been known in India for ages. If some one claims to have invented this use now and gets a patent for it, then this is biopiracy. The list of biopiracy is long. The "Gene Campaign" gives some examples of biopiracy. You can see how the so-called invention on which the patent has been granted, is nothing but the imitation of indigenous knowledge, by the striking similarity between their traditional use and the modern patented use (Table – 1).

The list is neither exhaustive with regard to plants nor comprehensive with regard to the indigenous and patented uses. However, it does make amply clear that the patented uses are not innovations but mere imitations of existing indigenous knowledge. Different groups of actors, such as government departments, industry, intellectual property experts, members of civil society need to cooperative in order to define mechanisms for preventing biopiracy.

Patenting of Plant Properties: Jeevani and the Kani Tribes

The Kani tribes are inhabitants in the mountainous region of south-western India. There are about 16,000 Kanis distributed in 'hamlets' throughout the forest areas. In December 1987, scientists working on the All India Coordinated Research Project of ethnobiology (AICRPE) were trekking through the forests, along with Kani tribal people. They found that tribals were not tried even scientist were tried off. On enquiry it was noted that tibal consumes black fruits of some plants every day to overcome tiredness. These fruits were offered to the scientists and they were told that it would relive off their tiredness and lethargy. The AICRPE team members then tried and found that their energy is restore. Subsequently the Kani tribes' people introduced the scientists to the 'magical' plant, which was later identified as '*Trichopus zeylanicus* var. *travancoricus*'. Latter research showed that the leaf of the plant contained various glycolipids and some other non-steroidal compounds with aptogenbic and immuno-enhancing properties and the fruits showed mainly anti-fatigue properties.

Table – 1: Potential of commonly used plant materials in India

Sl. No.	Plant Name	Indigenous Use	Use for which patent is granted
1.	*Aegle marmelos* (Bel)	• Treating diabetes.	• Treating diabetes.
2.	*Aloe vera* (Ghritakumari)	• Skin disorders • Hair tonic • General weakness	• Skin care formulations • Cleansing articles for hair • Nutritional composition
3.	*Commifora mukul* (Guggul)	• Lowering body fat • Skin diseases	• Method for treating hyperlipidemia (excess fat)
4.	*Curcuma longa* (Haldi)	• Would heading • Skin diseases, descolouration of skin, • Allergic conditions • Jaundice	• Cosmetics and Skin lightening compositions • Wound healing • Skin conditioning, antiirritant, anti-inflammatory agents
5.	*Nigella sativa* (Kalajira)	• Oral hygiene • Jaundice • Skin disorders	• Dental healing • Treatment of hepatitis • Chapped skin
6.	*Emblica officinalis* (Amla)	• Skin diseases • Grey hair dyeing composition • Health tonic	• Cosmetic formulations • Grey hair composition • Nutritional formulations
7.	*Piper nigrum* (Kalimirch)	• Treatment of skin diseases • Arthritic diseases • As a condiment	• Treatment of skin diseases • For healing joints • Flavouring agent
8.	*Rauwolfia serpentine* (Chandrabhaga)	• Epilepsy, schizophrenia • High blood pressure	• Treatment of skin diseases
9.	*Rubia cordifolia* (Manjistha)	• Skin diseases • Paralysis	• Treatment of heart diseases • Skin care compositions • Neuro-vascularization
10.	*Tamarindus indica* (Imli)	• Fruit drink • Boiled seeds used for dressing boils • Cooling food, anti inflammatory action	• Beverages • Wound-covering materials
11.	*Withania somnifera* (Ashwagandha)	• General tonic, heart diseases • Rheumatism	• Food, pharmaceutical, • Cosmetics and industrial application • Anti-fatigue/stress
12.	*Terminalia arjuna* (Arjuna)	• Cardiac tonic, heart diseases • Treating high blood Pressure	• Arthritis • Enhancing • Cardiovascular performance • Control of high blood • Pressure and high levels of cholesterol
13.	*Terminalia chebula* (Harra)	• For dysentery and diarrhea, stomach complaints, ulcers, vomiting and worms • Flatulence	• Treating and preventing Helicobactor pyloric associated stomach gastritis, and ulcers
14.	*Terminalia bellerica* (Bahera)	• Germicidal • For treating stomach disorders and improving digestion • Enlargement of the spleen	• Tooth powder • Treating and preventing Helicobactor pyloric associated stomach gastritis, and ulcers • Hepato-protective compositions

The Tropical Botanical Garden Research Institute (TBGRI) successfully developed a scientifically valid and standardised herbal drug, based on the plant properties. The drug was called Jeervani and was released for commercial production in 1995 by Arya Vaidya Pharmacy by license. TBGRI agreed to share the license fee and royalties with the tribal community 50/50. A special trust was set up in order to receive the fund for benefit of Kani tribes, and the fund will be used for the purpose of welfare activities of the tribe. The TBGRI then went on to train several tribal families to cultivate the plant in the forest, from which they earned money for the sale of the leaves.

