A Framework for Managing India's Biodiversity Resources in the Context of CBD and GATT

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The world stands today on the threshold of major changes brought about by revolutionary developments in the field of biotechnology. These have prompted the development of new Intellectual Property Rights (IPR) regimes, as well as new regimes of management of biodiversity resources, embodied in the Trade Related Intellectual Property Rights (TRIPs) component of GATT, and in the Convention on Biological Diversity (CBD)[1]. These technological advances are propelling us towards an age of knowledge-based enterprises. With its wealth of scientific talent, and of genetic resources, this could be turned into an era of unprecedented opportunities for India[2].

Under the CBD regime, genetic resources are the sovereign property of a country. While each country must facilitate access to these resources, such access should only be with prior informed consent on the basis of mutually agreed terms. These terms should favour the country of origin of genetic resources through transfer of technology on concessional terms, as well as by setting up of R&D activities in that country[3].

Parties to the Convention are expected to respect the role of local communities in conservation and sustainable use of biodiversity resources and to share with them benefits flowing from modern commercial uses of these resources. At the same time TRIPs oblige member countries to accept IPRs over micro-organisms, micro-biological processes and plant

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varieties. These IPR provisions are already much more extensive in countries like the USA and it is possible that India too would soon be obliged to accept very wide coverage of patent rights over living organisms and their products[4]

A Promotional Approach

Our approach to the question of how to protect our interests in the genetic resources that are now India's sovereign property may either emphasize regulatory, or promotional measures. The regulatory measures would focus on denying access to our genetic resources, and to information pertaining to their location, properties and uses to outsiders. The thrust of the promotional measures would be to develop good information on our genetic resources, make it widely and easily accessible and make its use attractive to both Indian and foreign enterprises. This approach would facilitate easy access not only to information, but to the material resources as well, on the basis of reasonable material and information transfer agreements and while charging appropriate fees for access to information and material resources. We may then use the funds so generated to three ends: to build our own scientific and entrepreneurial capabilities to reward our people living close to nature for their conservation traditions; to enhance knowledge of sustainable use of living resources, and to motivate them to continue to conserve our heritage of biodiversity. The promotional approach is desirable on many grounds.

Most pertinently, of course, an exclusively regulatory approach will simply not work. A fair amount of our genetic material, and most of the scientific information relating to these resources is already in the hands of industrial countries. Another large fraction is shared with neighbouring countries, such as Pakistan, China, Bangladesh, Nepal, Bhutan, Sri Lanka and Myanmar. These countries may not all co-operate with us in maintaining a monopolistic hold on these resources. Thirdly, given our large trade in biological produce, it is very difficult to control ongoing export of genetic resources. If we want to sell Basmati rice to the UK, there is no way to prevent a UK based company from using this material to isolate the chemical compound responsible for the delicate aroma, or the genes responsible for the production of the compound. Finally, genetic resources need to be taken out in small quantities, and to prevent their smuggling out is well nigh impossible.

After all, history tell us that in spite of their best efforts, Peru could not prevent cinchona seeds from being smuggled out, nor could Brazil prevent rubber seeds leaving the country. Today, a single hair pulled out from its root is enough to make any number of copies of the genetic material of a human being, or an antelope or a lion, and literally thousands of such hairs with their living roots could be carried in a small vial in coat pocket. Guarding against smuggling of genetic material is, therefore, a completely hopeless proposition.

Defining Genetic Resources

A workable system must, therefore, depend on mutual co-operation amongst countries of South and North, with both sides facilitating fullest use of the genetic resources in a sustainable fashion, accompanied by a building up of the technological capabilities of the South, and equitable sharing of benefits, between countries as also with local communities inhabiting gene rich localities[5]. This calls for (a) gene rich countries openly sharing their genetic resources and pertinent information regarding their uses, and (b) industrial countries agreeing to a transparent system of acknowledging the use of genetic resources from gene rich countries. This would require that all countries maintain open access to their territories, and public collections and specially constituted data bases, provided that those accessing the resources fully acknowledge and reasonably compensate for any use/export of material or information pertaining to genetic resources. This must be supported through all countries organizing a system of recording of import and export of genetic resources[6]. For this purpose, it is necessary to adequately define genetic resources which we should treat as synonymous with biodiversity resources, in a broader sense to include use of biochemicals, such as alkaloids or esters as well[7].

