



Legal and Practical Perspectives on Sui Generis Options

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A. Concerns of the South

The problem and concerns

[- distinction between creativity of indigenous peoples and local communities and that of corporate interests; - gap between source materials and end producers; - gap between producers and users.]

Contemporary jurisprudence draws a distinction between the creativity of indigenous peoples and local communities, and, the creativity of corporate interests. Only the latter are accorded value and reward. Corporate interests of the North invade the local commons of the South, freely tap its biological diversity for source materials, classify any 'improvement' or modification to them as an 'invention', and then claim intellectual property rights over the end product. This inequity threatens the viability of knowledge systems of indigenous peoples and local communities. And serious repercussions flow from this.

For it is this knowledge that has fed, healed and clothed the world and continues to do so. It is estimated, for example, that three-quarters of the plants that provide active ingredients for prescription drugs came to the attention of researchers because of their use in traditional medicine.¹ Of the 120 active compounds currently isolated from the higher plants and widely used in modern medicine today, 75% show a positive correlation between their modern therapeutic use and the traditional use of the plant from which they were derived.²

The current value of the world market for medicinal plants derived from leads given by indigenous peoples and local communities is estimated to be US\$43 billion.³ The value of crop varieties improved and developed by traditional farmers to the international seed industry is estimated to be US\$15 billion.⁴ Other natural products so derived, like sweeteners, perfumes, bio-pesticides, fabrics and cosmetics are much in demand today and their value continues to rise.⁵

International instruments sanction this usurpation of bio-knowledge. The Union for the Protection of Plant Varieties (UPOV) allows for breeders' rights in respect of plant varieties that are 'improved' modifications of farmers' germplasms. UPOV 1991 extends the gap between source materials and improved varieties in terms of value and ownership rights attached to them. This revised instrument allows for both breeders' rights and patents for plant varieties. Finally, the Trade Related Intellectual Property Rights (TRIPS) agreement under the World Trade Organisation (WTO), allows for patents over life forms and requires that plant varieties be protected by patents or a sui generis system. In all of these instruments, the definitional constructs preclude recognition of innovations that are inter-generational, collective and for social good - hallmarks of the way indigenous peoples create and innovate.

It is the view of countries of the North, in particular the USA and the European Commission, that the creativity represented by indigenous knowledge cannot be protected, and hence rewarded, under TRIPS. On this view only the products and processes emanating largely from the North will be thus rewarded. Further, it is suggested that only a UPOV or UPOV-like law will fulfill the requirements of the sui generis option in TRIPS.

The Article in TRIPS [Art. 27(3)(b)] is up for review this year. It is suggested, again by the same protagonists, that the review is merely to provide transparency as to the implementation of TRIPS; that initially, developing countries will be the subject of this exercise; and that come the 1st day of January 2000, these countries have no option but to provide protection to plant breeders, most of whom, of course, are multinational seed companies.

This article examines the validity of these several contentions.

The Contentions assessed

1. The CBD obligations and understanding

An opening to protect alternative knowledge systems and the creativity it spawns is provided by the Convention on Biological Diversity (CBD). The membership of the CBD and the WTO is constituted by the same countries, the US being a notable non-member of the CBD. The CBD vests sovereignty over natural resources and the right to grant access to genetic resources to national governments. The knowledge, innovations and practices of indigenous and local communities are considered key to the conservation, and sustainable use of biodiversity. Governments are required to respect, preserve and maintain these elements [Art 8(j)], to protect customary use of bio-resources [Art 10(d)], to act according to national law to develop and use traditional and indigenous technologies [Art 18(4)], and to adopt economically and socially sound measures that act as incentives for the conservation and sustainable use of components of biological diversity [Art 11].

The cumulative effect of these provisions is to make it mandatory for governments to enact a law recognizing indigenous and local community knowledge systems. In any event, they are entitled to enact such a law to fulfil their obligations under the CBD.