This story is one of success that was mutually beneficial and worked well. Admittedly not all companies would be as willing to share their profits so freely, however, it shows that it can work in practice. However, the 'sharing' of profits is not necessary, although mutually beneficial schemes are encouraged. Nevertheless, without the scientists the tribe would not have gained anything, neither would have the wider benefit for the society, as the benefits of the fruits would not have been made accessible. Without patenting the properties the AICRPE would not have been able to put in the necessary research and development as costs would not have been recouped. They also would not have been able to subsequently noticed and licensed it to the pharmaceutical company, who in turn made it accessible, without the patent system.

Convention on Biodiversity (CBD)

In fact the approach that inspired the term 'biopiracy' has already been curbed, by the Convention on Biological Diversity in 1992, which sought to strike a balance between conservation and the sustainable use of plant properties for development of new drugs and such type of compounds. This is not simply a flimsy piece of political appraisement, there are real consequences if this treaty is ignored. It has the power to lead to the cancellation of patents on natural product inventions, if the rules are not adhered to, the research would be deemed, "tainted".

It is probably wise for countries to enter into benefit sharing contracts with local people, however, it is not a necessary requirement. The patenting of plant properties is heavily regulated, in three main ways, through international treaties, national laws and by professional self-regulators. The majority of researchers act in strict compliance with such measures and therefore to deem their actions to be that of 'pirates' is an accusation misplaced and ill informed, they are under no obligation to share their rewards, as with any other type of patented product or process.

The importance of the patenting of plant properties within the pharmaceutical industry is shown by the current value of the world market for medicinal plants derived from materials utilised by indigenous communities. It is estimated that it is worth US-$43 billion, annually. The estimates for annual markets of products developed from genetic resources form, in the pharmaceutical industry between US$75 and 150 billion, which reflects at a low estimate that natural products form 25% of the global market, a high estimate going up to 50% of the market.

In 2003 investors ploughed $17 billion into biotech companies, despite the fact that the majority of the companies at that time would have had no marketable products and a loss was likely. Patents are needed to attract investors into risky research projects. Those discoveries and inventions that do become successful have an increased value if patented, which "provide(s) incentives for private sector investment into biotechnology development".

Bio-piracy of Traditional Knowledge

Traditional knowledge has always been an easily accessible treasure and thus has been susceptible to misappropriation. The traditional knowledge, particularly, related to the treatment of various diseases has provided leads for development of biologically active molecules by the technology rich countries. In other words, traditional knowledge is being exploited for bio-prospecting. Also Traditional knowledge is often

misappropriated, because it is conveniently assumed that since it is in public domain, communities have given up all claims over it. Traditional Knowledge includes both the codified (documented) as well as non-codified information (not documented but may be orally transmitted).

Bio-piracy of codified Indian traditional knowledge continues, since, this information exists in regional languages, and there exists a language barrier due to which the patent offices are unable to search this information as prior art, before granting patents. Formulations used for the treatment of human ailments from traditional knowledge are time-tested since they have been in practice for centuries. The reliability of the traditional medicine systems coupled with the absence of such information with patent offices, provides an easy opportunity for interlopers for getting patents on these therapeutic formulations derived from traditional medicine systems.

Misappropriations of Traditional Knowledge

The grant of patents on non-patentable knowledge (related to traditional medicines), which is either based on the existing traditional knowledge of the developing world, or a minor variation thereof, has been causing a great concern to the developing world. These illustrates the bio-piracy of traditional knowledge and in many of these cases the country had to fight for revocation of the granted patents, Revocation, may not be a feasible option possible for all the patents taken on the traditional knowledge since it involves huge costs and time.

Protecting Codified Traditional Knowledge

Patent examiners, in the international patent offices, while examining the patentability of any claimed subject matter, use available resources for searching the appropriate non-patent literature sources. Patent literature, is usually wholly contained in several distinctive databases and can be more easily searched and retrieved whereas non-patent literature prior art is often buried somewhere in the many and diverse sources. Therefore, a need was felt to create more easily accessible non-patent literature databases on traditional knowledge of India.