Similarly, it would be desirable to record access to informational resources that promote such function of genetic resources. These may include both technical knowledge, and folk knowledge of propagation of a local cultivar with high levels of drought resistance, or use of a vegetable dye, or a fish poison, or a drug against hepatitis and so on.

IPR Specifications

Potentially the most effective source of information on the use of genetic

resources is the intellectual property rights (IPR) applications, and India should do its best to persuade all countries to agree to include in their patent, or protected plant varieties legislation a proper specification of the country(ies) of origin and prior public knowledge of uses[8]. The four universally accepted requirements for the patentability of any invention include: novelty, non-obviousness, usefulness and adequate specification. Every IPR application must disclose details of the invention with the help of an IPR specification that describes an invention in sufficient detail to: (i) allow the patent office, and other interested parties to assess its claims of novelty, non-obviousness and usefulness; and to (ii) allow a person skilled in the art to reproduce it. Such a specification or disclosure statement has to accompany, or shortly follow every IPR application. Patent legislation has historically developed in relation to mechanical and chemical innovations. The specification requirements for innovations involving the use of biological materials are, therefore, only now beginning to evolve, primarily through judicial interpretations. Such interpretations have resulted in the requirement of deposition of the appropriate living material in an internationally recognized repository, such as the Fermentation Research Institute of Japan or the European collection of Animal Cell Cultures in the United Kingdom[9]. But there is no clear-cut understanding today that the specification must include fuller details regarding the biological material, such as the country of origin. Nor is there, so far, any formal acknowledgment of the need to accord recognition to community based or other public domain knowledge. However, many patent specifications do voluntarily provide such information. Thus, European Patent 0010061 A1 800416, concerning novel pharmaceutical preparations containing an extract of the mollusc *Perna canaliculus* states it to be found on the shores of New Zealand (McFarlane and Croft). In the case of American Patent 05298251 (1992) regarding fungicides derived from neem oil there is a mention of prior knowledge of communities regarding its uses[10].

Evidently, quite marginal increase in the formal requirements of the specification would admirably serve the purpose of providing information relating to the countries of origin and indigenous communities involved in sustainable use of the concerned biological resources. The proposed requirement should not only cover inventions which result in living material, such as a micro-organism isolated in a culture, seed of a variety of cultivated plant, or a transgenic animal. It should also cover

other products dependent on biological sources, such as alkaloids derived from plants and used as therapeutic agents or pesticides. Furthermore, the requirement should also extend to products that are essentially derived from biological sources, for instance, a synthetic molecule that differs a little from but has the same aroma as sandal (*Santalum album*) and was inspired by it. In all these cases, the specification should include a clear mention of the biological source material, the known country or countries of origin of that material, and all known information pertaining to knowledge in the public domain, such as information pertaining to practices of sustainable use of that biological source material by local communities in the country(ies) of origin. This, of course, raises the very complex question of how to interpret the term country(ies) of origin[11].

Country of Origin

Ascription of a country(ies) of origin to any genetic resource is evidently related to the patterns of geographical distribution of living organisms; patterns that have been changing over geological and historical times. Certain groups of organisms are ubiquitous in their distribution. This is likely to be the case with spore forming micro-organisms. Thus, most species of the slime mould genus *Dictyostelium* range over all continents and from tropics to arctics[12]. However, such wide ranging species are likely to harbour considerable intra-specific genetic variation within their populations. It is, therefore, possible that specific genetic variants may be confined to one or few countries of origin. Other micro-organisms commensalic with higher plants or animals may have more restricted distributions. Thus, the ectomycorrhiza *Tricholoma marsutaki* is known only from the host *Pinus densiflora* in certain specific habitats in Japan[13]. Few higher organisms are ubiquitous, and most have distributions limited to one or few countries or had such distributions prior to the modern era of global transport that commenced around 1500 A.D. Many species of even highly mobile organisms like birds are endemic to just one country. Thus, of 969 species of Indian birds, 69 are endemic, while of a total of 1519 species of Indonesian birds as many as 258 occur in no other country. Levels of endemism are higher in other, less mobile groups of organisms. Thus, of 206 Indian species of amphibians as many as 110 are endemic, and of 270 Indonesian species, fully 100 are endemic[14].

