

## Intellectual property rights and biological resources: Specifying geographical origins and prior knowledge of uses

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### Intellectual property rights

Humans put to use a tremendously wide variety of other living organisms. Given the modern understanding and capabilities of manipulation of genetic material, this range now potentially encompasses all of living organisms. This has prompted an interest in claiming intellectual property rights (IPRs) over knowledge pertaining to uses of living organisms—not only novel organisms created through genetic manipulation, but even those merely isolated from nature. IPRs are also claimed over a variety of products of living organisms modified through human agency to varying degrees<sup>1</sup>.

Living organisms have of course been genetically modified for millennia by farmers selecting seeds. A variety of biological products have also been used in applications ranging over cosmetics and pesticides to drugs. While such usage and knowledge may have been kept limited amongst certain clans or communities in the past, formal claims of IPRs are a recent development. In 1873 Louis Pasteur was awarded a patent on a yeast culture. Subsequently, many patents have been awarded on 'non-naturally occurring compositions of matter' based on living organisms designed for a variety of uses such as drugs and pesticides. Seeds began to receive patent-like protection in 1930s in the US and a genetically modified organism, a synthetic, plasmid injected *Pseudomonas* capable of degrading crude oil was awarded a US patent in 1980. In agreeing to the award of this patent, the US Supreme Court remarked that the US congress intended the statutory subject matter of the Patent Act to 'include anything under the sun that is made by man'. By now IPRs in the US extend to plasmids, vectors, cell lines, microorganisms isolated from nature, strains of cultivated plants and man-made animal forms such as polyploid oysters and transgenic mice<sup>2</sup>. Other countries are beginning to follow suit, and a greater and greater range of materials derived from living organisms,

processes involving living organisms as well as self-reproducing living entities are now subject to IPRs.

The General Agreement on Trade and Tariff (GATT) aiming to reduce distortions and impediments to international trade includes an agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS). TRIPS addresses itself to the issue of IPRs over living organisms and products and processes derived from them. It stipulates that members must accept patenting of microorganisms and microbiological processes, as well as protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. TRIPS presently permits members to exclude from protection plants (other than plant varieties) and animals and essentially biological processes for the production of plants and animals<sup>3</sup>. It is however likely that protection would be extended to these areas as well when GATT next comes up for review in 1999.

### Convention on biological diversity

Concern for access to living resources, and their conservation has grown hand in hand with the rapidly expanding scope for use of living organisms towards human ends. These concerns led to the Convention on Biological Diversity (CBD) that came into force in December 1993, and has a current membership exceeding 125 countries. CBD aims to promote conservation of biological diversity, sustainable use of its components and equitable sharing of the resultant benefits. Till CBD living organisms were considered a common heritage of the humankind, this convention accepts them as a sovereign property of the nation states<sup>4</sup>. But living organisms are widely distributed over the world especially so since 1500 AD with rapid development of transoceanic transport. CBD therefore specifically recognizes 'countries of origin' of living resources and agrees to certain special

treatment to such countries of origin, in particular those that belong to the categories of developing countries and small island states. All member countries of CBD agree to facilitate access to biological resources of which they are sovereign owners. In return the Convention promises developing countries of origin of such resources preference in location of research and development activities, favourable terms for transfer of technology and assistance towards development of technological capabilities. It promises such treatment not only on behalf of national governments, but private enterprises as well. It of course stipulates that this shall be on mutually agreed terms and in consonance with the IPR agreements (Articles 16 and 18, Convention on Biological Diversity<sup>4</sup>).

CBD not only recognizes special claims of developing countries of origin of living resources, but recognizes the role of indigenous communities also, in particular their womenfolk in conservation and sustainable utilization. It calls for a recognition of their conservation practices and their knowledge of manifold uses of living resources and stresses the need for equitable sharing of benefits of utilization of these resources with the indigenous communities (Article 8j, Convention on Biological Diversity<sup>4</sup>).

### Two approaches

GATT (including TRIPS) and CBD thus represent two significant and separate approaches to the utilization of living resources of the earth to human ends. GATT aims to promote global economic growth by removing impediments to international trade. TRIPS aims to promote such economic growth through fostering technological innovation by guaranteeing on a uniform, international basis some degree of exclusivity to inventors on their inventions in order to be assured of a reasonable profit and to justify risks of development. CBD would also contribute to such global economic growth by

facilitating access to living resources. But CBD equally focuses on conservation and sustainable use, coupled to equitable sharing of benefits of such use. In its attempts to promote conservation, Article 22 of CBD stipulates that the obligations of the contracting parties under the convention are to take precedence over their obligations arising from other international agreements where the latter obligations would cause serious damage or a threat to biological diversity. In its attempts to create a stake for developing countries in conservation of biodiversity CBD stresses the need to share with them benefits of use of living resources, including the need to share development of and transfer of technology. These provisions have been criticized, in particular by US representatives as a serious interference with the intellectual property principles embodied in TRIPS and GATT. It was primarily on these grounds that the US has remained outside CBD, although almost all other major industrial and developing countries have joined it<sup>5</sup>.