Traditional Knowledge Digital Library (TKDL) - A tool for prevention of mis-appropriations of traditional knowledge

TKDL targets Indian Systems of Medicine, viz., Ayurveda, Unani, Siddha and Yoga available in public domain. This is being documented by sifting and collating the information on traditional knowledge from the existing literature existing in local languages such as Sanskrit, Urdu, Arabic, Persian and Tamil in digitized format, which will be available in five international languages which are English, German, Spanish, French and Japanese. Traditional Knowledge Resource Classification (TKRC), an innovative structured classification system for the purpose of systematic arrange-ment, dissemination and retrieval was evolved for about 5,000 subgroups against few subgroups available in International Patent Classification (IPC), related to medicinal plants. The information is being structured under section, class, subclass, group and subgroup as per the International Patent Classification (IPC) for the convenience of its use by the international patent examiners. Information comprising about 2 lakh formulations has been transcribed for realizing the objective of TKDL Project.

Ancient literature provide traditional knowledge in the form of ‘Sloka’. Each Sloka is read and converted into a structured language using Traditional Knowledge Resource Classification by subject (Ayurveda, Unani, Siddha or Yoga) experts. The codes are then filled into the data entry screen. The Slokas are also saved in the database. The translated version of all the TKRC codes is ported in the database. The abstraction is done by the subject experts. The codes once

saved in meta data directory are converted in different languages based on Unicode technology. The formulations are presently being converted into English, German, French Japanese and Spanish languages. The converted format of the formulation is readable and can be understood by a layman though it is targeted towards a patent examiner.

TKDL software with its associated classification system i.e., TKRC converts text in local languages into multiple languages as mentioned above. It may be noted that the software does not transliterate, rather it does a knowledge-based conversion, where data abstracted once is converted into several languages by using Unicode, Metadata methodology. Software also converts traditional terminology into modern terminology, for example, Jwar to fever, Turmeric to Curcuma longa, and Mussorika to small pox etc.

TKDL includes a search interface providing full text search and retrieval of traditional knowledge information on IPC and keywords in multiple languages. The search features include single or multiple word searches, complex Boolean expression search, Proximity search, Field search, Phrase search, etc in the form of simple and advance search options. Simple search lets the user search a combination of keywords. Advance search lets the user search using Boolean expressions, using the expressions like "near", "and", "and not". Searches are also available on IPC and TKRC codes.

TKDL acts as a bridge between formulations existing in local languages and a Patent Examiner at a global level, since the database will provide information on modern as well as local names in a language and format understandable to Patent Examiners. It is expected that the issue of the gap on lack of access to prior art traditional knowledge shall get addressed.

Some examples of bio-piracy of traditional knowledge

Indian examples:

- **Turmeric (*Curcuma longa* Linn.)**

The rhizomes of turmeric are used as a spice for flavouring Indian cooking. It also has properties that make it an effective ingredient in medicines, cosmetics and dyes. As a medicine, it has been traditionally used for centuries to heal wounds and rashes.

In 1995, two expatriate Indians at the University of Mississippi Medical Centre (Suman K. Das and Hari Har P. Cohly) were granted a US patent (no.5, 401,504) on use of turmeric in wound healing. The Council of Scientific & Industrial Research (CSIR), India, New Delhi filed a re-examination case with the US PTO challenging the patent on the grounds of existing of prior art. CSIR argued that turmeric has been used for thousands of years for healing wounds and rashes and therefore its medicinal use was not a novel invention. Their claim was supported by documentary evidence of traditional knowledge, including ancient Sanskrit text and a paper published in 1953 in the Journal of the Indian Medical Association. Despite an appeal

by the patent holders, the US PTO upheld the CSIR objections and cancelled the patent. The turmeric case was a landmark judgment case as it was for the first time that a patent based on the traditional knowledge of a developing country was successfully challenged. The US Patent Office revoked this patent in 1997, after ascertaining that there was no novelty; the findings by innovators having been known in India for centuries.

- **Neem (*Azadirachta indica* A. Juss.)**

Neem extracts can be used against hundreds of pests and fungal diseases that attack food crops; the oil extracted from its seeds can be used to cure cold and flu; and mixed in soap, it provides relief from malaria, skin diseases and even meningitis. In 1994, European Patent Office (EPO) granted a patent (EPO patent No.436257) to the US Corporation W.R. Grace Company and US Department of Agriculture for a method for controlling fungi on plants by the aid of hydrophobic extracted Neem oil. In 1995, a group of international NGOs and representatives of Indian farmers filed legal opposition against the patent. They submitted evidence that the fungicidal effect of extracts of Neem seeds had been known and used for centuries in Indian agriculture to protect crops, and therefore, was unpatentable. In 1999, the EPO determined that according to the evidence all features of the present claim were disclosed to the public prior to the patent application and the patent was not considered to involve an inventive step. The patent granted on was Neem was revoked by the EPO in May 2000. EPO, in March 2006, rejected the challenge made in 2001 by the USDA and the chemicals multinational, W. R. Grace to the EPO's previous decision to cancel their patent on the fungicidal properties of the seeds extracted from the neem tree.