The question of country of origin would also be complicated in case of organisms produced through human intervention from multiple lineages. Thus, the high yielding rice variety, *IR 64*, produced at the International Rice Research Institute in the Philippines is based on genes from 20 landraces coming from 8 different countries, namely China, India, Indonesia, Korea, the Philippines, Thailand, the USA and Vietnam. The situation is apt to become even more complex in days to come. Already there exist transgenic organisms like *Nicotiana tabacum* with an endotoxin producing gene from *Bacillus thuringensis*[15]. *Nicotiana tabacum* may be assigned to several tropical American countries as countries of origin, but *Bacillus thuringensis* has a worldwide distribution. How to deal with issues of geographical origin of such transgenics clearly calls for further thinking.

The greatest complication of all is the fact that living organisms have dispersed on their own, inadvertently through human agency, as well as deliberately through human efforts over many parts of the world. Such dispersal, of course, continues to gather pace in a rapidly shrinking world. How should we then define the country of origin, say of the blue rock pigeon, *Columba livia*, which probably originated somewhere in the Middle East, but is now distributed all over the world? Or what of chilli peppers, *Capsicum annum*, which originated in South and Central American countries including Mexico, Guatemala and Peru reaching India during Emperor Akbar's reign in early 1500's? By now chillies have been extensively cultivated in India over 5 centuries and have diversified into a number of indigenous cultivars. One such is the bright red Byadgi strain of Dharwad district of Karnataka, unusual in being cultivated in the monsoon season and in much demand as a source of the alkaloid capsaicin and for the red vegetable dye. It would be unfair to Byadgi farmers to treat Mexico or Peru as the countries of origin of all genetic resources of the chilli crop. But other species such as neem *Azadirachta indica* have been planted in only last few decades in several countries outside of its native home of India and Myanmar and have not diversified genetically in those countries, and it may not be reasonable to consider all such countries as countries of origin.

India might propose that the international community agrees to define a country of origin as that country in which a biological resource that has never been domesticated is known to have occurred under natural

conditions at a certain cut off date. An appropriate cut off may be the beginnings of large scale global trade in 1500 A.D. Alternatively, it could be December 1993, the date on which the Convention of Biological Diversity came into force. Many domesticated species have spread since 1500 A.D. For them countries of origin may be all those countries in which the species had extensively diversified genetically by December 1993, as evident from depositions in recognized national or international collections of crop genetic resources.

Crop Genetic Resources

The richest collection of crop genetic resources today is with the institutions belonging to the Consultative Group for International Agricultural Research (CGIAR) system. Thus, today the collection of rice germ plasm at the International Rice Research Institute in the Philippines may include strains of Indian origin that have gone out of cultivation in India with the introduction of high yielding varieties, and may not even be available with our own Rice Research Institute in Cuttack. However, by and large there is proper record of the countries from which these strains have been obtained under the earlier regime that treated genetic resources as a common heritage of mankind. India should propose that in these cases the countries providing the strains must be treated as countries of origin. All applications for protection of plant varieties should mandatorily give credit to all the countries of origin that may have provided the genes for the concerned variety.

Specifications accompanying patent or other IPR applications are open to public to varying degrees and after varying intervals following the filing of an application. It is suggested that this part of the specification relating to the biological source, country(ies) of origin and knowledge and practices of sustainable use by indigenous communities be open to full public scrutiny for an adequate period at the appropriate time after the filing of the IPR application. This would permit countries with possible claims as countries of origin, and as repositories of public knowledge and practices of sustainable use to examine the patent applications and make any submissions that they may wish to make. It would also permit other parties, such as NGOs interested in furthering the interests of indigenous communities to make such submissions.

Clearing House

Such a system of specification in the IPR applications would make available the required information on country(ies) of origin and prior knowledge in the public domain very easily and at no additional cost to any concerned party. The proposed, "clearing house", serving CBD could organize collation of such information from the various countries and its full sharing[16]. This would be an excellent indication of the relative contribution of the genetic resources from different countries of the world to the development of biodiversity based enterprises.