Member countries of the CBD are bound to ensure that patents and other intellectual property rights (IPRs) are supportive of the objectives of the Convention and do not undermine them [Art 16(5)]. It is also the view of the WTO, in particular its Trade and Environment Committee, and the EC that the WTO and the CBD should be mutually supportive.

The upshot then is that international obligations and understanding allow for the enactment of laws protective of the creativity of indigenous peoples and local communities.

2. TRIPS does not exhaust subject matter that may be covered

Article 1.1 of TRIPS states that more extensive protection may be provided than that required by the agreement. All that is required is that the protection must not contain the provisions of the agreement.

TRIPS sets out a set of minimum obligations in each area of IPR law. There is nothing that constrains countries from setting up a different area of protection with broader rights. Areas outside TRIPS are entirely permissible. Indeed, countries have laws outside of the areas identified in TRIPS (namely, copyright, trademarks, geographical indications, industrial designs, patents, layout designs of integrated circuits and 'undisclosed information').

These 'outsiders' include the following :

- a. utility models: these protect minor mechanical inventions. These are recognized by Spain, Germany, Japan, Brazil, Mexico, Argentina and the Andean Group countries.
- b. breeders' rights at presently provided for and regulated by UPOV.
- c. The European Union Directive on the Legal Protection of Data Bases (No. 96/9).
- d. Internet Domain Names may also be similarly protected by a sui generis right.

This means that legislation which recognizes the creativity of indigenous peoples and local communities may be enacted without violating TRIPS.

3. Article 8 of TRIPS - another basis for community intellectual right law

This Article allows measures to be taken to

- a. protect public health and nutrition, and,
- b. to promote the public interest in sectors of vital importance to their socio-economic and technological development.

First, 80% of the world's people, living almost entirely in the Third World, depend upon traditional medicine and medicinal plants for their health needs. It is clear that measures taken to protect the knowledge systems

that makes this resource available would be measures to protect public health. A law This complies with the first limb of Article 8.

Further, protecting community knowledge and indigenous technologies which provide sources of medicine, which result in the development of new resilient plant varieties, which protects biodiversity and enhances its sustainable use, and which also spawn a whole host of other useful products and processes is of vital importance to a Third World country's socio-economic development. Most Third World societies have a rural informal sector which relies upon their knowledge systems to survive. Serious social instability can ensue if such reliance were impaired or curtailed in any way.

Measures taken under Article 8 must be consistent with the provisions of the TRIPS agreement. This consistency may be assessed, *inter alia*, in the light of the objectives of TRIPS as set out in Article 7. This Article makes it clear that the protection of IPRs should

- a. contribute to the promotion of technological innovation, and,
- b. in a manner conducive to social and economic welfare.

Article 18(4) of TRIPS states clearly the need for countries to develop and use indigenous technologies for the conservation, and the sustainable use, of biodiversity in accordance with their national legislation. This is in the context of a clear acknowledgment in Article 8(j) that such indigenous technologies are the sources of innovation. A law to protect and further the knowledge systems of indigenous peoples and local communities would clearly contribute to the promotion of technological innovation in furtherance of social and economic welfare of large segments of the Third World's populace.

4. Countries free to define criteria for defining 'invention' under TRIPS

The TRIPS agreement does not define what constitutes an 'invention'. It merely states the basic requirements, for example, for patents, the invention must be new, involve an inventive step and be capable of industrial application. 'Capable of industrial application' is clarified as being synonymous with 'useful'. Countries are free then to set the criteria for the innovative activity that will be accorded recognition and protection.

The key issue here is: can countries exclude the patenting of biological materials which exist in nature? This is especially important as genetic engineering now makes it possible to reproduce biological materials. Patents have been given to materials taken from, or identified as existing in, humans, plants and animals. Often it is no more than a discovery. By conventional norms of intellectual property rights legislation, they do not qualify to be protected as an invention.

The European Patent Convention and US law have adopted a very expansive approach that really blurs the distinction between patents and discoveries. European law allows for the patenting of a substance found in nature, if it can be characterized by its structure, its process of obtaining it or by other criteria, so long as it was not previously available to the public. In the US, an isolated and purified form of a natural product can be patented if it is found in nature in a non-purified form. The principles for IPR protection have been broadened in these countries to allow for claims to the patenting of natural genes.