- **Basmati Rice (*Oryza sativa* Linn.)**

Rice Tec. Inc. had applied for registration of a mark "Texmati" before the UK Trade Mark Registry. Agricultural and Processed Food Exports Development Authority (APEDA) successfully opposed it. One of the documents relied upon by Rice Tec as evidence in support of the registration of the said mark was the US Patent 5,663,484 granted by US Patent Office to Rice Tec on September 2, 1997 and that is how this patent became an issue for contest.

This US utility patent was unique in a way to claim a rice plant having characteristics similar to the traditional Indian Basmati Rice lines and with the geographical delimitation covering North, Central or South America or Caribbean Islands. The US patent office granted the patent to Rice Tec on September 2, 1997. The said patent covered 20 claims covering not only novel rice plant but also various rice lines; resulting plants and grains, seed deposit claims, method for selecting a rice plant for breeding and propagation. Its claims 15-17 were for a rice grain having characteristics similar to those from Indian Basmati rice lines. The said claims 15-17 would have come in the way of Indian exports to US, if legally enforced.

Evidence from the IARI (Indian Agricultural Research Institute) Bulletin was used against claims 15-17. The evidence was backed up by the germplasm collection of Directorate of Rice Research, Hyderabad since 1978. CFTRI (Central Food Technological Research Institute) scientists evaluated the various grain characteristics and accordingly the claims 15-17 were attacked on the basis of the declarations submitted by CFTRI scientists on grain characteristics. Eventually, a request for re-examination of this patent was filed on April 28,

2000. Soon after filling the re-examination request, Rice Tec chose to withdraw claims15-17 along with claim 4.

International examples:

Biopiracy of traditional knowledge is not limited to India alone. In fact, there have been several examples from other countries where traditional knowledge biopiracy has become a concern.

- **Kava *(Piper methysticum* Forster*)***

Kava is an important cash crop in the Pacific, where it is highly valued as the source of the ceremonial beverage of the same name. Over 100 varieties of Kava are grown in the Pacific, especially in Fiji and Vanuatu, where it was first domesticated thousands of years ago. In North America and Europe, Kava is now promoted for a variety of uses through patenting. French company L'Oreal - a global giant with US $10 billion a year in sales - has patented the use of Kava to reduce hair loss and stimulate hair growth

.

- **Ayahuasca *(Banisteriopsis caapi* Mort.*)***

For generations, Shamans of indigenous tribes throughout the Amazon basin have processed the bark of *B. caapi* Mort. to produce a ceremonial drink known as "Ayahuasca". The Shamans use Ayahuasca (which means "wine of the soul") in religious and healing ceremonies to diagnose and treat illness, meet with spirits, and divine the future.

American, Loren Miller obtained US Plant Patent (no. 5, 751 issued in 1986), granting him rights over an alleged variety of *B. caapi* Mort. which he had collected from a domestic garden in Amazon and had called "Da Vine", and was analyzing for potential medicinal properties. The patent claimed that Da Vine represented a new and distinct variety of *B. caapi* Mort., primarily because of the flower colour.

The Coordinating Body of Indigenous Organisations of the Amazon Basin (COICA), which represents more than 400 indigenous tribes in the Amazon region, along with others, protested about a wrong patent that was given on a plant species. They protested that Ayahuasca had been known to natives of the Amazon rainforest and it is used in traditional medicine and cultivated for that purpose for generations, So, Loren Miller could not have discovered it, and should not have been granted such rights, which in effect, appropriated indigenous traditional knowledge. On reexamination, US patent office revoked this patent on 3rd November 1999. Latter, the inventor was able to convince the US patent office on 17th April 2001, the original claims were reconfirmed and the patent rights restored to the innovator.

- **Quinoa *(Chenopodium quinoa* Willd.*)***

Quinoa is a staple food crop for millions in the Andes, especially Quechua and Aymara people who have bred a multitude of quinoa varieties. One traditional quinoa variety, Apelawa, is the subject of US patent no. 5, 304, 718 held by two Professors from Colorado State University who claim the variety's male sterile cytoplasm is key to developing hybrid quinoa. The patent claims any quinoa crossed with male sterile Apelawa plants.

- **Hoodia *(Hoodia gordonii* (Masson) Sweet ex Decne*)***

For thousands of years, African tribesmen have eaten the Hoodia cactus to stave off hunger and thirst on long hunting trips. The Kung bushmen, San who live around the Kalahari desert in southern Africa used to cut off a stem of the cactus about the size of a cucumber and munch it.