The "clearing house" should go one step further and with the help of the Ministries of Industry in various countries collect information on the patents or protected plant varieties actually being worked in each country, and the country of origin of biological resources indicated in the IPR specifications. This would provide a very reliable indication of the relative contribution of the genetic resources from different countries to the actual economic activity of the biodiversity based enterprises.

Access to this information through the "clearing house" would permit all countries to gauge the dependence of enterprises in other countries on their genetic resources and the dependence of enterprises in their country on genetic resources from other countries. This would facilitate all countries mutually agreeing on location of R&D activities in countries of origin of genetic resources as well as on transfer of technology on special terms to countries of origin of genetic resources.

Biodiversity Conservation Fund

Over and above this, all countries could agree to levying a biodiversity conservation cess on all products of biodiversity based enterprises. A portion of this cess could be used internally by the country to promote within country conservation measures. Another portion could be deposited in a Global Biodiversity Conservation Fund which may come to replace the currently functional Global Environment Facility.

The fraction of the national biodiversity conservation cess deposited in the Global Biodiversity Conservation Fund should: (a) increase with the per capita GNP of a country, and also (b) increase with the extent of a country's dependence on use of genetic resources of origin outside the

country. The Global Biodiversity Conservation Fund should be used to support conservation programmes in gene rich developing countries in particular to reward local communities for their continuing participation in conservation efforts.

Any country's share in grants from the Global Biodiversity Conservation Fund should be proportional to the extent of use of genetic resources for which it is a country of origin in the patents being worked by biodiversity enterprises throughout the world. This would encourage all countries to promote the use of their genetic resources by biodiversity based enterprises. Industrialized countries may voluntarily forego claiming their share of this fund in interest of helping the developing world undertake conservation measures more vigorously.

According to this proposal, biodiversity based enterprises would have to pay a fixed cess in a given country, based on the volume of their sales, but independent of where and how they have accessed genetic resources, from within the country or outside. The enterprises would then lose nothing by providing correct information regarding the source of the genetic resource. This information regarding the source would then determine the fraction of the nationally collected cess deposited by the country in the Global Biodiversity Conservation Fund. This may, of course, induce governments to persuade their industries to conceal some information; hopefully this would not be a major problem if the international community succeeds in creating an atmosphere of mutual co-operation. Over and above the cess, the biodiversity based enterprises may be obliged to pay some royalties, but this would depend on specific material or information transfer agreements they may have executed with other parties, a practice that is already prevalent today.

Indian Patent Laws

It is necessary that India accepts the broad framework of the intellectual property rights regime prevalent in the industrial countries to function efficiently within the emerging global framework. Of course, this regime has been devised by the industrial countries primarily to serve their own interests. But there is an asymmetry in our relationships. The industrial countries can do without access to Indian markets; we have not developed any technologies they need. They can even do without formal access to India's genetic resources, for many of these are already

available to them through *ex situ* collections, others could be accessed with the help of neighbouring countries like Pakistan, Nepal, Bangladesh or Myanmar. So they can impose on us an intellectual property rights regimes of their design. It is best to accept this reality and then actively work towards modifying the IPR regime to serve our interests better.

One such modification was suggested above, namely, making it mandatory that all IPR applications, including those for biochemicals and protected plant varieties include specifications of the identity of the biological source materials, information regarding country(ies) of origin and an acknowledgement of public domain knowledge of related uses. The IPR applications should also include proof that the biological material has been obtained from one of the countries of origin through prior informed consent.

Material Transfer Agreement

The latter must be based on a material transfer agreement to be registered with and approved by an appropriate agency of the government of the country of origin[17]. In India this could be the Technology Transfer Division of the Council of Scientific and Industrial Research, which could work in co-ordination with the Ministry of Environment and Forests and the Indian Council of Agricultural Research. We must also try to persuade governments of countries importing genetic resources to similarly register the Material Transfer Agreements with an appropriate government agency. This would provide a basis for the Government of India to pursue proper sharing of benefits such as concessional transfer of technology and location of R&D activities based on such genetic material in India. An appropriate system would also have to be developed for recording transfer of technologies such as for manufacture of biochemicals based on Indian genetic resources in R&D laboratories located in India. For instance, Hoechst may develop a pharmaceutical based product on an Indian plant in its R&D facility at Bombay, and then manufacture it in another country using a closely related plant species. It would be fair that the role of Indian genetic resources be recorded in an appropriate fashion. Such a requirement could be part of the licence granted to a company like Hoechst in the first place.