But this approach need not be followed. This means that it is possible to exclude the patenting of these biological materials in a law on community rights.

5. The exception under Article 27.2 of TRIPS - ordre public and morality

TRIPS allows countries to refuse patents for inventions whose commercial exploitation would be against ordre public or morality. This includes, but is not confined to, situations where human, animal or plant life or health and the environment needs protection.

First, scientific evidence is emerging which suggests that genetically engineered plants and animals, commodities and products derived from them, may pose serious consequences to plant and animal life and to human health.⁶ There is therefore a basis for refusing patents for genetically modified organisms and derived products if, based on the precautionary principle, it can be shown that the commercial exploitation of the patent would harm human, animal or plant life or health; or that otherwise, there would be serious prejudice to the environment.

The patent may also be refused if it offends against morality. The European Patent Office considers an

invention immoral if the general public would consider it so abhorrent that patenting would be inconceivable. Most Third World societies would consider the patenting of life forms not merely immoral, but as being antithetical to their cultural, social and religious values.

6. National Treatment need not apply to modalities of IPRs not covered by TRIPS.

The national treatment in TRIPS- each member must accord no less favorable rights to others that it gives to its own nationals (Art 3) - has no applicability in respect of modalities not covered by TRIPS. Hence there is no national treatment under UPOV and utility model laws. Benefits are accorded on the basis of reciprocity. The US 1984 Semiconductor Chips Protection Act has a similar strong reciprocity clause.

Similarly, as regards "neighbouring rights", in Europe, foreign authors and artists cannot participate on the same footing as nationals in the distribution of revenues from videos and audio levies. Canada's Bill C-32 recognises neighbouring rights (ie rights of performers, producers of phonograms and broadcasting organisations) on sound recordings. These rights would not apply to nationals of countries where similar rights are not reciprocally conferred.

The EU Directive on the legal protection of data bases is only for nationals of member states or those who have habitual residence in the EU. Data bases made in other countries may be protected on the basis of agreements to be concluded by the Council acting on a proposal from the EU Commission (Article 11.3).

7. Exclusion of plants and animals and essentially biological processes

TRIPS allows for these to be excluded. The US allows the patenting of genetically modified life forms on the ground that they are human made inventions.⁷ The European Patent Office has also interpreted a similar exclusion from patenting to extend only to animals and plants 'as such', animal races and animal and plant species.

Countries are within their rights to reject this development of essentially western patent laws. The exclusion in the Article is of plants and animals and 'essentially' biological processes for the production of plants and animals'. A modified plant or animal retains all its basic characteristics. Chakrabarty, whose case allowed for the patenting of life forms, said of his insertion of genes from three oil eating bacteria into a fourth bacteria to produce a super bacteria which he hoped would slurp up oil slicks created by spills, "I simply shuffled genes, changing bacteria that already existed. It's like teaching your pet cat a few new tricks." Key Dismukes of the National Academy of Sciences in the US said,

"...Chakrabarty did not create a new life form; he merely intervened in the normal processes by which strains of bacteria exchange genetic information, to produce a new strain with an altered metabolic pattern. 'His' bacterium lives and reproduces itself under the forces that guide all cellular life."

Even recent advances in recombinant DNA techniques which allows for more direct biochemical manipulations of bacterial genes are, says Dismukes, only modulations of biological processes. Further, the exclusion of 'essentially biological processes' is limited to processes 'other than non-biological'. But a plant or an animal is produced by a process that is part biological. The scientists who produced Tracy (the sheep whose mammary glands were engineered with human genes to produce a protein, found in mother's milk, for the pharmaceutical industry) admit to using 'junk DNA' to get a high yield of the protein. As the corporation's director said, "We left some of these random bits of DNA in the gene, essentially as God provided it and that produced high yield." The use of, and reliance on, the junk DNA constitutes a biological process.