Hoodia is now at the centre of a bio-piracy row. In 1995, South African Council of Scientific & Industrial Research (CSIR) patented Hoodia's appetite-suppressing element (P57) and hence, its potential cure for obesity. In 1997 they licensed P57 to British Biotech Company, Phytopharm. In 1998, Pfizer acquired the rights to develop and market P57 as a potential slimming drug and cure for obesity (a market worth more than £ 6 billion), from Phytopharm for $ 32 million. The San people eventually learned of this exploitation of their traditional knowledge, and in June 2001, launched legal action against South African CSIR and the pharmaceutical industry on grounds of bio-piracy. They claimed that their traditional knowledge has been stolen, and the South African CSIR had failed to comply with the rules of the Convention on Biodiversity, which requires the prior informed consent of all stakeholders, including the original discoverers and users.

Phytopharm conducted extensive enquiries but were unable to find any of the knowledge holders. The remaining San were apparently at the time living in a tented camp 1500 miles away from their tribal lands. The South African CSIR claimed that they have planned to inform the San of the research and share the benefits, but wanted to make sure that the drug proved successful.

The two sides entered into negotiations for a benefit-sharing agreement, despite complications regarding who should be compensated: the person who originally shared the information, their descendants, the tribe, or the entire country. The San are nomads spread across four countries.

However, in March 2002, a landmark was reached in which the San will receive a share of any future royalties. The settlement will not directly affect Phytopharm or Pfizer since the San would be paid out of the CSIR's royalties, as South African CSIR is the patent holder. South African CSIR will probably receive a royalty of around 10% from Phytopharm, which itself will receive royalties from sales from Pfizer. Thus San are likely to end up with only a very small percentage of eventual sales.

Other examples:

To cite some more examples of biopiracy, the plant *Phyllanthus amarus* Schum.et Thonn. is used for Ayurvedic treatment for jaundice, a US patent has been taken for use against Hepatitis- B. The plant, *Piper nigrum* Linn. is used for Ayurvedic treatment for vitiligo (a skin pigmentation disorder). A patent has been taken in UK for the application of a molecule from *Piper nigrum* Linn. for use in treatment of vitiligo.

The appropriation of elements of this collective knowledge of societies into proprietary knowledge for the commercial profit of a few is one of the concerns of the developing world. An urgent action is needed to protect these fragile knowledge systems through national policies and international understanding linked to IPR, while providing its development and proper use for the benefit of its holders. What is needed is a particular focus on community knowledge and community innovation, enterprise and investment is particularly important.

The local communities or individuals do not have the knowledge or the means to safeguard their property in a system, which has its origin in very different cultural values and attitudes. The communities have a storehouse of knowledge about their flora and fauna, their habits, their habitats, their seasonal behaviour and the like- and it is only logical and in consonance with natural justice that they are given a greater say as a matter of right in all matters regarding the study, extraction and commercialization of the biodiversity. A policy that does not obstruct the advancement of knowledge, and provides for valid and sustainable use and adequate intellectual property protection with just benefit sharing is what is needed.

The campaign against "biopiracy": Introducing a disclosure of origin requirement

Developing countries rich in biodiversity, local communities and indigenous peoples, have been long struggling to establish ownership and maintain sovereign control over their genetic resources and traditional knowledge to protect them from misappropriation and unfair exploitation, particularly by foreign bio-technology-based industries. These developing countries consider that the current intellectual property system does not serve their interests in this respect, and thus call for changes both within and outside the intellectual property system.

A number of environmental and sustainable development NGOs have been supportive of the efforts of developing countries in multiple processes at the international level. NGOs have been long concerned with the adverse effects of biotechnology on health and the environment. Given that many new biotechnology products and processes are now protected by intellectual property rights, they have further concerns that access to the genetic resources may be facilitated for users without the consent and sharing of benefits with the providers, mainly in developing countries. Moreover, NGOs have effectively raised public awareness and sparked concern at the national and international level on the inequity in the access and use of genetic resources and traditional knowledge, in particular through their direct involvement and role in highlighting cases of alleged mis-appropriation, also known as "biopiracy".

In this regard, NGOs have been closely involved in the growing discussion about the relationship between intellectual property rules, genetic resources and the protection of traditional knowledge. The main issue of controversy is the extent to which intellectual property systems are seen to be incompatible with objectives related to the conservation and sustainable use of genetic resources and protection of traditional knowledge. Developing countries and NGOs have historically been in favour of keeping genetic material and innovations based on it in the public domain or providing protection for these innovations through a *sui generis* system that differs from traditional forms of intellectual property rights.