India has extensive trade in biological resources, such as basmati rice, or orchid flowers which are not being exported as genetic resources. It

would be possible to use this route to import material which is then used as a genetic resource. The only feasible solution is to require that all importers of Indian biological material certify that it will not be used as a genetic resource in the sense defined above and then permit its export freely as at present.

People's Rights

Another important area in which India should include innovative provisions in its patent and protected plant varieties legislation is acknowledgement of the contribution of public domain knowledge, and protection of rights of local communities[ix]. A basic provision should be the protection of rights of all people to use in perpetuity for a variety of subsistence purposes all plant and animal material naturally produced on their private lands and on common lands and waters. Other kinds of provisions may be appropriate for use of naturally produced living material for certain types of commercial purposes, and of domesticated plants and animals. In future, some of the products of natural plants or animals, such as some Ayurvedic drugs may become patented. Similarly, cultivated plants may be produced from seeds of protected plant varieties. In these cases Indian laws may protect the rights of individuals to produce the drug for personal use or non-commercial exchange, and the seeds for sowing on one's own land or for across-the-fence exchange.

A much more difficult question is how the intellectual property rights legislation will deal with community based, or public domain knowledge other than broadly acknowledging its existence. Thus, an anti-hepatitis drug based on *Phyllanthus niruri* should specify that this plant was widely used in treatment of hepatitis in many different traditional medicinal systems in many countries of Asia. Or a salinity tolerant protected plant variety of rice using a gene from the brackish water Kagga paddy of coastal Karnataka should acknowledge that several farming communities were using the parental line for cultivation in saline environments. It is going to be far more contentious to point to particular small groups or individuals as sources of such knowledge. It is suggested that this should be based on a country wide system of "People's Biodiversity Registers" (PBR), that should serve both as a tool for sustainable management of the country's biodiversity resources, and as a source of documentation relevant to intellectual property rights

issues. About 75 such PBRs have now been prepared as a pilot project in some 10 states of the country. This initiative is fully discussed elsewhere[19].

Conclusion

These are challenging times, for they are times of rapid change. But they are also times of unprecedented opportunities for those nimble enough to seize them. It is important that India and other gene rich countries of the South work together to quickly adapt themselves to these new challenges by proposing a commonly agreed framework for reconciling the provisions of GATT and CBD[20]. The framework suggested above for India may with suitable modifications serve such a purpose. It is hoped that this contribution may stimulate further debate and help us progress towards this objective.

End Notes

1 Article 27 of TRIPs, CBD, 1992; GATT, 1994; Glowka et al., 1994; Krattiger et al., 1994; Nijar, 1994; Sanchez and Juma, 1994; Yamin, 1995;

2 See also Flitner et al., 1995; Moran, 1994.

3 CBD, UNEP, 1996.

4 Reid et al., 1993; Morrow and Britt, 1992; Swanson, 1995.

5 Cameron and Makuch, 1995; Karnataka Planning Board, 1996.

6 Walden, 1995

7 Biodiversity or genetic resources may then be taken to include (a)Biological material serving as a source of scientific information, which may not necessarily be put to any immediate commercial use, e.g. herbarium or museum specimens, blood samples, samples of seeds in cryoscopic storage, etc. (b) Biological material serving as an input for creating improved sources of a recognized commercial product through breeding or other intervention, e.g. as a source of disease resistance in a crop (c) Biological material serving as an input to a source of some new commercial product through breeding or other intervention, such as a food additive (d)Biological material serving as a source of a new commercial product, such as vegetable dye or a drug.

8. Gadgil and Devasia, 1995.

9. Jong and Brimingham, 1990.

10. Locke, Walter and Larew, 1992

11 Gadgil and Devasia, 1995

12 Cavender, 1976

13 Harley and Smith, 1983

14 Groombridge, 1992

15 Barton, Whiteley and Yang 1987

16 CBD 1996

17 Walden, 1995; CBD, UNEP, 1996.

18 Nijar 1994, Posey and Dutfield 1996, Yamin 1995

19 Gadgil 1996

20 Flitner et al 1995, Moran 1994

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