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**BIOLOGICAL DIVERSITY:
AN INDIAN PERSPECTIVE
ON NORTH- SOUTH ISSUES**

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Biodiversity is perhaps one of the few issues in which the North and South uniformly believe in the need for preservation. Issues of biodiversity have a different impact in the developed and the developing world. The developed countries are not rich in the bio-resources but are better equipped in research and development, and therefore need the resources for furtherance of research and development. The developing countries, on the other hand, are rich in such bio-resources and are under threat of losing their diversity on account of improper management of the same. Though both share the common concern for protecting and enhancing biodiversity for the benefit of mankind, the difference in perception is the root of the issues that arise in this area.

The difference in perception is also manifested in the concerns shown for conservation of biodiversity. The concern of the developed countries is to enable access to the resources to corporations for research and to provide adequate protection in the form of intellectual property rights. However, the diversity is concentrated in developing countries, often with traditional and indigenous societies. It is important to note that the holders of the diversity, the indigenous societies, have been using such genetic resources and knowledge as a way of life. The concern of these countries is to preserve the diversity, culture and the traditions of these people on the one hand, and to ensure that they get compensated adequately on the other hand, if the genetic resources are to be shared.

The initial step towards making biodiversity a commodity evolved from the United Kingdom wanting to use high-quality seeds for agricultural production. This slowly led to the Companies selling registered seeds. Later, the Government rewarded individuals who improved seeds further. This led to the development of Breeders Rights that became more commercialized and very soon restrictive.

The concept of vesting monopoly rights over plants and biological “inventions” resulted in scientists from developed countries taking knowledge

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from the indigenous societies and later developing the same, resulting in patents that have enriched them and/or the concerned corporations by millions of dollars. This left the original holders of the property with the feeling of having been deceived, especially since most of the original holders of the property live in conditions that are devoid of technology, such that they would require great development to catch up with “civilization.”

Examples of the above range from the *neem*, the turmeric in India, to the rosy periwinkle of Madagascar and the *asteraceae* of Paraguay. Each of these are examples of shrubs that have been used for centuries in countries in which they were found, and were later sought to be patented. In the case of the *asteraceae*, the importance of the compound (it comes from a shrub that is most commonly used in Paraguay and is some 100 times as sweet as sugar) has now given rise to a multi-billion dollar market that will not in any manner benefit the original holders of the property.

The rosy periwinkle, unique to Madagascar, contains properties that combat certain cancers. The anti-cancer drugs vincristine and vinblastine have been developed from this plant. This has resulted in an annual sales of around U.S. \$100 million for Eli Lilly. The island nation and its people gained virtually nothing.

The patents for turmeric were filed by two non-resident Indians in 1995 over a total of six applications. There was an opposition to the same and eventually the application was withdrawn, after the Indian Center for Scientific and Industrial Research claimed “prior art” and presented documents from Sanskrit dating from 1853 to prove it.

The patenting of *neem* was yet another long-drawn fight for India. The U.S. Patent office has granted two patents on *neem* for W.R. Grace for storage process. A complaint was filed with the U.S. Patent office by the Indian Government. But the same has not been revoked as yet.

W. R. Grace, a U.S. company, along with the U.S. Department of Agriculture, filed with the E.U. Patent office for a patent over *neem* about six years ago, for an anti-fungal product. The Corporate Vice President of W. R. Grace dismissed the Indian People’s discovery and development of the plant’s uses as “folk medicine.” This patent was eventually revoked after six years, when, at a hearing in Munich, the manager of an Indian Agricultural company proved that he had been using the *neem* extract for the same purpose several years before the patent was filed.

There are also other applications for patents on various qualities that are prevalent in substances like *amla*, *jar amla*, *anar*, *salai*, *dudhi*, *gulmendhi*, *bagbherenda*, *karela*, *rangoon-ki-bel*, *erand*, *vilayetishisham*, *chamkura*—all of which are day-to-day materials in India. The fact of these applications is in itself a reflection of the extent of bio-piracy that has been going on. The intellectual property rights of the developed systems allow patents to be filed on discoveries in the particular country, despite the fact that identical ones may already be existing and in use in other parts of the world. For example, prior foreign activity anticipates a U.S. patent only when the

foreign activity is in a tangible, accessible form such as a published document or a patent. However, prior foreign knowledge, use and invention are all excluded when the question of prior art is considered in relation to a U.S. patent application.

Such ideological differences were apparent right from the start, in the 1981 U.N. Draft Declaration on the Rights of the Indigenous People. Later, in 1987 the U.N. Environment Program (UNEP) organized a Governing Council, where the countries tried to negotiate under the UNEP's auspices for a Protocol to the Vienna Convention on the Protection of the Ozone Layer. It was here that the first layers for the Biodiversity Convention were set; eventually the principles were concretized in the year 1992 in the form of the Convention on Biological Diversity (CBD).