This is because the intellectual property right system in relation to genetic resources and traditional knowledge, particularly in the framework of the World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), that came into force in 1995 and is seen as largely favouring the interests of developed countries that generally seek access to genetic resources and associated traditional knowledge that lies mainly in developing countries.
Thus, a large part of the debate has focused on ensuring a proper balance between intellectual property systems and other instruments to regulate access and benefit sharing at the

international level. One of the main issues of contention that has received wide attention from governments and NGOs is whether there is any conflict between the principles concerning access to genetic resources and benefit sharing enshrined in the Convention on Biological Diversity (CBD), which concluded in Rio de Janeiro in 1992, and the TRIPS Agreement. Developing countries and many environmental and sustainable development NGOs believe that there is a conflict between the CBD and TRIPS, and accordingly, consider that in order for TRIPS to be reconciled with the CBD, the TRIPS Agreement must be amended.

NGOs have been closely involved in the growing discussion about the relationship between intellectual property rules, genetic resources and the protection of traditional knowledge. The main issue of controversy is the extent to which intellectual property systems are seen to be incompatible with objectives related to the conservation and sustainable use of genetic resources and protection of traditional knowledge.

TRIPS Issues

The TRIPS Agreement on the other hand, established minimum international standards of the protection and enforcement of intellectual property rights. It is the first international treaty that makes it possible to patent life forms, by establishing that governments can exclude plants and animals from patentability, but not microorganisms or non-biological and micro-biological processes. Moreover, plant varieties must be protected under some kind of intellectual property right; either patents or a sui generis system. Given that developing countries only agreed to these conditions as a compromise during the TRIPS negotiations, it was established that these provisions would be subject to review, among other things, to ensure that the TRIPS Agreement and the CBD are supportive of each other.

The relationship between the TRIPS Agreement and the CBD is currently being discussed as an "outstanding implementation issue" under the Doha Round work programme, set up at the WTO Ministerial at Doha in 2001, expected to conclude in 2006. In the context of ensuring that the CBD and TRIPS are mutually supportive, one of the proposals that has been made by many developing countries and supported by NGOs is for countries to adopt international disclosure of origin requirements that would require patent applicants to disclose the origin of the genetic material and traditional knowledge used in the invention, and show evidence that the provider gave prior informed consent and received a share of the benefits.

The campaign for disclosure of origin of biological materials:

The initial awareness-raising on the importance of establishing international rules to prevent the misuse of genetic resources and traditional knowledge was undertaken by environmental and sustainable development NGOs as far back as the 1970s. NGOs pointed to multiple cases of so-called "biopiracy" or grant of invalid patents over inventions based on genetic material and/or traditional knowledge, and highlighted concerns about the unequal exploitation of such resources.

Over the years governments and NGOs have put forth a number of initiatives to conserve and regulate the use of and access to genetic resources, as well as the sharing of benefits derived from their use. Some initiatives have clashed with other efforts to protect new biotechnological products and processes for intellectual property rights. For example, NGOs such as the Action Group on Erosion, Technology and Concentration (ETC Group), know formerly as RAFI, and GRAIN11 were very involved in laying out the framework for what would be the first international commitments to conserve genetic resources and ensure their benefits to all, embodied in the 1981 International Undertaking on Plant Genetic Resources for Food and Agriculture (IU) under the Food and Agriculture Organisation of the United Nations (FAO). The IU was meant to be a legally-binding convention that would counteract the privatisation of genetic resources by establishing their status as the "common heritage of mankind", at the time when the system of plant breeders rights (PBRs), a form of intellectual property protection on plants, was expanding under the Union for the Protection of Plant Varieties (UPOV).

NAGOYA PROTOCOL on Access and Benefit Sharing

The Nagoya Protocol on access and benefit sharing is a landmark in the international governance of biodiversity. The Convention on Biological Diversity (CBD) had already established the fair and equitable sharing of benefits as one of its main objectives, and also outlined basic principles such as prior informed consent and mutually agreed terms. Yet these principles remained largely unimplemented, with a range of difficulties and different views on ways of overcoming them. With the Nagoya Protocol, the fair and equitable sharing of benefits has been reaffirmed as a fundamental component of biodiversity strategies. In addition, a set of rules has been agreed upon to facilitate, promote and ensure its effective implementation.

The main provisions of the Nagoya Protocol include:

- A definition of the objective, use of terms, scope and relationship with other international instruments of the Nagoya Protocol;
- Elaboration on the principles and main requirements on the fair and equitable sharing of benefits and access to genetic resources and traditional knowledge;
- Several possible mechanisms for implementation, including a multilateral benefit sharing mechanism and an access and benefit-sharing clearinghouse;
- Measures to promote compliance with legal and regulatory requirements, as well as with mutually agreed terms; and
- Measures to promote tools and awareness raising, capacity building and transfer of technology activities on access and benefit sharing.

What activities are covered under its access and benefit sharing requirements?

Access and benefit sharing requirements of the Nagoya Protocol apply to "genetic resources" and the benefits derived from the "utilization of genetic resources." This is also the scope of access and benefit sharing as established in the CBD. The Nagoya Protocol, however, through a definition of "utilization of genetic resources," now provides an expansive interpretation of the scope of access and benefit sharing. In particular, the interpretation of "utilization of genetic resources" clearly covers research and development linked to the biochemical composition of plants and other components of biodiversity.