Further the regenerative capacity of the organism creates the future generations of the animal - clearly an essentially biological process.

The upshot is that plants and animals, including those that are genetically modified, may be excluded from patenting under Article 27(3)(b).

8. Protection of Plant Varieties

Article 27(3)(b) states that members must provide for protection for plant varieties either by patents or by an effective sui generis system or by a combination of both. Unlike the community intellectual rights regime which, as discussed, may be enacted outside TRIPS, the plant variety protection regime clearly falls within TRIPS. This means any law made in fulfillment of the Article must be reported to the TRIPS Council and subject to the dispute settlement procedures under the WTO.

The sui generis option gives countries the option to develop a law that will not undermine the tradition of their farming communities and indigenous peoples in innovating and developing new plant varieties and enhancing biodiversity. Nothing in TRIPS obliges countries to join UPOV or enact UPOV-like laws - especially since it is now widely canvassed that the obligations of UPOV will undermine the interest of farmers in the Third World as well as erode biodiversity.⁸

Essentially, UPOV only gives rights to commercial breeders. Traditional breeders are accorded no recognition and hence no reward. And this despite the international recognition⁹ that much of the plant genetic diversity is maintained and continued by the innovative activity of small farmers. The rights of commercial breeders is based upon applying breeders' techniques to germplasms developed by farmers.

There is indeed little purpose to join yet another international convention which will hamper national legislative activity - unless the country intends to participate very actively in the export of plant varieties. The provisions of UPOV can be replicated by a national law without joining this international organisation. At least then there is freedom to act in the country's interest and change the law as and when required.

What if countries have already joined UPOV? Often the question then asked is: can a national law be enacted which tries to balance the rights of commercial breeders and traditional breeders? Generally the country cannot really depart from the obligations it has undertaken under UPOV. But there is a provision in both UPOV 1978 and 1991 that allows the restriction of breeder's rights for reasons of public interest [sections 9(1) and 17(1) respectively]. This term 'public interest' is nowhere defined. It will be permissible then to adopt some of the exclusionary elements in sections 8 (read with section 7), 27(2), 30 and 31 of the TRIPS agreement, as well as the key features of the CBD, as constituting the 'public interest'. On this basis the expansive rights of farmers to their traditional breeding innovations can be enacted in a national plant variety law as a counterbalance to the rights accorded to commercial breeders.

The essential elements of such a regime

The law should include the following essential elements: 1. Recognition of Rights

The law should recognise and protect the rights of traditional breeders over plant varieties developed by them - whether inter-generationally, collectively and for the social good or howsoever otherwise and for whatever purpose.

This right should extend to any variety essentially derived from the variety developed by traditional breeders.

The following provisions will have to be included in the law:

- a. The State shall recognise and protect the rights of traditional breeders over their traditional varieties and land races.
- b. The traditional breeder's prior informed consent must be obtained by any commercial breeder wishing to use the variety to develop other varieties.
- c. This protection shall be extended to varieties that are essentially derived from varieties developed by traditional breeders.

1.2 The right should be recognised in accordance with the customs and practices of traditional breeders. This also means that there is no need to apply for the grant of the right. It follows that there will be no need to apply for, and obtain, registration. Further, proof of its existence can be established in a form or manner accepted by the traditional breeder's customary law, traditions and practices. This could include oral tradition. Finally, the customary practice of free exchange amongst communities shall not be affected.

Provisions to be included could be as follows

- a. definition of knowledge : to include cultural and traditional practices of communities within which the knowledge is generated.
- b. The right to the plant variety is recognised regardless of whether or not it is registered.
- c. The right to the plant variety shall be established in a manner and form compatible with the culture, tradition and practices of the community.

d. Nothing in the law affects the right of traditional breeders to freely exchange the plant varieties amongst themselves provided no commercial use is intended.

2. Content of the Right

The right includes the following:

- a. the right to save, reuse, and exchange seeds from whichever source;
- b. the right to sell the harvest from whichever source;
- c. the right over any distinct and identifiable variety wherever derived from.