The object of the Convention on Biological Diversity is essentially two-fold. One is to ensure Conservation and the other is to ensure Sustainable Use of Biodiversity. The Convention asserts the concern that biological diversity has been depleted by certain human activities. The preamble of the Convention notes that:

It is vital to anticipate, prevent and attack the causes for significant reduction or loss of biological diversity of source. The conservation and sustainable use of biological diversity will strengthen friendly relations between the states. The Convention asserts a DESIRE to enhance and complement the existing arrangements and a DETERMINATION for the conservation and sustainable use for the benefit of the present and the future generations.

The Convention broadly seeks to do this by providing access to genetic resources for the developed world, and access to technology for the developing countries in exchange.

Article 1 of the CBD details the following objectives to be pursued "in accordance with the relevant provisions":

- Conservation of biological diversity
- Sustainable use of its components
- Fair and equitable sharing of the benefits arising out of the utilization of the genetic resources.

This can be achieved through:

- Appropriate access to genetic resources
- Appropriate access to transfer of technology

The Convention clarifies that the logic in conservation is for the sustainable use to result in fair and equitable sharing of the resources. In doing so, the Convention also asserts that States have Sovereign Rights over their own biological resources.

Sovereign Rights of the States: Article 3 (read with the Preamble for an affirmation of the principle of Sovereignty) emphasizes that States have the authority to determine access to resources by national legislation, subject to creating conditions to facilitate access to genetic resources. However, there is no similar provision that obligates access to technology. Articles 15 and 16 of the Convention emphasize that the parties shall seek to share the benefits of the research and the development upon mutually agreed terms.

It is interesting to note that the Convention asserts that the right to biological diversity is a sovereign issue. However, the Convention details that the sovereign should, by national legislation, provide for access to genetic resources. Such access has to be made in accordance with the provisions of the Conventions.

On the other hand, a reading of the Convention suggests that it mandates access to genetic resources. However, how the access is provided is a sovereign issue left to the State. It is unclear whether in such circumstances there is a need for formal national legislation, or whether the CBD in itself provides the access to genetic resources without national legislation. In other words, can a sovereign refuse access of the genetic resources on the basis that there is no national legislation? If that is not possible, sovereignty, provided by the CBD, is subject to providing access to genetic resources by national legislation. The Convention not only dictates what the Sovereign should do, but also specifies how the Sovereign should facilitate the same. The Convention details the manner and mechanism through which “sovereign” rights can be asserted.

This sovereignty issue becomes more important as there are restrictions on the transfer of technology, which can occur only with mutual consent. Today any access to technology is incomplete unless it is accompanied by a proper intellectual property right and by an Agreement that defines the contours of the accessed technology. The Convention gives the right to access technology in Article 16, but emphasizes that the same will be provided under fair and favorable terms. On a plain reading one is unable to appreciate what would amount to a fair and favorable term versus what would amount to a preferential term in such Agreements.

Again, the Convention does not detail any mechanism whereby there is benefit-sharing over the intellectual property right that is acquired from the genetic resource that was accessed, nor does it provide detail about mandatory requirements in Agreements such as royalties over the profits, *etc.* For example, the Convention does not discuss the rights that the original holders may have over patents that may be acquired from the genetic resource that is shared. Article 1 discusses fair and equitable sharing of the benefit, but this has not been adequately elaborated. The Convention merely discusses

intellectual property rights over technology sought to be shared, and elaborates that the same will be provided on terms that are recognized and are consistent with the rights.

The theory of mutual consent is possibly the most practical theoretical basis. However, the consent that is envisaged is between the poorest of nations and the developed countries. In most cases the countries and the holders are possibly not even aware of the extent of development that is prevalent. There is a clear distortion in the bargaining powers of the concerned parties. The object of the CBD, that the resources of the world should be shared, is interesting to note at a time when the most valuable rights of the world are knowledge-based.

The Convention does not detail the factors relating to private benefit to either the Community or the individual holders. The cost to the community in having to share such information has also not been detailed. The benefit that the community would derive, if at all, from such sharing is unclear—especially since the transfer of technology under Article 16 will be based on mutual consent. It is not clear how many developing and under-developed countries have the knowledge and the bargaining power to effectively exploit the mutual agreement clause. This is all the more glaring since there seems to be no such subjective clauses (except for “prior informed consent”) defined for sharing the genetic resources.