The "utilization of genetic resources" was not defined by the CBD. Experts and national legislations offered different interpretations on the types of activities covered by the term. There was no argument that activities such as the use of enzymes, genes or small molecules for the development of pharmaceutical, industrial and agricultural products fell under the scope of access and benefit sharing. Yet there were questions as to the degree that research and development based on naturally occurring biochemical compounds - rather than on genetic material itself - was also subject to access and benefit sharing requirements.

Will the Nagoya Protocol apply to new uses or all uses of genetic resources?

During negotiations of the Nagoya Protocol, there were different positions on when benefit-sharing requirements become applicable. Should benefit sharing apply solely in relation to plant material accessed after the entry of force of the new rules (for example, medicinal plants to be collected during a screening program in late 2012)? Or should these requirements extend to all new uses of genetic resources, even if access took place before the Nagoya Protocol (though after the adoption of the CBD)? Such would be the case, for instance, in the identification and development as a cosmetic ingredient of a type of fruit seed oil previously known only for its properties as a dietary supplement.

Are there any changes to existing access and benefit sharing requirements?

The Nagoya Protocol maintains the CBD approach to access and benefit sharing, based on the principles of prior informed consent and mutually agreed terms1. Notwithstanding, in developing these principles, the Nagoya

Protocol contains significant innovations. In the CBD, the fair and equitable sharing of benefits is already a self-standing obligation. Nevertheless, access and benefit sharing seems to be presented as a step-by-step process. Access is based on prior informed consent and mutually agreed terms. These terms thus ensure the subsequent sharing of benefits in a fair and equitable manner. In the Nagoya Protocol, the need to share the benefits derived from the use of genetic resources appears to have been detached from access to these resources. Fair and equitable sharing of benefits must still take place on the basis of mutually agreed terms, but it is not clear that benefit sharing requires, or only takes place ensuing, access procedures. For example, the proposed Global Multilateral Benefit Sharing Mechanism may allow or require the sharing of benefits derived from the utilization of genetic resources even when the origin of such resources cannot be determined or when access took place prior to the entry into force of the Nagoya Protocol. The link between access and benefit sharing will also depend on national legislation

Which countries are required to establish measures for access and benefit sharing?

Compliance measures, aimed at ensuring observation of prior informed consent and mutually agreed terms requirements across national borders, are at the core of the Nagoya Protocol. Access and benefit sharing provisions in the CBD already established obligations not only for countries providing access to genetic resources, but also for countries where biodiversity based research, development and commercialization usually take place. Yet little progress was made on legislative, administrative or policy measures that would ensure international compliance with access and benefit sharing.

The Nagoya Protocol now requires all countries to establish "appropriate, effective and proportionate" measures to provide that genetic resources and traditional knowledge utilized within their jurisdiction have been accessed on the basis of prior informed consent and mutually agreed terms, as required by the country of origin. As a result, it would be not only Brazil or Malaysia, for example, which would need to establish mechanisms to regulate and control access to their biological resources. France or Japan, for instance, would also need to ensure that research, development and comercialization conducted within their countries utilizes genetic resources according to the requirements established by the countries of origin of these resources. According to the Nagoya Protocol, France or Japan - to continue using those examples – would also need to take appropriate, effective and proportionate measures in cases of non-compliance. They would also need to collaborate with Brazil or Malaysia and grant access to justice in cases of alleged violation of these countries' national access and benefit sharing legislations.

What does this mean for natural ingredients in food and personal care?

For companies working with biodiversity-based ingredients for food and personal care products, perhaps the most important development in the Nagoya Protocol is the clear incorporation of its activities into the scope of access and benefit sharing requirements. Research conducted on the biochemical composition of plants to determine beneficial properties, as well as the subsequent development and commercialization of bioactive compounds as ingredients is considered "utilization of genetic resources." It must therefore take place with prior informed consent and fair and equitable sharing of benefits. Though some companies in the food and personal care sectors were already considering access and benefit sharing in the context of their ethical sourcing practices, such a clarification reaffirms the need for all companies working with biodiversity-based ingredients to review their relevant policies and practices.

'Nagoya Protocol, a big victory for India'

In a hard-fought triumph for India and other developing nations, a new international treaty to ensure that the benefits of natural resources and their commercial derivatives were shared with local communities was signed in the Japanese city of Nagoya on Saturday.

However, the flip side is that the United States - one of the largest users of such resources - is not among the nearly 200 signatories of the Access and Benefit Sharing (ABS) rules of the Nagoya Protocol. Getting the Americans into the net will be a key aim of the next U.N. summit on biodiversity to be held in New Delhi in 2012.