3. Criteria for the right

- a. for traditional breeders the test should be distinctiveness and identifiability of the variety.

In those situations referred to earlier, where a claim is made by commercial breeder in respect of a variety developed from a variety which is not invested with the knowledge of indigenous peoples and local farming communities and the State decides to grant such a right, the following elements may be included:

4. Criteria for the right

- a. the test is : the variety shall be new, distinct, uniform and stable.

5. Scope of the right

The right should not extend beyond the production for purposes of commercial marketing, the offering for sale and the marketing, of the reproductive or vegetative propagating material as such of the variety.

In particular, the breeder's rights should not extend to the harvested crop of the traditional farmer growing the breeder's protected variety.

The concept of 'essentially derived variety' should be limited such that it does not impair or stifle innovation of traditional farmers.

Traditional farmers should be entitled to save, exchange, use their seeds and market their harvest from protected varieties.

6. No commercial plant breeders' rights shall be granted in the following situations (based on the provisions of the CBD and Articles 7, 8 and 27.2 of TRIPS and the 'public interest' element in Article 9 of UPOV 1978 and Article 19 of UPOV 1991) :

- a. where biodiversity may be affected;
- b. where the variety poses a possible hazard to the agricultural system and to human, animal and plant life or health, based on the precautionary principle;
- c. where the variety does not possess the normal regenerative and reproductive capacity associated with the variety;
- d. where the introduction of the variety may have an adverse socio-economic affect on the country or indigenous peoples and local communities;
- e. where there are ethical reasons for rejecting the right.

7. The following exclusions/limitations to the breeder's rights should be provided for (permitted by Article 30 of TRIPS and Article 15 of UPOV 1991) :

- a. acts done privately and for a non-commercial purpose;
- b. use of the variety for research and experimentation not designed for commercial exploitation;
- c. use of the variety for teaching purposes;

8. Compulsory licensing should be allowed in certain situations (permitted by Articles 30 and 31 read together with Article 8, 7 and 27.2 of TRIPS) :

- a. where anti-competitive practices of the rights holder are identified;
- b. where food sovereignty, food security or nutritional or health needs are affected;
- c. where a high proportion of the plant variety offered for sale is being imported;
- d. where the requirements of the farming community for propagating material of a particular variety are not met;
- e. where it is considered important to promote the public interest for socioeconomic reasons and for developing indigenous and other technologies.

9. The breeder's right may be revoked if, after the grant, any of the reasons set out in paragraph 6 (i) -(e) above are found to apply.

10. "Parallel imports" of any varieties in respect of which rights have been granted shall be allowed. (This is permitted by Article 6 of TRIPS).

9. No patents shall be granted in respect of plants, plant varieties or any parts or modifications thereof.

10. There shall be a ban on any technology such as that which renders the seed infertile in the following generation or which switches on, or off, specific genes, or, multi-gene traits, by the application of an external catalyst.

'Effective'

The provision which requires plant variety protection states as well that the protection must be effective. What is 'effective' will be determined ultimately by reference to the provisions of the WTO, and ultimately the dispute panel. There is no need for developing countries to accept the interpretation of developed countries that only UPOV will be an effective sui generis law. The term means 'real' protection and not the strongest possible protection. Protection should be given not only to commercial breeders but, as well, to traditional breeders. All that a sui generis law for plant varieties requires is an adherence to the minimum provisions of TRIPS, consistent as well with obligations of countries under other international instruments to which they are parties, such as the CBD, and its protocols.

It is also suggested by some developed countries that what is 'effective' must be adjudged from the view-point of the rights holder of the IPR. But if traditional breeders are given rights under a sui generis law, then they too are rights holders. Whether the law is effective to protect their creativity must be assessed from their interest as well. In these circumstances a sui generis law that balances the interest of both commercial breeders and traditional breeders can hardly be considered ineffective.

The Review of Article 27(3)(b) of TRIPS.