This Convention has not incorporated the reverse determination, which is a mandatory declaration to ensure that the tribals or the holders of traditional knowledge and/or indigenous material ought to be compensated and be the holders of the rights over such property. Strangely, the CBD expects that resources are to be shared for the benefit of “mankind” and that the most downtrodden societies of the world should be able to benefit, yet unfortunately, the Convention seems to have forgotten to mention the benefit to those other people who are also part of mankind. Perhaps, with a view to reducing the inequalities that are prevalent, the Convention has recognized (in the Preamble) the dependence of local communities, and has acknowledged their lifestyles embodying the biological resources and the desirability of sharing equitably the benefits arising from the use of the traditional knowledge.

The Convention, in Article 8(j), emphasizes the requirement of “prior informed consent” of the holders of such knowledge. Yet the Convention does not define the term ‘prior informed consent’. It has been argued that the degree of information that has to be imparted may vary depending on the people who possess the knowledge and the material in question. However, this lack of definition also leaves scope for misuse by the benefiting “mankind.” Adequacy of consent and components of “prior informed consent” will have to be clarified. There should also be emphasis on the extent of information to be provided in order to get the consent.

Interestingly, the UN Declaration discusses “free and informed consent.” However, there are no definitions of what amounts to a “free” consent or an “informed” consent. Is it information on the potential future commercial benefits that will flow to the party seeking the knowledge? Or is it the benefit that will be acquired if the knowledge is kept a secret for some more time, which will ensure that the value of the knowledge will increase? All these things are unclear. In a community, a free consent may be a consent that is also given and provided by the tribe. So the definition of free consent will be very important to validate the same if issues arise at a later period.

There are examples where “prior informed consent” has been a subject of determination and interpretation. In a case where the samples taken from members of Solomon Islands was used to make a U.S. Patent Claim, whether the person who gave the strains of blood and the spleen had given his consent for patenting became an issue at the later stage. This issue became all the more important when it was questioned whether the consent was made with full knowledge and information. However, the extent of information that was given to the donor was never known. The islanders were not aware of the commercial benefit that the multinational would obtain in the future.

The CBD has no clarity on the future course of action if it is proved that the information was not acquired with “adequate consent.” In any case, statutorily invalidating an information when the crux of the information has already been made public or known by virtue of a patent application is neither a deterrent nor a protective mechanism. On one hand, the CBD speaks about mandatorily sharing information. On the other hand, the Convention discusses prior informed consent. It is not clear which prevails over the other. It is not clear as to whether, if the holders of such knowledge refuse to give consent after getting to know the full circumstances of the case, it will amount to a violation of the CBD. If it does violate the CBD, the enforcement mechanisms are also not detailed. Similarly, the enforcement mechanism is not clear in cases where there has been a violation of the Material Transfer Agreement after the genetic resource has been transferred.

The intellectual property rights over such information that is sought to be passed is yet another interesting issue. Today, traditional knowledge does not fall within the realm of any of the prevailing intellectual property rights. It cannot be protected under patents because such knowledge typically has been prevailing for generations, and therefore does not qualify as an invention. The same does not qualify as a copyright because it is not fixed. In any case, the prevailing regime does not recognize concepts of community property rights.

Hence, the only possible method of preserving traditional knowledge today is as a trade secret. In such circumstances, it is interesting to raise the issue of whether the holders of the property can protect it as a trade secret. The CBD mandatorily requires the sharing of genetic resources for the benefit of the general good with the prior informed consent of the tribals. If

traditional knowledge is considered a trade secret, the holders will retain the right not to disclose it. It will be interesting to see whether the rights under trade secrets will prevail over the obligations under the Convention on Biodiversity. On the other hand, the UN Declaration provides for the right to protect cultural property. Thus, some information that the holders do not want to be parted with can be protected.

Under the prevailing legal regime, an inventor cannot be forced to disclose his invention under normal circumstances. Similarly, no author can be forced to publish his work against his wishes. Extending the same analogy, the tribals must also be given the right to keep their knowledge a secret. The clauses under the CBD possibly will be read as being subject to rights of the tribals listed out in the UN Declaration.

Enabling protection of the rights of the indigenous people as a form of intellectual property under TRIPS (Trade Related Intellectual Property Rights Agreement) would have gone a long way to ease the tensions concerning the implementation of the Convention. It is quite unfortunate and interesting to note that the World Trade Organization, in its wisdom, has not found it fit to include any aspects relating to protection of traditional knowledge or folklore in the TRIPS. It is all the more important because TRIPS is the weapon through which the WTO now seeks the enforcement of patent laws, and thereby seeks to grant justice to multinationals by ensuring that there is equality of treatment when it comes to patent laws. Though the same is perfectly agreeable considering that it is the multinationals that invent and invest (forgetting of course the human rights issues in developing countries such as increased drug prices amounting to dying populations), one would expect the application of the same logic to the art and the works of the indigenous people who are the holders of this knowledge.