"It is a big victory for India that both derivatives and pathogens are part of the ABS. As the incoming president [of the next summit], it was incumbent on us to play a major role," Environment Minister Jairam Ramesh told *The Hindu*. The ABS is the result of almost two decades of U.N. negotiations, where India leads a group of 17 mega diverse countries with rich reserves of exploitable natural resources.

(*Compiled by ENVIS Team*)

CURRENT NEWS

Endangered species not under trade ban, Deccan chronicle, Wednesday, Dec 21, 2011

Environmental activist Mr Leo F. Saldhana said, "Stating that the 190 species are normally traded commodities, the government exempted them from the list due to which they lost protection under the Biodiversity Act. The companies do not require prior permission for their export. Out of the 190 species, 15 are threatened, vulnerable or critically endangered. It has been proved how exports can drive endangered species to extinction."

To keep traditional knowledge under lock and key, Bhutan Daily December 2, 2011

With some 3,000 representatives from TK holding communities demanding an IP system that can protect TK, WIPO started working since 1998 and established a WIPO intergovernmental committee on intellectual property and genetic resources, traditional knowledge and folklore (IGC) in 2001. "It isn't speeding because the developed world isn't interested, because unprotected TK means more benefit to them," an IPD official said.

This is because the developed countries have capacity for extraction of components and inventories, where any products can be developed based on a traditional knowledge that they come across. "They get access to TK and don't have to share benefits, while genetic resources can be imported from the countries that have the resource available," a participant said.

According to an official from, National Bhutan Council (NBC), an IP system that protects TK can play a big role towards fair access and benefit sharing of TK. "The system will enable a fair access for those, who want to use TK for further invention; while it can also draw a process, where the benefit is shared with TK holders," he said.

Biological Shock Treatment: A Discussion with "Deadly Monopolies", Forbes, 20.12.2011

Harriet A. Washington reported that Michael, researchers and pharmaceutical companies have designs on the diverse biological riches of poor countries because much of the biodiversity of the West has vanished, having fallen victim to the shortsighted agricultural behavior of industrialized nations. We've seen the United States and much of Europe breed crops by selecting for traits that will maximize market performance such as hardiness, disease resistance, long shelf life, and even for easily-stacked shapes such as square tomatoes and watermelons. As huge farms crowd small ones out of business and giant supermarket firms dominate the market's botanical conformity sells.

Database on Indian bio-resources, The Times of India, Dec 27, 2011

The Unit for Research and Development of Information Products (URDIP), Council of Scientific and Industrial Research (CSIR), Pune has prepared a database of patents granted world-wide to Indian bio-resources, including food crops, forest trees, marine organisms, microbial resources, livestock, other animals and agro-resources.

The database is expected to help monitor patenting of bio-resources, detection of bio-piracy, commercial exploitation and benefit sharing.

FORTHCOMING EVENTS		
Events	**Date**	**Place & Correspondence**
Workshop on "Access to Benefit Sharing of Traditional Knowledge, Bio-piracy, Genetic Resources and Intellectual Property Rights Issues".	Dec 20, 2011	Colombo, Sri Lanka Website: http://www.researchgate.net/conference/ Email: incbd365@gmail.com
The 9th Annual BIO Asia International Conference	Jan. 31- Feb. 1, 2012	Osaka, Japan Customer Service: Inter Group Corporation Akasaka-Sanno Square Bld., 2-2-12 Akasaka, Minato-ku, Tokyo 107-0052, Japan Fax: +81-3-5549-3201 Email: bioasia2012@intergroup.co.jp General Inquiries : International: +1(202) 962-6666 Email : bioasia@bio.org http:// http://www.bio.org/node/4089
2nd Annual IFBA Conference: Global Biosafety and Biosecurity Building Sustainable Capacity	June 28 - 29, 2012	Johannesburg, South Africa Email: secretariat@internationalbiosafety.org http://www.internationalbiosafety.org/
Conference of the Parties (COP 11) to the Convention on Biological Diversity (CBD)	October 19, 2012	Hyderabad, India David Ainsworth +1 514 287 7025, Email: david.ainsworth@cbd.int; Johan Hedlund +1 514 287 6670, Email: johan.hedlund@cbd.int

QUERY FORM

Name:
Designation:
Email:
Area of specialization:
Views on our Newsletter
Suggestion for Improvement:
I would like to collect information on Environmental Biotechnology on the following:
Subject: **Key words:**

FROM	**To,**
ENVIS CENTRE **DEPARTMENT OF ENVIRONMENTAL SCIENCE UNIVERSITY OF KALYANI, KALYANI-741235, NADIA, WEST BENGAL**	**BOOK POST**