This Article states that this subparagraph shall be reviewed four years after the entry into force of the WTO. As a result the review process has been initiated for this year, 1999. What the TRIPS Council has done is to require the developing countries to answer a 3 page questionnaire. This information-gathering is to provide the basis for the review. The position of several leading developed countries is that the review is merely to see how far countries are providing for the protection of plant varieties i.e. to monitor the implementation of the provision in relation to plant varieties. The EU and the US state clearly that the review is thus limited and should not lead to a renegotiation of the Article. In particular they state that any attempt by developing countries to debate the relationship of TRIPS to other "aspects such as competition, environment, and its impact on health and welfare ...must be resisted..."

So opposition will be stiff. But what options are open to be placed on the table for discussion?

Those canvassed and worth considering for this purpose include :

1. To defer the time period for the implementation of the plant variety legislation until after the review is complete. This would require further time to be given from the end of the review.

2. To require that all biodiversity related issues be removed from TRIPS to the CBD, as the former is ill-equipped to deal with these matters with the right understanding and sensitivity of these matters. These would include matters relating to plants, animals, micro-organisms, community intellectual rights, including plant varieties.
3. To make specific proposals, for example, to exclude from patentability plants, animals, micro-organisms and parts thereof and any processes making use thereof or relating thereto; with a proviso that allows for the protection of plant varieties by a sui generis system for those countries that wish to do so.
4. To include within the TRIPS agreement a clear provision that states that the obligations of TRIPS shall be discharged in a manner fully consistent with a member's obligation under the CBD and any protocols thereunder.
5. For developing countries to state in the discussions in a uniform and cohesive manner, that it is their clear understanding that the TRIPS agreement, and in particular Article 27(3)(b), should be interpreted in a manner which allows them to fulfil their obligations in the CBD and any protocol thereunder.

1. Conclusion

It is perfectly possible, therefore, for countries to enact a law for community rights outside of TRIPS which is nonetheless consistent with the TRIPS Agreement. Further, a sui generis law within TRIPS for plant varieties which takes into account the innovations of farmers can also be enacted.

The broad legislative options open to countries are summarised in the table below.

Natural Resource Law required Complies with

1. All resources within State Collector' C Art. 15(1) CBD
2. Community Crops, medicinal plants, forest Sui generis law : Community Rights Act (incorporating Farmers' Rights, protecting traditional breeders) CBD
3. Commercial sector Possible option: Plant Variety Act protecting commercial breeders, but without prejudicing the rights of traditional breeders TRIPS - Art 27(3)(b)
4. State sector forest reserve, marine, etc Act regulating collection of resources : Collectors' Act/ Access laws and contracts CBD Art 15(1)

Footnotes:

1. Andrew Gray, 'Between the spice of life and the melting pot : biodiversity conservation and its impact on indigenous peoples', International Working Group for Indigenous Affairs, document 70, 1991.
2. Farnsworth, et al, 'Medicinal Plants in Therapy,' Bulletin of the World Health Organisation (WHO), 1985, 63, p.965-966.
3. Andrew Gray, 'Indigenous peoples and the marketing of the rainforest,' The Ecologist, v.20, No 6, 1991.
4. Ibid.
5. Stephen Brush, 'Indigenous knowledge of biological resources and intellectual property rights : the role of anthropology', American Anthropologist, 95(3) : 653-686, 1993.
6. For detailed information : see 'Biosafety : scientific findings and elements of a protocol, Report of the independent group of scientific and legal experts on Biosafety', 1996, Third World Network; Mae Wan Ho, Genetic engineering : Dream or Nightmare, Gateway Books, 1998.
7. Decision of the US Supreme Court in Ananda Mohan Chakrabarty v US Patent and Trademark Office [1971]
8. 'Ten reasons not to join UPOV', Grain-Gaia Foundation publication, 1998.
9. FAO Conference resolutions 4/89 and 5/89 incorporating Farmers' Rights. Farmers Rights were negotiated through the Commission on Plant Genetic Resources (established under the FAO) and unanimously adopted by 160 countries.

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