TRIPS makes a deviation from the western intellectual property regime in Article 27.3, which mandates protection of plant varieties either "by patents or by an effective *sui generis* system." However, the Agreement conveniently does not describe or even seek to define what *sui generis* is, and hopes that the developing countries will have an 'effective' *sui generis* system by Jan 2000, and the least-developed by Jan 2006. The word "effective" has also not been defined.

Though the developing countries are very critical of the provisions of the CBD, realities dictate that the WTO is here and all-pervading. Today, the exploitation of the provisions of the CBD for the benefit of the nations is the most practical method. The CBD provides avenues for countries to seek benefits and terms that can lead to development in developing countries. It is in the hands of the countries to exploit the provisions to their advantage.

Just as there are stories of the turmeric and the *neem*, there are also cases where tribals have benefited from such transfer of technology. One such example is the case of Shama Pharmaceuticals, Inc, a South San Francisco-based company focusing on isolating bioactive compounds from tropical plants having a history of medicinal use. The company's field

research teams visit tropical regions to collect information on the use of plant medicines to treat various illnesses.

Shama, as a part of its program, approached a particular tribe in Peru. The tribe/community demanded that they enter into an Agreement with the Company to get short- and long-term benefits. Now, Shama regularly takes knowledge from communities around the world and have corporatized the benefit mechanism by having three kinds of programs for the communities that enter into Agreements with them:

- *Short term reciprocity* addresses immediate needs of the community, like building an airstrip extension in the Ecuadorian Amazon, organizing workshops on community-based public health, forest conservation, and offering direct medical care to partner communities, etc.
- *Medium term reciprocity* focused on benefits not immediately apparent, but which nonetheless accrue before profit-sharing might. Specific examples of this have included providing chemical reagents, high pressure liquid chromatography equipment, scientific software, books, and other resources used for training the local-country scientists.
- *Long term reciprocity* involves returning a portion of the profits to the indigenous communities once a commercial product is realized.

Though the company does not share the patents with the tribals, nevertheless this is a good beginning. It will not be long before the tribals refuse to sign the dotted line unless the patents or royalties are shared.

INDIA'S RESPONSE

As a response to the CBD and TRIPS, India has drafted *the Protection of Plant Varieties and Farmers Rights Bill of 1999* and *the Biodiversity Bill of 1998*.

The Protection of Plant Varieties and Farmers Rights Bill was passed to: provide a system of protection for plant breeders and farmers; to encourage development of new varieties of plants; and to attempt to conform with Article 27 (b) (3) of TRIPS, which states that members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.

The Bill covers, "cultivated plants or anything that belonged to the plant kingdom and specifically excludes the micro-organisms." Section 3 provides for establishment of an Authority to: Protect the rights of breeders and the farmers; promote new plant varieties; maintain a system of registration of new plant varieties subject to requirement of such terms and

conditions, thereby providing for collective rights; develop characterization and documentation of the varieties; and catalog the varieties and maintain registration, collect statistics etc.

The Bill establishes a corpus fund from which the money can be used for meeting the various expenses. The Bill provides that the “traditional rights of the farmers to save, use, exchange, share or sell his farm produce is protected.”

Biodiversity is another subject on which there has been several attempts to pass an Act. There have been nearly six versions of the Bill so far, each draft being an attempt to conform with the Convention on Biological Diversity.

The Biodiversity Bill of 1998 includes within the fold of biological diversity, “the variability among the living creatures from all sources including *inter alia* terrestrial, marine and other aquatic ecosystems and ecological complexes of which they are a part and includes diversity within species, between species and of ecosystems.” The biological resources covered include collection of species, sub species, etc., but does not include human genetic material.

The Bill seeks to establish a National Biological Diversity Authority and Biodiversity Management Committees in Local bodies to grant approvals within their prescribed jurisdictions, respectively. A National Benefit Fund for the purpose of depositing the money collected from benefit-sharing of the material between the person with the resource and those who are interested in getting the same is also sought to be established. Section 11 relates to prior informed consent, for which each of the bodies will be responsible.

The local bodies have not been empowered with rights of decision, as members of the local bodies are more likely to have the first hand knowledge of the biodiversity in the area and the use of the same diversity. More often than not, a person sitting in the head office will be located in a city and therefore it will be difficult to expect him to access the situation.

Links with patent legislation are also not established—which is an important part of the follow-up to the CBD. Unless such linkage is provided, there is a danger of this legislation ending up merely perpetuating the worst aspects of bureaucracy, potentially harassing every tribal collecting a medicinal plant, every commercial enterprise developing a biodiversity based product, and every scientist doing research on Indian material.