### Development and conservation

In the emerging world order it is now necessary to flesh out the provisions of CBD to clarify their relationship with IPR-related regulations and to promote CBD's vital objective of long term conservation of biological diversity. The CBD provisions in this context attempt to create a stake in conservation of biodiversity for biodiversity-rich developing countries and indigenous communities of such countries living close to the natural world. CBD acknowledges that development to alleviate poverty is necessarily a high priority for these countries and communities. Biodiversity conservation would therefore involve serious opportunity costs for them, for which they must be compensated in order to motivate them to participate in conservation efforts. The precise mechanisms to achieve this must now be worked out.

### Need for recognition

Such an effort would require as a first step appropriate recognition of countries of origin of specific elements of biodiversity, and of pertinent knowledge and conservation efforts of indigenous communities. While the details of transfer of

financial resources and technology that such an effort would entail are likely to be controversial, the desirability of according due recognition to the countries of origin and indigenous communities should be a universally acceptable proposition.

As of today, there are no formal mechanisms to accord such recognition to countries of origin of genetic resources, or to the indigenous communities for their knowledge and practices of sustainable use. CBD visualizes all member countries organizing an effort at inventorying and monitoring biodiversity and developing appropriate information systems. This is however a massive undertaking and would take considerable time, more so because many diversity-rich developing countries have inadequate scientific and technical capabilities to undertake such an exercise. Such an exercise may also leave out of its ambit documentation of knowledge and practices of sustainable use of various elements of biodiversity by indigenous communities. It is therefore necessary to work out additional mechanisms of awarding such recognition to countries of origin and to indigenous communities.

### Patent specifications

We suggest that appropriate augmentation of the requirements for the specification accompanying applications for patents and other IPR protection would be one such very useful mechanism. The four universally accepted requirements for the patentability of any invention include: novelty, nonobviousness, usefulness and adequate specification. Every patent application must disclose details of the invention with the help of a patent specification that describes an invention in sufficient detail to: (a) allow the patent office, and other interested parties to assess its claims of novelty, nonobviousness and usefulness; and (b) allow a person skilled in the art to reproduce it. Such a specification or disclosure statement has to accompany, or shortly follow a patent application<sup>2,6</sup>. 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<sup>2</sup>. But there is no clearcut 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 acknowledgement of the need to accord recognition to community-based 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<sup>7</sup>. 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<sup>8</sup>.

Evidently, a further, quite marginal increase in the formal requirements of the specification would admirably serve the purpose of according recognition 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 microorganism 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 and practices of sustainable use of that biological source material by indigenous communities in the country or countries of origin. In this context, it is essential to clarify the meaning of the term country or countries of origin. We suggest that the country/countries of origin be defined as those countries in which the biological material is known to have occurred as components

of natural biological communities, or under cultivation/domestication prior to the modern age of global transport beginning 1500 AD.

### Geographical distribution

Ascription of a country or countries of origin to any genetic resource is evidently related to the patterns of geographical distribution of living organisms. Certain groups of organisms are apparently ubiquitous in their distribution. This is likely to be the case with spore-forming microorganisms. Thus most species of the slime mould genus *Dictyostelium* range over all continents and from tropics to arctics<sup>9</sup>. However, such wide ranging species are likely to harbour considerable intraspecific genetic variation within their populations. It is therefore possible that specific genetic variants may be confined to one or few countries of origin. Other microorganisms commensal with higher plants or animals may have more restricted distributions. Thus the ectomycorrhiza *Tricholoma matsutake* is known only from the host *Pinus densiflora* in certain specific habitats in Japan<sup>10</sup>. A few higher organisms are ubiquitous, but most have distributions limited to one or few countries or had such distributions prior to the suggested cut off date of 1500 AD. 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<sup>11</sup>.

### Multiple lineages

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 Philippines is based on genes from 20 landraces coming from eight different countries namely China, India, Indonesia, Korea, Philippines, Thailand, USA and Vietnam<sup>12</sup>. 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 thuringiensis*<sup>13</sup>. *N. tabacum* may be assigned to several tropical American countries as countries of origin, but *B. thuringiensis* has a worldwide distribution. How to deal with issues of geographical origin of such transgenics clearly calls for further thinking.

### Public scrutiny

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/countries of origin and knowledge and practices of sustainable use by indigenous communities be open to full public scrutiny immediately 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.

### Inclusion in CBD and TRIPS

Inclusion of such specification in the patent application of course does not commit the inventor or others working the innovation to share the benefits arising therefrom in any way. That would obviously remain a matter of further negotiation. However, the specification would immediately help motivate potential country/countries of origin to document their own biological resources and to participate in *in situ* conservation efforts. It would also promote efforts to document and help perpetrate knowledge and practices of sustainable use by indigenous communities. Both these are important objectives of the CBD, with very broad-based acceptance at the international level. We therefore suggest that such specification should be accepted not only as an elaboration of CBD by all countries party to it, but also be made a part of the TRIPS under the GATT.

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